IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IBSA INSTITUT BIOCHIMIQUE SA, IBSA PHARMA INC. and ALTERGON SA,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

COMPLAINT

IBSA Institut Biochimique SA ("IBSA"), IBSA Pharma Inc. ("IBSA Pharma"), and Altergon SA ("Altergon") (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Teva Pharmaceutical USA, Inc. ("Teva"), allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Teva's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Teva seeks approval to market a generic version of Plaintiffs' pharmaceutical product Tirosint® prior to the expiration of United States Patent Nos. 7,691,411 (the "'411 patent") and 7,723,390 (the "'390 patent").

THE PARTIES

2. Plaintiff IBSA is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Via al Ponte, 13, CH-6900 Massagno, Switzerland.

3. Plaintiff IBSA Pharma is a corporation organized and existing under the laws of Delaware, having a principal place of business at 8 Campus Drive, Suite 201, Parsippany, NJ 07054.

4. Plaintiff Altergon is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Via Dogana Vecchia 2, CH-6901 Lugano, Switzerland.

5. On information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

THE PATENTS-IN-SUIT

6. On April 6, 2010, the United States Patent and Trademark Office issued the ’411 patent, entitled “Pharmaceutical Formulae for Thyroid Hormones and Procedures for Obtaining Them,” a copy of which is attached to this Complaint as Exhibit A. Altergon is the owner of all right, title, and interest in the ’411 patent. IBSA is the exclusive licensee, and IBSA Pharma is its exclusive sublicensee, of patent rights relating to Tirosint® in the United States, including for the ’411 patent.

7. On May 25, 2010, the United States Patent and Trademark Office issued the ’390 patent, entitled “Pharmaceutical Formulations for Thyroid Hormones,” a copy of which is attached to this Complaint as Exhibit B. Altergon is the owner of all right, title, and interest in the ’390 patent. IBSA is the exclusive licensee, and IBSA Pharma is its exclusive sublicensee, of patent rights relating to Tirosint® in the United States, including for the ’390 patent.

TIROSINT®

8. IBSA holds approved New Drug Application No. 021924 (the "Tirosint® NDA") for levothyroxine sodium capsules, with dosage strengths of, *inter alia*, 88 mcg, 100 mcg and 125 mcg. IBSA Pharma sells the product of the Tirosint® NDA under the trade name Tirosint®.

9. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '411 and '390 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence" (the "Orange Book"), with respect to Tirosint®.

TEVA'S ANDA

10. On information and belief, Teva submitted ANDA No. 213256 ("Teva's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of levothyroxine sodium capsules, 88 mcg, 100 mcg and 125 mcg ("Teva's Product").

11. On information and belief, Teva's ANDA refers to and relies upon the Tirosint® NDA and contains data that, according to Teva, demonstrate the bioequivalence of Teva's Product and Tirosint®.

12. By letter to IBSA and Altergon, dated September 25, 2019, Teva stated that Teva's ANDA contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '411 and '390 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva's Product (the "Paragraph IV Certifications"). Teva attached a memorandum to its September 25, 2019 letter, in which it purported to allege factual and legal bases for its Paragraph IV Certifications.

13. Plaintiffs' infringement claims are based on 35 U.S.C. § 271(e)(2)(A), which makes the submission of an ANDA containing a Paragraph IV certification to the FDA an act of patent infringement, as well as the information presently available to Plaintiffs.

JURISDICTION AND VENUE

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

15. This Court has personal jurisdiction over Teva because, *inter alia*, Teva is a Delaware corporation, Teva maintains a presence in Delaware, has conducted and is conducting business in Delaware, is registered to do business in Delaware, derives and has derived revenue from conducting business in Delaware, has previously consented to personal jurisdiction in this Court, has purposefully availed itself of this Court's jurisdiction, and has engaged in systematic and continuous contacts with the State of Delaware.

16. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b) because Teva is incorporated in Delaware.

COUNT I
INFRINGEMENT OF
U.S. PATENT NO. 7,691,411

17. Plaintiffs re-allege and incorporate by reference the allegations of Paragraphs 1-16 of this Complaint.

18. Teva has infringed the '411 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Teva's ANDA, by which Teva seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Teva's Product prior to the expiration of the '411 patent.

19. Teva's sale, offer for sale, use, or commercial manufacture of Teva's Product within the United States or importation of Teva's Product into the United States, during the term of the '411 patent would infringe claims 1-32 of the '411 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

20. Plaintiffs will be harmed substantially and irreparably if Teva is not enjoined from infringing the ’411 patent.

21. Plaintiffs have no adequate remedy at law.

22. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT II
INFRINGEMENT OF
U.S. PATENT NO. 7,723,390

23. Plaintiffs re-allege and incorporate by reference the allegations of Paragraphs 1-16 of this Complaint.

24. Teva has infringed the ’390 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Teva’s ANDA, by which Teva seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Teva’s Product prior to the expiration of the ’390 patent.

25. Teva’s sale, offer for sale, use, or commercial manufacture of Teva’s Product within the United States or importation of Teva’s Product into the United States, during the term of the ’390 patent would infringe claims 1-10 of the ’390 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

26. Plaintiffs will be harmed substantially and irreparably if Teva is not enjoined from infringing the ’390 patent.

27. Plaintiffs have no adequate remedy at law.

28. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys’ fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Teva and respectfully request the following relief:

A. A judgment that Teva has infringed the ’411 patent;

B. A judgment that Teva has infringed the ’390 patent;

C. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Teva, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Teva’s Product within the United States, or importing Teva’s Product into the United States, prior to the expiration of the ’411 or ’390 patents, including any extensions, adjustments, and exclusivities;

D. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Teva’s ANDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the ’411 or ’390 patents, including any extensions, adjustments, and exclusivities;

E. If Teva commercially manufactures, uses, offers to sell, or sells Teva’s Product within the United States, or imports Teva’s Product into the United States, prior to the expiration of the ’411 or ’390 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Plaintiffs monetary relief, together with interest;

F. Attorneys’ fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

G. Costs and expenses in this action; and

Such other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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