IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EGALET US, INC. and EGALET LTD.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Egalet US, Inc. and Egalet Ltd. (collectively, "Egalet"), by way of Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), alleges as follows:

PARTIES

1. Plaintiff Egalet US, Inc. is a corporation organized under the laws of Delaware with a principal place of business located at 600 Lee Road, Suite 100, Wayne, PA 19087. Egalet is a fully integrated specialty pharmaceutical company focused on developing and commercializing treatments for those living with pain.

2. Plaintiff Egalet Ltd. is a company organized and existing under the laws of the United Kingdom, with a principal place of business at Dechert Llp, 160 Queen Victoria Street, London EC4V 4QQ, United Kingdom.

3. Upon information and belief, Teva is a corporation organized under the laws of Delaware, with a principal place of business at 1090 Horsham Road, North Wales, PA 19454. Teva manufactures and markets generic drugs in the United States.

NATURE OF THE ACTION

4. This is an action for infringement of U.S. Patent Nos. 9,044,402 ("the '402 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*,

including 35 U.S.C. §§ 271 and 281. This action relates to Teva's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, sell, offer to sell and import generic pharmaceutical products prior to the expiration of the asserted patents.

JURISDICTION AND VENUE

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

6. This Court has personal jurisdiction over Teva because, *inter alia*, it is a corporation organized and existing under the laws of the State of Delaware. Teva is in the business of manufacturing, importing, marketing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva regularly and continuously transacts business in this District and, directly or through its wholly-owned subsidiaries, manufactures, imports, markets and sells generic drug products throughout the United States and in this judicial district. Upon information and belief, Teva purposefully has conducted and continues to conduct business directly, or through its wholly-owned subsidiaries, in this judicial district, and this judicial district is a likely destination of Teva generic products. Teva has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting claims and counterclaims in other civil actions initiated in this jurisdiction.

7. This Court also has personal jurisdiction over Teva because, as a domestic corporation, Teva is registered to do business with the Delaware Department of State Division of Corporations. Teva has also designated Corporate Creations Network Inc. as its agent for

services of process in the State of Delaware. Corporate Creations Network is located at 3411 Silverside Road Tatnall Building Suite 104, Wilmington, Delaware 19810.

8. On information and belief, Teva has at all relevant times purposefully directed activities at residents in the State of Delaware, including but not limited to its business of preparing generic pharmaceutical products that it distributes in the State of Delaware, and Teva plans to continue such activities.

9. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Teva is a corporation organized and existing under the laws of Delaware.

FACTUAL BACKGROUND

10. The U.S. Patent and Trademark Office ("USPTO") issued the '402 patent on June 2, 2015, entitled "Abuse-Deterrent Pharmaceutical Compositions for Controlled Release." A true and correct copy of the '402 patent is attached as Exhibit A.

11. Egalet is the owner of the '402 patent by virtue of assignment.

12. The '402 patent expires on July 1, 2033.

13. The '402 patent is directed to and claims, *inter alia*, controlled-release morphine sulfate tablets.

14. Egalet is the holder of New Drug Application ("NDA") No. 208603 for morphine sulfate tablets 15 mg, 30 mg, and 60 mg, which the FDA approved on January 9, 2017.

15. Egalet markets morphine sulfate tablets in the United States under the trademark Arymo® ER.

16. Egalet lists the '402 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as "the Orange Book") for NDA No. 208603.

COUNT I: INFRINGEMENT OF THE '402 PATENT

17. Egalet incorporates by reference the allegations of the preceding paragraphs as if fully set forth herein.

18. Upon information and belief, Teva submitted ANDA No. 210533 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell Teva's generic Morphine Sulfate Extended-Release Tablets, 15 mg, 30 mg, and 60 mg (hereinafter "Teva's ANDA product") prior to the expiration of the '402 patent.

19. On or about February 23, 2018, Egalet received a letter from Teva dated February 22, 2018 ("Teva Letter"), purporting to include a Notice of Certification for ANDA No. 210533 pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95 as to the '402 patent.

20. The Teva Letter alleged that claims 1-23 of the '402 patent are invalid for obviousness under 35 U.S.C. § 103(a).

21. The Teva Letter also alleged that claims 1-23 of the '402 patent are not infringed by Teva's ANDA product.

22. The opinions set forth in the Teva Letter that the '402 patent is not infringed and is invalid due to obviousness are devoid of any objective, good faith basis in either facts or law.

23. By submitting, or causing to be submitted, to the FDA ANDA No. 210533, seeking approval to manufacture, use, import, offer to sell and sell Teva's ANDA product before expiration of the '402 patent, Teva has infringed at least one claim of the '402 patent under 35 U.S.C. § 271(e)(2)(A), including but not limited to claim 1.

24. By filing ANDA No. 210533, Teva has represented to the FDA that Teva's ANDA Product has the same active ingredient as Arymo® ER, has the same dosage form and

strength as Arymo® ER, and is bioequivalent to Arymo® ER. Teva has also represented that Teva's ANDA Product has the same abuse deterrent properties of Arymo® ER.

25. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits under the Act, including a stay of approval of the generic drug for up to 30 months during the pendency of litigation, as appropriate. 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii).

26. This action is being commenced before the expiration of 45 days from the date Egalet received the Notice Letter, which triggers a stay of FDA approval of Teva's ANDA No. 210533, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

27. Upon information and belief, Teva's ANDA product will, if approved and marketed, infringe at least one claim of the '402 patent, either literally or under the doctrine of equivalents.

28. Upon information and belief, Teva had actual knowledge of the '402 patent prior to filing ANDA No. 210533 and was aware that filing the ANDA was an act of infringement of one or more claims of the '402 patent.

29. Teva has violated its duty of care to avoid the known patent rights of the '402 patent.

30. Egalet will be substantially and irreparably damaged and harmed if Teva is not enjoined from infringing one or more claims of the '402 patent. Egalet does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE Egalet respectfully requests that the Court grant judgment in its favor and against Teva on the patent infringement claim set forth above and respectfully requests the following relief:

a. Enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed one or more claims of the '402 patent through submission of ANDA No. 210533 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Teva's ANDA product in the United States before expiration of the '402 patent;

b. Enjoin Teva from the manufacture, use, import, offer for sale and sale of Teva's ANDA product until the expiration of the '402 patent, or such later date as the Court may determine;

c. Award Egalet all available and legally permissible damages sufficient to compensate Egalet for Teva's infringement of the '402 patent, together with interest, in an amount to be determined at trial;

d. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Egalet costs, expenses and disbursements in this action, including reasonable attorney's fees; and

e. Award Egalet such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs

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