

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

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

ROYALTY PHARMA COLLECTION TRUST,

Defendant.

C.A. No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR DECLARATORY JUDGMENT

Merck Sharp & Dohme Corp. (“Merck”), for its Complaint against Royalty Pharma Collection Trust (“RP”), alleges as follows:

NATURE OF ACTION

1. Merck seeks a declaratory judgment of non-infringement and/or invalidity of U.S. Patent Nos. 6,303,661 (the “661 Patent”), 6,803,357 (the “357 Patent”), 7,157,429 (the “429 Patent”), 6,890,898 (the “898 Patent”), 7,078,381 (the “381 Patent”), 7,459,428 (the “428 Patent”), 7,829,530 (the “530 Patent”), 8,318,669 (“669 Patent”), 8,513,190 (the “190 Patent”) and 9,044,424 (the “424 Patent”).

PARTIES

2. Merck Sharp & Dohme Corp. is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at One Merck Drive, Whitehouse Station, NJ 08889.

3. RP is a statutory trust organized and existing under the laws of the State of Delaware, having a place of business at 110 East 59th Street, 33rd Floor, New York, New York 10022.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 2201(a), and 35 U.S.C. §§ 100 *et seq.*

5. This Court has personal jurisdiction over RP because it is a statutory trust organized and existing under Delaware law.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

A. Merck's Januvia®, Janumet® And Janumet® XR Diabetes Treatments

7. Merck discovered the active pharmaceutical ingredient, sitagliptin phosphate, in its laboratories for the treatment of Type II diabetes, and Merck Sharp & Dohme Corp. currently owns New Drug Application Nos. 021995, 022044 and 202270, pursuant to which it lawfully markets Januvia®, Janumet® and Janumet® XR (collectively, the "Sitagliptin Products").

8. Januvia® contains sitagliptin phosphate as the sole active pharmaceutical ingredient and is marketed in at least three dosage strengths.

9. Janumet® contains sitagliptin phosphate and metformin hydrochloride as active pharmaceutical ingredients and is marketed in at least two dosage strengths.

10. Janumet® XR contains sitagliptin phosphate and metformin hydrochloride as active pharmaceutical ingredients and is marketed in at least three dosage strengths.

11. Sitagliptin is a dipeptidyl peptidase IV inhibitor ("DPP-IV inhibitor"), which is useful in treating Type II diabetes. Metformin is also useful in treating Type II diabetes, and is frequently used in combination with other therapies in the treatment of Type II diabetes.

B. The Relationship Between The Parties

12. Merck (formerly known as Merck & Co., Inc.) and a company then known as Probiodrug Gesellschaft Fur Arzneimittelforschung mbH (“Probiodrug”) entered into to a License Agreement dated October 31, 2000 (the “Probiodrug Agreement”). RP acquired Probiodrug’s rights in the Probiodrug Agreement in or around June 2011.

13. Merck (formerly known as Merck & Co., Inc.) and a company then known as Prosidion Limited (“Prosidion”) entered into a Second License Agreement dated June 29, 2005 (the “Prosidion Agreement,” and together with the Probiodrug Agreement, the “License Agreements”). RP acquired Prosidion’s rights in the Prosidion Agreement in or around June 2011.

14. RP purports to own the ‘661 Patent (the “Probiodrug Patent”), which is licensed to Merck Sharp & Dohme Corp., for non-exclusive use in the Probiodrug Agreement.

15. RP purports to own the ‘357 Patent, the ‘429 Patent, the ‘898 Patent, the ‘381 Patent), the ‘428 Patent, the ‘530 Patent, the ‘669 Patent, the ‘190 Patent and the ‘424 Patent (collectively, the “Prosidion Patents,” and together with the Probiodrug Patent, the “Patents-in-Suit”), which are licensed to Merck Sharp & Dohme Corp., for non-exclusive use in the Prosidion Agreement.

16. In correspondence dated April 29, 2015 to Merck, RP referred to the Patents-In-Suit as the “Diabetes Use Patents” and thus, upon information and belief, contends that the Patents-In-Suit are (i) valid, (ii) cover Merck’s Sitagliptin Products and (iii) would be infringed by Merck’s Sitagliptin Products in the absence of the License Agreements.

17. In compliance with the License Agreements, Merck has made substantial royalty payments to RP relating to the sales of Merck’s Sitagliptin Products. Merck brings this declaratory judgment action because it believes and maintains that it is no longer required to pay

royalties on the sales of Sitagliptin Products because the Patents-In-Suit do not cover Merck's Sitagliptin Productions or alternatively, are invalid pursuant to 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 102, 103, and 112.

C. The Patents-In-Suit

1. The Probiodrug Patent

18. Upon information and belief, RP holds title (by assignment) to the '661 Patent, entitled "Use of Dipeptidyl Peptidase IV Effectors For Lowering the Blood Glucose Levels in Mammals," issued on October 16, 2001. The '661 Patent is directed generally to methods of lowering elevated blood glucose levels in mammals (*i.e.*, treating Type II diabetes) by administering a DPP-IV inhibitor. A true and correct copy of the '661 Patent is attached hereto as Exhibit A.

19. The '661 Patent claims priority to an April 25, 1996 German patent application.

2. The Prosidion Patents

20. Upon information and belief, RP holds title by assignment to the '357 Patent, entitled "Method Of Regulating Glucose Metabolism And Reagents Related Thereto," issued on October 12, 2004. The '357 Patent is directed generally to methods of treating Type II diabetes in animals by administering to an animal one or more DPP-IV inhibitors in an amount sufficient to treat Type II diabetes but not sufficient to suppress the immune system. Claims 23-30 of the '357 Patent recite administering a composition including a boronyl peptidomimetic of a peptide selected from Pro-Pro, Ala-Pro, or (D)-Ala-(L)-Ala. A true and correct copy of the '357 Patent is attached hereto as Exhibit B.

21. Upon information and belief, RP holds title (by assignment) to the '429 Patent, entitled "Method Of Regulating Glucose Metabolism And Reagents Related Thereto," issued on January 2, 2007. The '429 Patent is directed generally to methods of modifying glucose

metabolism by administering to a glucose intolerant animal a composition including either a boronate or boronyl moiety in an amount sufficient to modify glucose metabolism but not sufficient to suppress the immune system. A true and correct copy of the '429 Patent is attached hereto as Exhibit C.

22. Upon information and belief, RP holds title (by assignment) to the '898 Patent, entitled "Method Of Regulating Glucose Metabolism And Reagents Related Thereto," issued on May 10, 2005. The '898 Patent is directed generally to methods of modifying glucose metabolism of an animal by conjointly administering to the animal a DPP-IV inhibitor in an amount sufficient to modify glucose metabolism but not sufficient to suppress the immune system and one or more other therapeutic agents. A true and correct copy of the '898 Patent is attached hereto as Exhibit D.

23. Upon information and belief, RP holds title (by assignment) to the '381 Patent, entitled "Method Of Regulating Glucose Metabolism And Reagents Related Thereto," issued on July 18, 2006. The '381 Patent is directed generally to methods of modifying glucose metabolism by conjointly administering to an animal in need of modification of glucose metabolism a DPP-IV inhibitor or pharmaceutically acceptable salt thereof in an amount sufficient to modify glucose metabolism but not sufficient to suppress the immune system and one or more other therapeutic agents. A true and correct copy of the '381 Patent is attached hereto as Exhibit E.

24. Upon information and belief, RP holds title (by assignment) to the '428 Patent, entitled "Method Of Regulating Glucose Metabolism And Reagents Related Thereto," issued on December 2, 2008. The '428 Patent is directed generally to methods of treating Type II diabetes in an animal by conjointly administering to the animal metformin and a DPP-IV inhibitor or a

pharmaceutically acceptable salt thereof in an amount sufficient to treat Type II diabetes but not sufficient to suppress the immune system. A true and correct copy of the '428 Patent is attached hereto as Exhibit F.

25. Upon information and belief, RP holds title (by assignment) to the '530 Patent, entitled "Method Of Regulating Glucose Metabolism And Reagents Related Thereto," issued on November 9, 2010. The '530 Patent is directed generally to methods of treating Type II diabetes by conjointly administering to an animal in need thereof metformin and a DPP-IV inhibitor having a boronate in an amount sufficient to treat Type II diabetes but not sufficient to suppress the immune system. A true and correct copy of the '530 Patent is attached hereto as Exhibit G.

26. Upon information and belief, RP holds title (by assignment) to the '669 Patent, entitled "Method Of Regulating Glucose Metabolism And Reagents Related Thereto," issued on November 27, 2012. The '669 Patent is directed generally to methods of modifying glucagon-like peptide 1 ("GLP-1") by administering to an animal in need thereof a DPP-IV inhibitor or pharmaceutically acceptable salt thereof once daily in an amount sufficient to inhibit DPP-IV proteolysis of GLP-1 but not sufficient to suppress the immune system. A true and correct copy of the '669 Patent is attached hereto as Exhibit H.

27. Upon information and belief, RP holds title (by assignment) to the '190 Patent, entitled "Method Of Regulating Glucose Metabolism And Reagents Related Thereto," issued on August 20, 2013. The '190 Patent is directed generally to methods of treating Type II diabetes by administering to an animal in need thereof a DPP-IV inhibitor or pharmaceutically acceptable salt thereof once daily to obtain a therapeutic effect for at least about 24 hours, and the DPP-IV inhibitor is administered in an amount sufficient to treat Type II diabetes but not sufficient to

suppress the immune system. A true and correct copy of the '190 Patent is attached hereto as Exhibit I.

28. Upon information and belief, RP holds title (by assignment) to the '424 Patent, entitled "Method Of Regulating Glucose Metabolism And Reagents Related Thereto," issued on June 2, 2015. The '424 Patent is directed generally to methods of modifying glucose metabolism by administering a DPP-IV inhibitor once daily to obtain a therapeutic effect for at least about 24 hours in an amount sufficient to increase the plasma half-life of GLP-1 but not sufficient to suppress the immune system. A true and correct copy of the '424 Patent is attached hereto as Exhibit J.

29. The Prosidion Patents all have the same inventors, have identical specifications, and all claim priority to the same provisional patent application filed on February 2, 1998. As with the Probiodrug Patent, and notwithstanding the differences in claim language, the Prosidion Patents are all directed to the use of a DPP-IV inhibitor to treat Type II diabetes.

D. The Claims Of The Patents-In-Suit Are Invalid Or Not Infringed By The Use Of Merck's Sitagliptin Products

1. The Patents-In-Suit Are Anticipated Or Obvious

30. As noted above, the Probiodrug Patent and Prosidion Patents claim priority to applications filed on April 25, 1996 and February 2, 1998, respectively.

31. In September 1995, prior to the earliest-claimed priority date of any of the Patents-In-Suit, Deacon *et al.* published "Both Subcutaneously and Intravenously Administered Glucagon-Like Peptide I Are Rapidly Degraded From the NH₂-Terminus In Type II Diabetic Patients and in Healthy Subjects," *Diabetes*, Vol. 44, at 1126 (September 1995) ("Deacon 1995") attached hereto as Exhibit K. Deacon 1995 provided persons of skill in the art with a teaching,

suggestion and motivation to use DPP-IV inhibitors to treat Type II diabetes, and it renders the Patents-In-Suit obvious, either on its own or in combination with other references.

32. Additionally, as early as 1994, Kikuchi *et al.* reported the use of a DPP-IV inhibitor, AY4166 (“AY”) to suppress postprandial hyperglycemia. An abstract of Kikuchi’s 1994 poster presentation is attached hereto as Exhibit L (“Kikuchi 1994”).

33. Kikuchi later reported on the efficacy of AY in a 1996 printed publication, a copy of which is hereto as Exhibit M (“Kikuchi 1996”). AY, which is also known as nateglinide, was subsequently discovered to be a DPP-IV inhibitor.

34. Upon information and belief, Kikuchi 1994, Kikuchi 1996 and the use of nateglinide reported therein inherently anticipate the Patents-In-Suit by using a DPP-IV inhibitor for the treatment of Type II diabetes.

35. Based on at least the foregoing prior art, one or more claims of the Patents-In-Suit are either anticipated or obvious, and therefore invalid.

2. The Patents-In-Suit Are Invalid Under 35 U.S.C. § 112

36. One or more of the claims of the Patents-In-Suit are invalid under 35 U.S.C. § 112 for failing to satisfy the written description and enablement requirements.

37. As noted above, the Patents-In-Suit are directed generally to the administration of DPP-IV inhibitors in the treatment of Type II diabetes. The Prosidion Patents all have the same specifications. With the claims directed to a very broad DPP-IV genus, the Patents-In-Suit fail to convey to a hypothetical person of skill in the art (“POSA”) that the inventors were in possession of the full scope of the claimed invention. The Patents-In-Suit fail to describe with specificity a sufficient number of DPP-IV inhibitor species or structural elements of DPP-IV inhibitors from which a POSA could conclude that the inventors were in possession of the full scope of the claimed invention.

38. The Patents-In-Suit do not enable a POSA to practice the claimed invention absent undue experimentation. The Patents-In-Suit fail to provide a POSA with any guidance in the selection of a compound as a potential, therapeutically effective DPP-IV inhibitor, or provide any structural clues from which the identity of therapeutically effective DPP-IV inhibitors can be ascertained. Indeed, even with regard to the claims reciting a base structure with options as to substituents, a POSA has no way of determining, in the absence of undue experimentation, which claimed compounds will act as inhibitors, let alone therapeutically effective DPP-IV inhibitors without suppressing the immune system.

3. Merck's Sitagliptin Products Do Not Contain A Boron-Substituted-DPP-IV Inhibitor

39. Certain claims of the Patents-In-Suit do not cover Merck's Sitagliptin Products. For example, the '429 Patent claims, the '530 Patent claims and claims 23-30 of the '357 patent are directed to DPP-IV inhibitors that include boronate or boronyl groups. Merck's Sitagliptin Products do not contain a boronate or boronyl group, and therefore, Merck's Sitagliptin Products do not infringe the claims of the Patents-In-Suit directed to DPP-IV inhibitors having boronate or boronyl groups.

COUNT I

(Declaratory judgment of non-infringement and invalidity of the '661 Patent)

40. Merck incorporates the allegations of paragraphs 1-39 above as if set forth herein in full.

41. The claims of the '661 Patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 102, 103, and 112.

42. The manufacture, use, sale, offer for sale, and/or importation of Merck's Sitagliptin Products does not infringe any valid claim of the '661 Patent, and would not infringe any valid claim of the '661 Patent in the absence of the License Agreements.

43. An actual and justiciable controversy exists between Merck and RP with respect to the '661 Patent, and Merck is entitled to a declaratory judgment that the '661 Patent is invalid and not infringed by Merck's Sitagliptin Products.

COUNT II

(Declaratory judgment of non-infringement and invalidity of the '357 Patent)

44. Merck incorporates the allegations of paragraphs 1-43 above as if set forth herein in full.

45. Claims 1-22 of the '357 Patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 102, 103, and 112.

46. Claims 23-30 of the '357 Patent which are directed to DPP-IV inhibitors having boronate or boronyl groups. Merck's Sitagliptin Products do not include a boronate or boronyl group and do not infringe claims 23-30 of the '357 for at least that reason.

47. The manufacture, use, sale, offer for sale, and/or importation of Merck's Sitagliptin Products does not infringe any valid claim of the '357 Patent, and would not infringe any valid claim of the '357 Patent in the absence of the License Agreements.

48. An actual and justiciable controversy exists between Merck and RP with respect to the '357 Patent, and Merck is entitled to a declaratory judgment that the '357 Patent is invalid and not infringed by Merck's Sitagliptin Products.

COUNT III

**(Declaratory judgment of
non-infringement of the '429 Patent)**

49. Merck incorporates the allegations of paragraphs 1-48 above as if set forth herein in full.

50. The claims of the '429 Patent which are directed to DPP-IV inhibitors having boronate or boronyl groups. Merck's Sitagliptin Products do not include a boronate or boronyl group and do not infringe the claims of the '429 Patent for at least that reason.

51. The manufacture, use, sale, offer for sale, and/or importation of Merck's Sitagliptin Products does not infringe any valid claim of the '429 Patent, and would not infringe any valid claim of the '429 Patent in the absence of the License Agreements.

52. An actual and justiciable controversy exists between Merck and RP with respect to the '429 Patent, and Merck is entitled to a declaratory judgment that the '429 Patent is not infringed by Merck's Sitagliptin Products.

COUNT IV

**(Declaratory judgment of
non-infringement and invalidity of the '898 Patent)**

53. Merck incorporates the allegations of paragraphs 1-52 above as if set forth herein in full.

54. The claims of the '898 Patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 102, 103, and 112.

55. The manufacture, use, sale, offer for sale, and/or importation of Merck's Sitagliptin Products does not infringe any valid claim of the '898 Patent, and would not infringe any valid claim of the '898 Patent in the absence of the License Agreements.

56. An actual and justiciable controversy exists between Merck and RP with respect to the '898 Patent, and Merck is entitled to a declaratory judgment that the '898 Patent is invalid and not infringed by Merck's Sitagliptin Products.

COUNT V

**(Declaratory judgment of
non-infringement and invalidity of the '381 Patent)**

57. Merck incorporates the allegations of paragraphs 1-56 above as if set forth herein in full.

58. The claims of the '381 Patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 102, 103, and 112.

59. The manufacture, use, sale, offer for sale, and/or importation of Merck's Sitagliptin Products does not infringe any valid claim of the '381 Patent, and would not infringe any valid claim of the '381 Patent in the absence of the License Agreements.

60. An actual and justiciable controversy exists between Merck and RP with respect to the '381 Patent, and Merck is entitled to a declaratory judgment that the '381 Patent is invalid and not infringed by Merck's Sitagliptin Products.

COUNT VI

**(Declaratory judgment of
non-infringement and invalidity of the '428 Patent)**

61. Merck incorporates the allegations of paragraphs 1-60 above as if set forth herein in full.

62. The claims of the '428 Patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 102, 103, and 112.

63. The manufacture, use, sale, offer for sale, and/or importation of Merck's Sitagliptin Products does not infringe any valid claim of the '428 Patent, and would not infringe any valid claim of the '428 Patent in the absence of the License Agreements.

64. An actual and justiciable controversy exists between Merck and RP with respect to the '428 Patent, and Merck is entitled to a declaratory judgment that the '428 Patent is invalid and not infringed by Merck's Sitagliptin Products.

COUNT VII

(Declaratory judgment of non-infringement of the '530 Patent)

65. Merck incorporates the allegations of paragraphs 1-64 above as if set forth herein in full.

66. The claims of the '530 Patent which are directed to DPP-IV inhibitors having boronate or boronyl groups. Merck's Sitagliptin Products do not include a boronate or boronyl group and do not infringe the claims of the '530 Patent for at least that reason.

67. The manufacture, use, sale, offer for sale, and/or importation of Merck's Sitagliptin Products does not infringe any valid claim of the '530 Patent, and would not infringe any valid claim of the '530 Patent in the absence of the License Agreements.

68. An actual and justiciable controversy exists between Merck and RP with respect to the '530 Patent, and Merck is entitled to a declaratory judgment that the '530 Patent is not infringed by Merck's Sitagliptin Products.

COUNT VIII

(Declaratory judgment of non-infringement and invalidity of the '669 Patent)

69. Merck incorporates the allegations of paragraphs 1-68 above as if set forth herein in full.

70. The claims of the '669 Patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 102, 103, and 112.

71. The manufacture, use, sale, offer for sale, and/or importation of Merck's Sitagliptin Products does not infringe any valid claim of the '669 Patent, and would not infringe any valid claim of the '669 Patent in the absence of the License Agreements.

72. An actual and justiciable controversy exists between Merck and RP with respect to the '669 Patent, and Merck is entitled to a declaratory judgment that the '669 Patent is invalid and not infringed by Merck's Sitagliptin Products.

COUNT IX

(Declaratory judgment of non-infringement and invalidity of the '190 Patent)

73. Merck incorporates the allegations of paragraphs 1-72 above as if set forth herein in full.

74. The claims of the '190 Patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 102, 103, and 112.

75. The manufacture, use, sale, offer for sale, and/or importation of Merck's Sitagliptin Products does not infringe any valid claim of the '190 Patent, and would not infringe any valid claim of the '190 Patent in the absence of the License Agreements.

76. An actual and justiciable controversy exists between Merck and RP with respect to the '190 Patent, and Merck is entitled to a declaratory judgment that the '190 Patent is invalid and not infringed by Merck's Sitagliptin Products.

COUNT X

**(Declaratory judgment of
non-infringement and invalidity of the '424 Patent)**

77. Merck incorporates the allegations of paragraphs 1-76 above as if set forth herein in full.

78. The claims of the '424 Patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 102, 103, and 112.

79. The manufacture, use, sale, offer for sale, and/or importation of Merck's Sitagliptin Products does not infringe any valid claim of the '424 Patent, and would not infringe any valid claim of the '424 Patent in the absence of the License Agreements.

80. An actual and justiciable controversy exists between Merck and RP with respect to the '424 Patent, and Merck is entitled to a declaratory judgment that the '424 Patent is invalid and not infringed by Merck's Sitagliptin Products.

DEMAND FOR JURY TRIAL

81. Merck hereby requests a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Merck respectfully requests that this Court enter judgment in its favor and against RP and grant the following relief:

- A. Declare that the claims of the '661 Patent are invalid;
- B. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of its Sitagliptin Products does not infringe any valid claims of the '661 Patent and would not infringe any valid claims of the '661 Patent in the absence of the License Agreements;
- C. Declare that claims 1-22 of the '357 Patent are invalid;

D. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of its Sitagliptin Products does not infringe claims 23-30, or any valid claims of the '357 Patent and would not infringe any valid claims of the '357 Patent in the absence of the License Agreements;

E. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of its Sitagliptin Products does not infringe any valid claims of the '429 Patent and would not infringe any valid claims of the '429 Patent in the absence of the License Agreements;

F. Declare that the claims of the '898 Patent are invalid;

G. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of its Sitagliptin Products does not infringe any valid claims of the '898 Patent and would not infringe any valid claims of the '898 Patent in the absence of the License Agreements;

H. Declare that the claims of the '381 Patent are invalid;

I. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of its Sitagliptin Products does not infringe any valid claims of the '381 Patent and would not infringe any valid claims of the '381 Patent in the absence of the License Agreements;

J. Declare that the claims of the '428 Patent are invalid;

K. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of its Sitagliptin Products does not infringe any valid claims of the '428 Patent and would not infringe any valid claims of the '428 Patent in the absence of the License Agreements;

L. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of its Sitagliptin Products does not infringe any valid claims of the '530 Patent and would not infringe any valid claims of the '530 Patent in the absence of the License Agreements;

M. Declare that the claims of the '669 Patent are invalid;

N. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of its Sitagliptin Products does not infringe any valid claims of the '669 Patent and would not infringe any valid claims of the '669 Patent in the absence of the License Agreements;

O. Declare that the claims of the '190 Patent are invalid;

P. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of its Sitagliptin Products does not infringe any valid claims of the '190 Patent and would not infringe any valid claims of the '190 Patent in the absence of the License Agreements;

Q. Declare that the claims of the '424 Patent are invalid;

R. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of its Sitagliptin Products does not infringe any valid claims of the '424 Patent and would not infringe any valid claims of the '424 Patent in the absence of the License Agreements;

S. Award Merck its costs and reasonable attorneys' fees to the extent permitted by law; and

T. Award Merck such other and further relief as the Court deems just and proper.

DATED: August 28, 2015

MCCARTER & ENGLISH, LLP

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