IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH,	)	
Plaintiffs,	)	
v.	)	C.A. No._____
ASTRAZENECA PHARMACEUTICALS LP and AMYLIN PHARMACEUTICALS, LLC,	)	**DEMAND FOR JURY TRIAL**
Defendants.	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs sanofi-aventis U.S. LLC ("Sanofi") and Sanofi-Aventis Deutschland GmbH ("Sanofi Germany") (collectively, "Plaintiffs") bring this action for a declaratory judgment of patent non-infringement and invalidity against Defendants AstraZeneca Pharmaceuticals LP ("AstraZeneca") and Amylin Pharmaceuticals, LLC ("Amylin") (collectively, "Defendants").

STATEMENT OF THE CASE

1. This is an action brought by Sanofi and Sanofi Germany against Defendants to obtain a judgment declaring that (a) Sanofi has not infringed and will not infringe any claim of United States Patent Nos. 6,902,744 ("the '744 patent"), 7,399,489 ("the '489 patent"), and 7,521,423 ("the '423 patent"); and (b) the claims of the '744, '489, and '423 patents are invalid.

THE PARTIES

2. Plaintiffs are part of a global group of companies that are together a global healthcare leader focused on patients' needs and engaged in research, development, manufacturing and marketing of health products, with a diversified offering of medicines, vaccines and innovative therapeutic solutions. They market FDA-approved products ranging

from Afrezza® human insulin inhalation powder to Zaltrap® anti-cancer medication used to treat metastatic colorectal cancer. In relation to the treatment diabetes mellitus, they market (with FDA approval) products including Afrezza® human insulin inhalation powder, Apidra® insulin glulisine for injection, iBGStar™ blood glucose meters, Lantus® insulin glargine for injection, and Toujeo® insulin glargine for injection.

3. Plaintiff Sanofi is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

4. Plaintiff Sanofi Germany is a company organized under the laws of Germany with its principal place of business at Brüningstrasse 50, D-65926, Frankfurt am Main, Germany.

5. Defendant AstraZeneca is a limited partnership organized and existing under the laws of the State of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850. Upon information and belief, AstraZeneca has appointed the Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, as its registered agent for service of process in this jurisdiction pursuant to 8 Del. C. §§ 371 and 376.

6. Defendant Amylin is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 9625 Towne Centre Drive, San Diego, California 92121. Upon information and belief, Amylin has appointed the Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, as its registered agent for service of process in this jurisdiction pursuant to 8 Del. C.§§ 371 and 376.

JURISDICTION AND VENUE

7. This action for a declaration of non-infringement and invalidity of patents arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court therefore has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has jurisdiction over the persons of Defendants because both Defendants are incorporated in the State of Delaware and therefore subject to the jurisdiction of this Court. As domestic corporations, AstraZeneca and Amylin are registered to do business with the Delaware Department of State, Division of Corporations. Furthermore, AstraZeneca has a principal place of business in Delaware.

9. In the alternative, and to the extent that Defendants are not subject to the jurisdiction of this Court as residents of Delaware, they are subject to the jurisdiction of the Court pursuant to 10 Del. C. § 3104. Specifically, Defendants regularly do or solicit business, engage in a persistent course of conduct, and derive substantial revenue from things used or consumed in Delaware and this District.

10. Defendants have also availed themselves of the benefits and protections of Delaware courts, including this Court. For example, Defendants have aggressively enforced their intellectual property in Delaware courts. Since the beginning of 2014, they (and other members of their corporate family) have brought at least sixteen patent infringement cases in this Court.

11. Among other instances, Defendants have asserted infringement of the '744 and '423 patents in litigation they have brought in this Court in *Astrazeneca LP and Amylin LLC v. Teva Pharmaceuticals USA LLC*, 1:14-cv-01478-GMS (D. Del. 2014). Also, Defendants have

not contested and thereby consented to this Court's jurisdiction in litigation brought against them including, among other instances, in response to litigation alleging non-infringement and invalidity of a patent related to the '423 patent, U.S. Patent No. 7,741,269 ("the '269 patent"), in *Teva Pharmaceuticals USA LLC v. Astrazeneca LP and Amylin LLC*, 1:15-cv-00050-GMS (D. Del. 2015).

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c) and 28 U.S.C. § 1400(b).

FACTUAL BACKGROUND

A. The Patents-in-Suit

13. The '744 patent, titled "Exendin Agonist Formulations and Methods of Administration Thereof," issued on June 7, 2005. The United States Patent and Trademark Office's ("USPTO") assignment database indicates that Defendants jointly own the '744 patent. A true and correct copy of the '744 patent is attached hereto as Exhibit A.

14. The '489 patent, titled "Exendin Analog Formulations," issued on July 15, 2008. The USPTO's assignment database indicates that Defendants jointly own the '489 patent. A true and correct copy of the '489 patent is attached hereto as Exhibit B.

15. The '423 patent, titled "Exendin Pharmaceutical Compositions," issued on April 21, 2009. The USPTO's assignment database indicates that Defendants jointly own the '423 patent. A true and correct copy of the '423 patent is attached hereto as Exhibit C.

16. The claims of the '744, '489, and '423 patents are all directed to formulations containing exendin-4 and/or exendin analogs.

B. The Parties' Products

17. Defendants market a pharmaceutical product under the trademark Byetta®. As described in the FDA-approved package insert, Byetta® is a twice-daily injection product intended to improve glycemic control in adults with type 2 diabetes mellitus. Byetta® contains the active ingredient exenatide (a synthetic version of exendin-4, a component of the venom of the Gila monster), which is a glucagon-like peptide-1 agonist ("GLP-1 agonist"). Byetta® is sold in the U.S. and throughout the world, including Europe.

18. Lyxumia® is a once-daily injection product, currently approved and marketed by Sanofi in Europe for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control. On July 27, 2015, Sanofi submitted a New Drug Application ("Sanofi's Lyxumia® NDA") seeking FDA approval to market Lyxumia® in the United States. Lyxumia® contains the active ingredient lixisenatide, which, like exenatide, is a GLP-1 agonist. Given the similarities of the indications and mechanism of action of the active pharmaceutical ingredients, Byetta® and Lyxumia® have been seen as competitive products, including by Defendants.

C. Defendants' Actions with regard to the Patents-in-Suit

19. In the U.S. Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") entry on Byetta®, Defendants listed the '744 and '423 patents (along with other patents including U.S. Patent No. 6,872,700 ("the '700 patent") and the '269 patent) as patents that could reasonably be asserted against anyone selling or seeking to sell a generic version of Byetta®.

20. The Orange Book-listed '700 and '269 patents are related to the patents-in-suit. The '700 patent is a grandparent of the '489 patent and shares a claim of priority to a provisional application with the '744 patent. The '269 patent is related to the '423 patent; one of their foreign counterparts is European Patent No. 996,459 ("the EP '459 patent").

21. In 2012 and 2013, Sanofi Germany filed nullity actions in the Netherlands and Germany seeking revocation of the Dutch and German registrations of the EP '459 patent. *See* Exhibits D and E.

22. On December 19, 2013, while those nullity actions were pending and coincident with the launch of Lyxumia® in the Netherlands as a prelude to Sanofi Germany's roll-out of Lyxumia® throughout Europe, Defendants sent a letter to Plaintiffs ("the Threat Letter") demanding that Plaintiffs either take a license to the EP '459 patent or else represent that they would not manufacture or market any products containing lixisenatide (including Lyxumia®) in the Netherlands while the EP '459 patent was in force. *See* Exhibit F. The Threat Letter makes clear that Defendants view the lixisenatide contained in Lyxumia® as falling within the scope of Defendants' patent claims directed to exendins and/or exendin analogs, including those of the EP '459 patent.

23. In particular, the Threat Letter stated that

> Amylin of is the opinion that your client' s product named Lyxumia containing the active ingredient lixisenatide, for which it has been granted a Marketing Authorisation through the centralized procedure (EU/1/12/811/001-005), is covered by the scope of protection of the ['459] Patent.

Ex. F at p.1.

24. The Threat Letter also stated that

> Given the fact that your client has applied for — [sic] and has been granted a Reimbursement Decision in the Netherlands for Lyxumia, there is an imminent

> threat of infringement as there are no formal obstacles for your client to actually launch its above mentioned product, if it has not already done so.

Ex. F at p.2.

25. The Threat Letter also stated that

> [I]n order to enable Amylin to protect its rights and to avoid unnecessary litigation and legal expenses, your client is being requested to undertake that it and/or any third parties acting pursuant to a licence [sic] or on basis of other collaboration with your client, will not manufacture or market any products containing lixisenatide including Lyxumia and/or will not engage in any other acts which would infringe the Amended Patent . . . .

Ex. F at p.2.

26. On January 3, 2014, Plaintiffs responded to the Threat Letter with a letter requesting that Defendants identify the manner of the alleged infringement of the EP '459 patent and the particular claims alleged to be infringed, along with a general denial of liability for infringement. *See* Exhibit G.

27. On January 10, 2014, Defendants responded to Plaintiffs with a letter refusing to articulate any detailed theories of infringement, and instead stating that Defendants "saw no reason to change" and thus maintained their opinion regarding alleged infringement of the EP '459 patent, and that Defendants reserved all rights and would continue to "consider which steps should be taken." *See* Exhibit H.

28. In 2014, Teva Pharmaceuticals USA LLC ("Teva") filed an Abbreviated New Drug Application ("ANDA") seeking approval to engage in the commercial manufacture, use and sale of a generic version of Byetta® prior to the expiration of the '744, '423, '700, and '269 patents. Teva also filed an accompanying Paragraph IV certification, alleging that its generic product would not infringe the claims of the '744, '423, '700, and '269 patents and/or that those

claims were invalid. Teva then sent to AstraZeneca and Amylin a letter notifying AstraZeneca and Amylin of its ANDA and Paragraph IV certification ("Teva's ANDA Notice Letter").

29. On December 12, 2014, allegedly within the 45-day statutory period after having received Teva's ANDA Notice Letter, AstraZeneca and Amylin filed a Complaint for Patent Infringement against Teva in this Court, which alleged infringement in part of the '744, '423, and '700 patents, but did not allege infringement of the '269 patent. *See AstraZeneca LP and Amylin LLC v. Teva USA*, 1:14-cv-01478-GMS (D. Del. 2014) ("Byetta Generic Lawsuit"), at DI 1 (attached hereto as Exhibit I).

30. On January 19, 2015, after Teva had requested from AstraZeneca and Amylin – but did not receive – a covenant not to sue with respect to the '269 patent, Teva filed a Complaint for Declaratory Judgment of Non-infringement in this Jurisdiction. *See Teva Pharmaceuticals USA LLC v. AstraZeneca LP and Amylin LLC*, 1:15-cv-00050-GMS (D. Del. 2015) ("Byetta Generic DJ Lawsuit"). AstraZeneca and Amylin responded to that Complaint with Counterclaims that, in part, asserted infringement of the '269 patent. *See* DI 7 (attached hereto as Exhibit J).

31. The Byetta Generic Lawsuit and Byetta Generic DJ Lawsuit have been consolidated and remain pending in this Court.

THE PRESENCE OF A CASE OR CONTROVERSY

32. The Threat Letter makes clear that Defendants view Lyxumia® as falling within the scope of Defendants' patent claims, including those of the EP '459 patent, as well as the '744, '489, and '423 patents, directed to exendins and/or exendin analogs.

33. Because Defendants filed their Complaint for Patent Infringement against Teva USA alleging that Teva has infringed the '744, '423, and '700 patents, and subsequently filed

Counterclaims alleging that Teva has infringed the '269 patent, Defendants have demonstrated an intent to enforce their patents concerning formulations containing GLP-1 agonists and uses thereof. Defendants have also demonstrated a general intent to enforce their patents aggressively through their bringing of at least sixteen patent infringement lawsuits in this Court since the beginning of 2014.

34. Plaintiffs have made, and will continue to make, substantial investment in activities relating to Sanofi's Lyxumia® NDA and pre-marketing activities relating thereto regarding sale of Lyxumia® in the United States.

35. For these reasons, Plaintiffs have a reasonable apprehension that Defendants will sue them for infringement of the claims of the '744, '489, and '423 patents at a time of Defendants' choosing and for the purpose of impairing Sanofi's ability to sell Lyxumia® in the United States.

36. Plaintiffs do not infringe any claim of the '744, '489, and '423 patents. Among other things, lixisenatide is not exendin-4, an exendin-4 peptide, an exendin, or an exendin analog (as those terms are used in the claims of the '744, '489, and '423 patents).

37. The claims of the '744, '489, and '423 patents are invalid. Among other things, they would have been obvious to a person of ordinary skill in the art at the time of the purported invention of the claims in light of prior art including U.S. Patent No. 5,424,286 (which discloses exendin-4, exendin-4 peptides, exendins, and exendin analogs), preformulation references, references regarding the deamidation of peptides, and the formulations of existing commercial peptide products at the time of purported invention.

38. An actual justiciable controversy therefore exists between the parties as to the non-infringement and invalidity of the claims of the '744, '489, and '423 patents.

39. To avoid legal uncertainty and to protect its substantial investment and anticipated future investment relating to Sanofi's Lyxumia® NDA and pre-marketing activities relating thereto regarding sale of Lyxumia® in the United States, Sanofi brings these claims for a declaration of rights with respect to the '744, '489, and '423 patents.

40. Resolving this controversy with a declaration of rights would serve the public policy interest.

COUNT I
Declaratory Judgment of Non-Infringement,
United States Patent No. 6,902,744

41. Plaintiffs incorporate by reference and re-allege the allegations in paragraphs 1 through 40 as if fully set forth herein.

42. An actual controversy exists between Defendants and Plaintiffs concerning the non-infringement of the '744 patent, which requires a declaration of rights by this Court.

43. Plaintiffs have not infringed, will not infringe, and are not liable for infringement of any claim of the '744 patent.

44. Plaintiffs are entitled to a declaratory judgment that they have not infringed, will not infringe, and are not liable for infringement of any claim of the '744 patent, and that the commercial manufacture, use, offer for sale, sale or importation of Sanofi's Lyxumia® product would not infringe any claim of the '744 patent, either literally or under the doctrine of equivalents.

COUNT II
Declaratory Judgment of Non-Infringement,
United States Patent No. 7,399,489

45. Plaintiffs incorporate by reference and re-allege the allegations in paragraphs 1 through 40 as if fully set forth herein.

46. An actual controversy exists between Defendants and Plaintiffs concerning the non-infringement of the '489 patent, which requires a declaration of rights by this Court.

47. Plaintiffs have not infringed, will not infringe, and are not liable for infringement of any claim of the '489 patent.

48. Plaintiffs are entitled to a declaratory judgment that they have not infringed, will not infringe, and are not liable for infringement of any claim of the '489 patent, and that the commercial manufacture, use, offer for sale, sale or importation of Sanofi's Lyxumia® product would not infringe any claim of the '489 patent, either literally or under the doctrine of equivalents.

COUNT III
Declaratory Judgment of Non-Infringement,
United States Patent No. 7,521,423

49. Plaintiffs incorporate by reference and re-allege the allegations in paragraphs 1 through 40 as if fully set forth herein.

50. An actual controversy exists between Defendants and Plaintiffs concerning the non-infringement of the '423 patent, which requires a declaration of rights by this Court.

51. Plaintiffs have not infringed, will not infringe, and are not liable for infringement of any claim of the '423 patent.

52. Plaintiffs are entitled to a declaratory judgment that they have not infringed, will not infringe, and are not liable for infringement of any claim of the '423 patent, and that the commercial manufacture, use, offer for sale, sale or importation of Sanofi's Lyxumia® product would not infringe any claim of the '423 patent, either literally or under the doctrine of equivalents.

COUNT IV
Declaratory Judgment of Invalidity,
United States Patent No. 6,902,744

53. Plaintiffs incorporate by reference and re-allege the allegations in paragraphs 1 through 40 as if fully set forth herein.

54. An actual controversy exists between Defendants and Plaintiffs concerning the validity of the '744 patent, which requires a declaration of rights by this Court.

55. The claims of the '744 patent are invalid pursuant to 35 U.S.C. §§ 102, 103 and 112, and/or for obviousness-type double patenting.

56. Plaintiffs are entitled to a declaratory judgment that the claims of the '744 are invalid.

COUNT V
Declaratory Judgment of Invalidity,
United States Patent No. 7,399,489

57. Plaintiffs incorporate by reference and re-allege the allegations in paragraphs 1 through 40 as if fully set forth herein.

58. An actual controversy exists between Defendants and Plaintiffs concerning the validity of the '489 patent, which requires a declaration of rights by this Court.

59. The claims of the '489 patent are invalid pursuant to 35 U.S.C. §§ 102, 103 and 112, and/or for obviousness-type double patenting.

60. Plaintiffs are entitled to a declaratory judgment that the claims of the '489 are invalid.

COUNT VI
Declaratory Judgment of Invalidity,
United States Patent No. 7,521,423

61. Plaintiffs incorporate by reference and re-allege the allegations in paragraphs 1 through 40 as if fully set forth herein.

62. An actual controversy exists between Defendants and Plaintiffs concerning the validity of the '423 patent, which requires a declaration of rights by this Court.

63. The claims of the '423 patent are invalid pursuant to 35 U.S.C. §§ 102, 103 and 112, and/or for obviousness-type double patenting.

64. Plaintiffs are entitled to a declaratory judgment that the claims of the '423 are invalid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Sanofi and Sanofi Germany respectfully request that this Court grant the following relief against Defendants:

A. A judgment declaring that Plaintiffs have not infringed, will not infringe, and are not liable for infringement of any claim of the '744, '489, and '423 patents, and that the commercial manufacture, use, offer for sale, sale or importation of Sanofi's Lyxumia® product would not infringe any claim of the '744, '489, and '423 patents, either literally or under the doctrine of equivalents;

B. A judgment declaring that claims of the '744, '489, and '423 patents are invalid;

C. An injunction permanently enjoining Defendants from seeking to enforce the '744, '489, and/or '423 patents against Plaintiffs;

D. An award to Plaintiffs of its costs and expenses in this action; and

E. Such other and further relief as this Court may deem just.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs sanofi-aventis U.S. LLC and Sanofi-Aventis Deutschland GmbH hereby demand a trial by jury of all issues so triable in this action.

Dated: July 31, 2015

Respectfully submitted,

NOVAK DRUCE CONNOLLY BOVE + QUIGG LLP

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