

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

AUXILIUM PHARMACEUTICALS, INC.,

Plaintiff,

v.

FCB I LLC,

Defendant.

C.A. No.: _____

REDACTED

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Auxilium Pharmaceutical, Inc. (“Auxilium”), by and through its undersigned counsel, files this complaint for declaratory judgment against FCB I LLC (“FCB I”) and alleges as follows:

NATURE OF ACTION

1. Auxilium brings this action seeking declaratory relief with respect to United States Patent Nos. 7,320,968, 7,608,605, 7,608,606, 7,608,608, 7,608,609, 7,608,610, 7,935,690, 8,063,029, 8,178,518, and claims 1-2 and 4-15 of U.S. Patent No. 7,608,607 (collectively, the “patents-in-suit”).

THE PARTIES

2. Plaintiff Auxilium Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 40 Valley Stream Parkway, Malvern, Pennsylvania 19355.

3. Defendant FCB I is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business located at 933 MacArthur Blvd, Mahwah, New Jersey 07430-2045.

JURISDICTION AND VENUE

4. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has subject matter jurisdiction over Auxilium’s declaratory judgment claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. This Court has personal jurisdiction over FCB I because FCB I has a principal place of business located at 933 MacArthur Blvd, Mahwah, New Jersey 07430-2045.

6. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b) because FCB I has a principal place of business in New Jersey.

THE PATENTS-IN-SUIT

7. The allegations of each above paragraph are incorporated herein by reference and realleged.

8. Auxilium was and is the exclusive licensee of the patents-in-suit by way of a License Agreement dated May 31, 2000 (the “License Agreement”), between Auxilium and Bentley Pharmaceuticals, Inc., which was the assignee of the patents-in-suit at that time. By way of an assignment dated June 30, 2008, and recorded at the PTO on August 13, 2008 (reel: 021380, frame: 0174), Bentley Pharmaceuticals, Inc. assigned its entire right, title and interest in the patents-in-suit to CPEX Pharmaceuticals, Inc. According to the PTO’s electronic records, FCB I is the current assignee of the entire right, title and interest in the patents-in-suit by way of an assignment from CPEX Pharmaceuticals, Inc. to FCB I dated April 5, 2011, which was recorded at the PTO on April 5, 2011 (reel: 026075, frame: 0498).

9. The patents-in-suit are related to each other and share a common specification.

10. U.S. Patent No. 7,320,968 (“the ’968 patent”), entitled “Pharmaceutical Composition” was issued by the PTO on January 22, 2008. A copy of the ’968 patent is attached

as Exhibit A. Claim 1 of the '968 patent (its sole independent claim) is directed to “[a] method for maintaining an effective concentration of testosterone in the blood serum of a male for treating hypogonadism which comprises transdermally delivering to the male by applying to the skin a composition which is in the form of a topical gel, . . . and comprises: (A) . . . testosterone; (B) . . . oxacyclohexadecan-2-one; (C) . . . a thickening agent . . .” Ex. A, col. 24:2-26.

11. U.S. Patent No. 7,608,605 (“the '605 patent”), entitled “Pharmaceutical Composition” was issued by the PTO on October 27, 2009. A copy of the '605 patent is attached as Exhibit B. Claim 1 of the '605 patent (its sole independent claim) is directed to “[a] method for maintaining an effective concentration of testosterone in the blood serum of a male for treating hypogonadism which comprises transdermally delivering to the male by applying to the skin a composition which is in the form of a topical gel, . . . and comprises: (A) . . . testosterone; (B) . . . oxacyclohexadecan-2-one; (C) . . . a thickening agent . . .” Ex. B, col. 23:5-17.

12. U.S. Patent No. 7,608,606 (“the '606 patent”), entitled “Pharmaceutical Composition” was issued by the PTO on October 27, 2009. A true and correct copy of the '606 patent is attached as Exhibit C. Claim 1 of the '606 patent (its sole independent claim) is directed to “[a] method for maintaining an effective concentration of testosterone in the blood serum of a male for treating hypogonadism which comprises transdermally delivering to the male by applying to the skin a composition which is in the form of a topical gel, . . . and comprises: (A) . . . testosterone; (B) . . . oxacyclohexadecan-2-one; (C) . . . a thickening agent . . .” Ex. C, col. 23:32 – col. 24:3.

13. U.S. Patent No. 7,608,607 (“the '607 patent”), entitled “Pharmaceutical Composition” was issued by the PTO on October 27, 2009. A copy of the '607 patent is attached as Exhibit D. Claims 1 and 10 of the '607 patent (the sole independent claims) are directed to

“[a] method for maintaining an effective concentration of testosterone in the blood serum of a male for treating hypogonadism which comprises transdermally delivering to the male by applying to the skin a composition which is in the form of a topical gel, . . . and comprises: (A) . . . testosterone; (B) . . . oxacyclohexadecan-2-one . . . ; (C) . . . a thickening agent” Ex. D, col. 23:32-43, col. 24:17-41.

14. U.S. Patent No. 7,608,608 (“the ’608 patent”), entitled “Pharmaceutical Composition” was issued by the PTO on October 27, 2009. A copy of the ’608 patent is attached as Exhibit E. Claim 1 of the ’608 patent (its sole independent claim) is directed to “[a] method for maintaining an effective concentration of testosterone in the blood serum of a male for treating hypogonadism which comprises transdermally delivering to the male by applying to the skin a composition which is in the form of a topical gel, . . . and comprises: (A) . . . testosterone; (B) a macrocyclic enhancer selected from the group consisting of . . . oxacyclohexadecan-2-one . . . ; (C) . . . a thickening agent” Ex. E, col. 23:32 – col. 24:10.

15. U.S. Patent No. 7,608,609 (“the ’609 patent”), entitled “Pharmaceutical Composition” was issued by the USPTO on October 27, 2009. A copy of the ’609 patent is attached as Exhibit F. Claims 1 and 8 of the ’609 patent (its sole independent claims) are directed to “[a] method for maintaining an effective concentration of testosterone in the blood serum of a male for treating hypogonadism which comprises transdermally delivering to the male by applying to the skin a composition which is in the form of a topical gel, . . . and comprises: (A) . . . testosterone; (B) . . . oxacyclohexadecan-2-one; (C) . . . a thickening agent” Ex. F, col. 23:33-43, col. 24:18-40.

16. U.S. Patent No. 7,608,610 (“the ’610 patent”), entitled “Pharmaceutical Composition” was issued by the PTO on October 27, 2009. A copy of the ’610 patent is attached

as Exhibit G. Claim 1 of the '610 patent (its sole independent claim) is directed to “[a] method for maintaining an effective concentration of testosterone in the blood serum of a male for treating hypogonadism which comprises transdermally delivering to the male by applying to the skin a composition which is in the form of a topical gel, . . . and comprises: (A) . . . testosterone; (B) a macrocyclic enhancer selected from the consisting of . . . oxacyclohexadecan-2-one . . . ; (C) . . . a thickening agent” Ex. G, col. 23:32-45.

17. U.S. Patent No. 7,935,690 (“the '690 patent”), entitled “Pharmaceutical Composition” was issued by the USPTO on May 3, 2011. A copy of the '690 patent is attached as Exhibit H. Claim 1 of the '690 patent (its sole independent claim) is directed to “[a] method for maintaining an effective concentration of an androgen in the blood serum of a male for treating hypogonadism which comprises transdermally delivering to the male by applying to the skin a composition which is in the form of a topical gel, . . . and comprises: (A) . . . an androgen selected from the group consisting of testosterone . . . ; (B) a macrocyclic enhancer selected from the group consisting of . . . oxacyclohexadecan-2-one . . . ; (C) . . . a thickening agent” Ex. H, col. 22:66 – col. 23:15.

18. U.S. Patent No. 8,063,029 (“the '029 patent”), entitled “Pharmaceutical Composition” was issued by the USPTO on November 22, 2011. A copy of the '029 patent is attached as Exhibit I. Claim 1 of the '029 patent (its sole independent claim) is directed to “[a] method for maintaining an effective concentration of an androgen in the blood serum of a male for treating hypogonadism which comprises transdermally delivering to the male by applying to the skin a composition which is in the form of a topical gel, . . . and comprises: (A) . . . testosterone; (B) . . . a Hsieh enhancer; (C) . . . a thickening agent” Ex. I, col. 23:30 – col. 24:6.

19. U.S. Patent No. 8,178,518 (“the ’518 patent”), entitled “Pharmaceutical Composition” was issued by the PTO on May 15, 2012. A copy of the ’518 patent is attached as Exhibit J. Claim 1 of the ’518 patent (its sole independent claim) is directed to “[a] pharmaceutical composition comprising” *inter alia*, (A) testosterone, (B) oxacyclohexadecan-2-one, and (C) a thickening agent. *See* Ex. J, col. 24:13-26.

20. On May 23, 2012, Auxilium and FCB I filed a complaint in U.S. District Court for the District of New Jersey against Watson Laboratories, Inc. (NV), Watson Pharmaceuticals, Inc., and Watson Pharma, Inc. (collectively, “Watson”), alleging infringement of the patents-in-suit. *See* C.A. No. 2:12-cv-03084-JLL-MAH, D.E. 1 (D.N.J. May 23, 2012).

21. Auxilium and FCB I subsequently narrowed their infringement claims against Watson to claim 3 of the ’607 patent by filing a series of stipulations and consent judgments: *First*, Auxilium and FCB I agreed to dismiss claims 5, 10, 14 and 15 of the ’607 patent, claim 4 of the ’610 patent, and claim 2 of the ’029 patent (C.A. No. 2:12-cv-03084-JLL-MAH, D.E. 261 (D.N.J. September 5, 2014)); *Second*, Auxilium and FCB I agreed to dismiss all asserted claims of the ’968, ’605, ’606, ’608, ’609, and ’518 patents (C.A. No. 2:12-cv-03084-JLL-MAH, D.E. 269 (D.N.J. September 14, 2014)); and *Third*, Auxilium and FCB I agreed to dismiss claims 1, 2, 4, and 9 of the ’607 patent, claims 1-3, 8-12, and 17 of the ’610 patent, claims 1-3 and 7-12 of the ’690 patent, and claims 1, 3-5, and 7-10 of the ’029 patent (C.A. No. 2:12-cv-03084-JLL-MAH, D.E. 292 (D.N.J. October 30, 2014)). Auxilium and FCB I also stipulated that “WHEREAS, in order to simplify the issues with respect to claim 3 of the ’607 patent, the parties agree that whether Watson’s ANDA infringes any valid and enforceable claim of the Non-Trial Patents [i.e., the ’968 patent, the ’605 patent, the ’606 patent, the ’608 patent, the ’609 patent, the ’610 patent, the ’690 patent, the ’029 patent, and the ’518 patent] and the Withdrawn Claims

[i.e., claims 1, 2, and 4-15 of the '607 patent] will be determined by the outcome of the trial and appeal with respect to claim 3 of the '607 patent as provided herein.” *Id.* As a result, the sole issue decided by the Court was the validity and enforceability of claim 3 of the '607 patent.

22. A six-day bench trial was held on September 5, 8-10, and 15-16, 2014. After trial, the District Court held claim 3 of the '607 patent invalid under 35 U.S.C. § 101 for improper inventorship, invalid under 35 U.S.C. § 102(f) for derivation, invalid under 35 U.S.C. § 103 as obvious, and not unenforceable. C.A. No. 2:12-cv-03084-JLL-MAH, D.E. 298 (D.N.J. December 16, 2014). Specifically, the District Court found that, despite Mr. Robert Gyurik being named as the sole inventor of the '607 patent, Dr. Dean Hsieh conceived of the three main elements of claim 3 of the '607 patent: (1) testosterone (an androgen), oxacyclohexadecan-2-one (a “Hsieh enhancer”), and a thickening agent. *See id.* at *60-*61. Further, the District Court found that Mr. Gyurik derived the subject matter of claim 3 of the '607 patent from Dr. Hsieh by reviewing Dr. Hsieh’s laboratory notebooks and other materials. *See id.* at *11-13, *16, *61. Finally, the District Court found claim 3 of the '607 patent obvious over the prior art because the suitability of testosterone for transdermal delivery was well known, and a person of ordinary skill in the art would have had a reasonable expectation of success in developing the claimed pharmaceutical formulation for use in the claimed methods. *See id.* at *23-*56.

23. The District Court subsequently entered Final Judgment against Auxilium and FCB I, from which neither party appealed. C.A. No. 2:12-cv-03084-JLL-MAH, D.E. 306 (D.N.J. February 26, 2015).

THE PRESENT DISPUTE

24. The allegations of each above paragraph are incorporated herein by reference and realleged.

[REDACTED]

26. As described herein *supra*, the District Court found that the claimed subject matter of the patents-in-suit was derived from Dr. Hsieh, and specifically that Dr. Hsieh conceived of compositions comprising: (1) testosterone (an androgen), oxacyclohexadecan-2-one (a “Hsieh enhancer”), and a thickening agent. C.A. No. 2:12-cv-03084-JLL-MAH, D.E. 298 at *11-*13, *16, *60-*61 (D.N.J. December 14, 2014. Each and every claim of the patents-in-suit requires a composition that includes testosterone, a Hsieh enhancer such as oxacyclohexadecan-2-one, and a thickening agent, and therefore the patents-in-suit are invalid for at least the same reasons as detailed in district court’s December 14, 2014 opinion.

27. FCB I became aware of that Dr. Hsieh should have been named as an inventor on each of the patents-in-suit during the course of fact and expert discovery in C.A. No. 2:12-cv-03084-JLL-MAH (D.N.J.). To-date FCB I has not attempted to add Dr. Hsieh as an inventor on the patents-in-suit, or to otherwise correct the inventorship of the patents-in-suit.

[REDACTED]

29. There exists an actual and justiciable controversy between, on the one hand,

Auxilium, and on the other hand, FCB I, regarding whether the patents-in-suit are invalid for at least the same reasons that the District Court of New Jersey found in entering final judgment against Auxilium and FCB I. As such, Auxilium and FCB I has adverse legal interests concerning the patents-in-suit.

30. In sum, there exists a substantial controversy between the exclusive licensee of the patents-in-suit, Auxilium, and the patent owner, FCB I. The nature of the controversy between Auxilium and FCB I is actual and justiciable such that it can be redressed by judicial relief, and is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Auxilium will continue to be harmed absent a declaratory judgment by this Court.

COUNT I
(Declaratory Judgment of Invalidity of the Patents-in-Suit)

31. The allegations of each above paragraph are incorporated herein by reference and realleged.

32. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Auxilium and FCB I concerning the validity of the patents-in-suit.

33. Auxilium asserts that no valid claim of the patents-in-suit exists, and that the differences, if any, between the previously adjudicated claim 3 of the '607 patent and the claims of the patents-in-suit do not materially alter the question of invalidity. *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013).

34. Auxilium asserts that the District Court's entry of final judgment on claim 3 of the '607 patent has a collateral and preclusive effect that similarly renders invalid the other claims of

the '607 patent, as well as each of the claims of the patents-in-suit. *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994).

35. Auxilium is entitled to a declaration that there are no valid and enforceable claims of the patents-in-suit.

36. Based on the principles of equitable estoppel, Auxilium is entitled to a preliminary and permanent injunction preventing FCB I from attempting to correct the inventorship of the patents-in-suit or otherwise add Dr. Hsieh as an inventor to the patents-in-suit.

PRAYER FOR RELIEF

WHEREFORE, Auxilium respectfully request the Court to enter judgment in its favor and grant the following relief:

- a) Declaring that the claims of the patents-in-suit are invalid for at least the reasons set forth in the Opinion in C.A. No. 2:12-cv-03084-JLL-MAH, D.E. 298 (D.N.J. December 14, 2014), or for failure to comply with any other provisions for patentability set forth in 35 U.S.C. § 100 *et seq.* or other judicially created grounds for relief;
- b) Declaring that FCB I and any parent, subsidiary, predecessor-in-interest, and/or successor-in-interest, FCB I's agents, representatives and attorneys, and any individuals and/or entities in active concert, participation and/or privity with FCB I are preliminary and permanently enjoined from correcting inventorship of the patents-in-suit on the principles of equitable estoppel;
- c) Issuing an injunction barring FCB I and any parent, subsidiary, predecessor-in-interest, and/or successor-in-interest, FCB I's agents, representatives and attorneys, and any individuals and/or entities in active concert, participation and/or privity with FCB I from

asserting the patents-in-suit against Auxilium, its parent, subsidiaries, customers, or users with respect to Auxilium's products, services, and/or activities;

- d) That this case be found exceptional under 35 U.S.C. § 285 and that Auxilium be awarded its reasonable attorneys' fees incurred in connection with this Action;
- e) For costs and expenses incurred in this Action; and
- f) For such other and further relief as the Court deems just and proper.

Dated: November 18, 2020

Respectfully submitted,

/s/ Eric Levi
Eric Levi (#281402018)
1200 19th Street, NW
Washington, D.C. 20036
Tel: (202) 912-4800
Email: elevi@cozen.com

Of Counsel:

Barry P. Golob (*Pro Hac Vice* to be filed)
Kerry B. McTigue (*Pro Hac Vice* to be filed)
W. Blake Coblentz (*Pro Hac Vice* to be filed)
Aaron S. Lukas (*Pro Hac Vice* to be filed)

COZEN O'CONNOR
1200 Nineteenth Street, NW
Washington, D.C. 20036
Tel: (202) 912-4800
Email: bgolob@cozen.com
kmctigue@cozen.com
wcoblentz@cozen.com
alukas@cozen.com

*Attorneys for Plaintiff Auxilium
Pharmaceuticals, Inc.*

CERTIFICATION UNDER LOCAL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that, the invalidity of the patents-in-suit has been alleged as a counterclaim in an arbitration proceeding captioned BLACK HORSE CAPITAL, BLACK HORSE MASTER FUND LTD., and L'ISOLA OPCO LLC v. AUXILIUM PHARMACEUTICALS, INC., Case No. 01-20-0000-3951, currently pending before the American Arbitration Association. The patent owner and named defendant FCB I, LLC is not a party to that proceeding.

/s/ Eric Levi
Eric Levi

CERTIFICATION UNDER LOCAL RULE 201.1

Pursuant to Local Civil Rule 201.1, I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that Plaintiff seeks, *inter alia*, declaratory relief and the amount in controversy exceeds the \$150,000 threshold of interest and costs and any claim for punitive damages.

/s/ Eric Levi
Eric Levi