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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP., Plaintiff, v. BRISTOL-MYERS SQUIBB CO., E. R. SQUIBB & SONS, L.L.C., and ONO PHARMACEUTICAL CO., LTD., Defendants.	Civil Action No. _____ (Filed Electronically) **COMPLAINT FOR DECLARATORY JUDGMENT**

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Merck Sharp & Dohme Corp. ("Merck"), for its Complaint against Defendants Bristol-Myers Squibb Co., E. R. Squibb & Sons, L.L.C., and Ono Pharmaceutical Co., Ltd. (collectively, "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. Merck seeks a declaratory judgment that U.S. Patent Nos. 8,779,105 ("the '105 patent") and 9,084,776 ("the '776 patent") (collectively, "the patents in suit") are invalid and are not infringed by Merck's KEYTRUDA® (pembrolizumab) cancer treatment, which was the first FDA-approved anti-PD-1 immunotherapy.

PARTIES

2. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 1 Merck Drive, Whitehouse Station, New Jersey, 08889.

3. Defendant Bristol-Myers Squibb Co. ("BMS") has its headquarters for its U.S. Operations and R&D U.S. Medical Affairs Group in Plainsboro, New Jersey. *See* http://www.bms.com/research/facilities/Pages/ default.aspx. BMS is a corporation organized under the laws of the state of Delaware, with a principal place of business at 345 Park Ave., New York, New York 10154.

4. Defendant E. R. Squibb & Sons, L.L.C. ("Squibb") is a limited liability company organized and existing under the laws of the state of Delaware, with its principal place of business at Route 206 & Province Line Road, Princeton, New Jersey 08543. Defendant Squibb is a wholly owned subsidiary of Defendant BMS.

5. Defendant Ono Pharmaceutical Co., Ltd. ("Ono") is a corporation organized under the laws of Japan, with a place of business at 8-2 Kyutaromachi 1-chome, Chuo-ku, Osaka 541-8654, Japan.

JURISDICTION AND VENUE

6. This action for declaratory judgment arises under the patent laws of the United States of America, 35 U.S.C. §§ 100 *et seq.*

7. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 2201(a).

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

9. This Court has personal jurisdiction over Defendants by virtue of their specific acts in, and their continuous and systematic contacts with, the State of New Jersey and (as to Ono) with the United States as a whole.

Defendant BMS

10. This Court has personal jurisdiction over BMS by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey, including its substantial physical presence in New Jersey; (2) its purposefully availing itself of the jurisdiction of this Court in the past; (3) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of a registered agent in New Jersey for the receipt of process; and (4) its conduct by, through, and in concert with Squibb and Ono.

11. On information and belief, Defendant BMS, including through actions of its subsidiaries, is in the business of, among other things, developing, manufacturing, obtaining regulatory approval for, marketing, distributing, and selling pharmaceutical products in New Jersey and throughout the United States, including products that allegedly practice the patents in suit.

12. BMS is largely New Jersey-based and describes its 106 acre facility in Plainsboro, New Jersey, as "the headquarters" of its U.S. Operations and R&D U.S. Medical Affairs Group. *See* http://www.bms.com/research/facilities/Pages/default.aspx. BMS has no fewer than sixty-six buildings in New Jersey — including at sites in New Brunswick and Plainsboro — and is believed to have more employees in New Jersey than in any other single State by a large margin. *See id.*; *see, e.g.*, http://www.bms.com/sustainability/worldwide_facilities/north_america/Pages/new_brunswick_new_jersey.aspx; http://www.bms.com/sustainability/worldwide_facilities/north_america/Pages/plainsboro_new_jersey.aspx.

13. BMS has previously submitted to the jurisdiction of this Court and asserted claims for relief in this jurisdiction. *See, e.g., Merck, Sharp & Dohm Corp., et al. v. Hetero USA Inc., et al.*, Civil Action No. 15-8099; *Bristol-Myers Squibb Co. v. Mylan Pharms., Inc.*, Civil Action No. 15-1949; *In re: Plavix Prod. Liability and Mktg. Litig.*, Civil Action No. 15-987; *Bristol-Myers Squibb Co. v. Aurobindo Pharma U.S.A., Inc., et al.*, Civil Action No. 14-3585; *Bristol-Myers Squibb Co. v. Dr. Reddy's Labs., Ltd., et al.*, Civil Action No. 13-4171; and *Merck, Sharp & Dohme Corp., et al. v. CIPLA USA, Inc., et al.*, Civil Action No. 13-4017.

14. BMS is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 2384001000, and has appointed The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628 as its registered agent for service of process in New Jersey.

Defendant Squibb

15. This Court has personal jurisdiction over Squibb by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey, including its principal place of business in Princeton, New Jersey and its manufacturing of a substantial volume of

pharmaceutical products in New Jersey; (2) its purposefully availing itself of the jurisdiction of this Court in the past; (3) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of a registered agent in New Jersey for the receipt of process; and (4) its conduct by, through, and in concert with BMS and Ono.

16. On information and belief, Defendant Squibb, including through actions of its corporate parent or other related entities, is in the business of, among other things, developing, manufacturing, obtaining regulatory approval for, marketing, distributing, and selling pharmaceutical products in New Jersey and throughout the United States, including products that allegedly practice the patents in suit.

17. As noted above in Paragraph 4, Squibb has its principal place of business at Route 206 & Province Line Road, Princeton, New Jersey 08543.

18. Squibb has previously submitted to the jurisdiction of this Court and asserted claims for relief in this jurisdiction. *See, e.g.*, *E.R. Squibb & Sons, Inc. v. Eastman Med. Prods., Inc.*, Civil Action No. 02-573; *USA v. Alcolac, Inc., et al.*, Civil Action No. 01-4097; and *Bristol-Myers Squibb Co., et al. v. Geneva Pharms., Inc.*, Civil Action No. 95-5694.

19. Squibb is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0600094312, and has appointed The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628 as its registered agent for service of process in New Jersey.

Defendant Ono

20. This Court has personal jurisdiction over Ono by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey and the United States; and (2) its conduct by, through, and in concert with BMS and Squibb. To the extent this Court concludes

that Ono's contacts with New Jersey do not support general or specific personal jurisdiction under Fed. R. Civ. P. 4(k)(1), this Court has personal jurisdiction over Ono pursuant to Fed. R. Civ. P. 4(k)(2).

21. On information and belief, Defendant Ono is in the business of, among other things, developing, manufacturing, obtaining regulatory approval for, marketing, distributing, and selling pharmaceutical products, and Defendant Ono has had significant contacts with New Jersey and the United States, including through collaborations with other entities and through litigation.

22. On information and belief, Ono's activities in New Jersey have included collaborative research, development, and commercialization work with Medarex, Inc. (which was headquartered in Princeton, NJ at the time of the collaborative work), including work that led to the technology claimed in the patents in suit. *See, e.g.*, Ono press release "Ono and Medarex Enter Into Collaborative Research Agreement on Antibody Product," May 12, 2005, *available at* https://www.ono.co.jp/eng/cn/contents/sm_cn_050512.pdf. Medarex, Inc. was acquired by Plaintiff BMS in 2009. *See, e.g.*, Erika Fry, "Bristol-Myers Squibb: Big Pharma's small wonder," in *Fortune*, June 2, 2014, *available at* http://fortune.com/tag/bristol-myers-squibb/. Medarex, Inc. later was renamed Medarex, L.L.C., and then in 2014 it merged into Defendant Squibb. *See* Medarex, L.L.C. Form 5 dated September 23, 2014, *available at* http://www.sec.gov/Archives/edgar/data/14272/000120919114059468/xslF345X03/doc5.xml (noting that Medarex, L.L.C. was "formerly known as Medarex, Inc." and is a wholly-owned subsidiary of BMS); Medarex, L.L.C. Form 4 dated October 2, 2014, *available at* http://www.sec.gov/Archives/edgar/data/874255/000120919114061106/xslF345X03/doc4.xml

(stating that Medarex, L.L.C. was merged into E.R. Squibb & Sons, L.L.C. on September 30, 2014).

23. On information and belief, Ono has engaged in enforcement activities concerning the patents in suit in New Jersey, including by granting BMS exclusive rights covering activities in New Jersey and imposing on BMS enforcement obligations that extend to New Jersey. *See, e.g.*, BMS Form 10-K for fiscal year ended December 31, 2015, *available at* http://investor.bms.com/investors/financial-information/sec-filings/default.aspx, at pp. 11, 74 (stating that BMS "has the exclusive right to develop, manufacture and commercialize *Opdivo* in all territories worldwide except Japan, South Korea and Taiwan," that "Ono is entitled to receive royalties," and that "[r]oyalty rates on net sales are 4% in North America and 15% in all other applicable territories, subject to customary adjustments"); *see also* "Bristol-Myers Squibb and Ono Enter into Strategic Agreement for Anti-PD-1 Antibody, BMS-936558/ONO-4538, and ORENCIA® (abatacept)," *BusinessWire* Sept. 20, 2011, *available at* http://www.businesswire.com/news/home/20110920007303/en/Bristol-Myers-Squibb-Ono-Enter-Strategic-Agreement-Anti-PD-1 (describing Ono-BMS collaborations and reporting story as located in "PRINCETON, N.J. & OSAKA, Japan"); Ono website "Business Development & Licensing" page, *available at* https://www.ono.co.jp/eng/alliances/licensing.html (mentioning "a strategic collaboration agreement with Bristol-Myers Squibb Company (BMS) regarding immuno-oncology therapies" in description of "Vigorous Activities for Licensing Initiatives"); Ono website "Alliances" pages, *available at* https://www.ono.co.jp/eng/alliances/license/bms.html (describing relationship with BMS). As explained *supra*, BMS regularly does business in New Jersey. *See* ¶¶ 10–14.

24. Ono has previously been found to be subject to the jurisdiction of this Court. *See M.D. Jon M. Rogers v. Katsura Kasahara, et al.*, Civil Action No. 06-2033.

MERCK'S KEYTRUDA® CANCER TREATMENT

25. Merck is a global, research-driven pharmaceutical company that discovers, develops, manufactures, and markets a broad range of innovative products to improve health.

26. Merck's KEYTRUDA® (pembrolizumab) cancer treatment is the first FDA-approved anti-PD-1 immunotherapy. It works with the body's natural immune system to fight cancer. KEYTRUDA® is a monoclonal antibody that binds to the PD-1 receptor and blocks interaction between the PD-1 receptor and its ligands. In this way, KEYTRUDA® up-regulates the immune response to tumor cells, allowing the immune system to more aggressively attack and remove cancer cells.

27. KEYTRUDA® was discovered and developed by scientists working for Merck and Merck's predecessors, independently of the work that led to the patents in suit.

28. On September 4, 2014, the United States Food and Drug Administration ("FDA") approved KEYTRUDA® for treatment of certain patients with melanoma, a type of cancer. On October 2, 2015, the FDA approved KEYTRUDA® for treatment of certain patients with non-small cell lung cancer, another type of cancer. On December 18, 2015, the FDA approved an expanded melanoma indication for KEYTRUDA®, including first-line treatment for certain patients.

29. Plaintiff Merck, including through actions of its corporate subsidiaries or other related entities, manufactures KEYTRUDA® for use in New Jersey and throughout the United States, and also markets, distributes, and sells KEYTRUDA® for such use.

THE PATENTS IN SUIT

The '105 Patent

30. U.S. Patent No. 8,779,105, entitled "Monoclonal Antibodies to Programmed Death 1 (PD-1)," states on its face that it issued on July 15, 2014. The '105 patent lists the following inventors: Alan J. Korman, Mohan Srinivasan, Changyu Wang, Mark J. Selby, Bing Chen, Josephine M. Cardarelli, and Haichun Huang.

31. The '105 patent lists Medarex, L.L.C. as assignee. Medarex, L.L.C. merged into Defendant Squibb on or about September 30, 2014. *See* supra Paragraph 22. On information and belief, Defendant Squibb acquired the ownership interest in the '105 patent that previously belonged to Medarex, L.L.C.

32. On information and belief, including based on public records held by the United States Patent Office, Defendant Ono also has an ownership interest in the '105 patent.

33. On information and belief, including based on public records held by the United States Patent Office, Defendants Ono and Squibb co-own the '105 patent and have rights to sue and recover for infringement thereof. On information and belief, Defendant BMS holds exclusive rights to the '105 patent and has rights to sue and recover for infringement thereof. *See supra* Paragraph 23.

34. The '105 patent issued from an application that was a continuation of an application that was the U.S. national phase entry of international application no. PCT/JP2006/309606 ("the PCT Application").

35. The '105 patent contains two independent claims and twenty-eight dependent claims. The first independent claim is directed to a monoclonal antibody or antigen-binding portion thereof that "cross-competes for binding to PD-1" with one of seven reference antibodies (claim 1), and the other independent claim is directed to a monoclonal antibody or antigen-

binding portion thereof that binds to the "same epitope" as one of the same seven reference antibodies (claim 5).

The '776 Patent

36. U.S. Patent No. 9,084,776, entitled "Methods for Treating Cancer Using Anti-PD-1 Antibodies," states on its face that it issued on July 21, 2015. The '776 patent lists the following inventors: Alan J. Korman, Mohan Srinivasan, Changyu Wang, Mark J. Selby, Bingliang Chen, Josephine M. Cardarelli, and Haichun Huang.

37. The '776 patent lists E.R. Squibb & Sons, L.L.C. and Ono Pharmaceutical Co., Ltd. as assignees.

38. On information and belief, including based on public records held by the United States Patent Office, Defendants Ono and Squibb co-own the '776 patent and have rights to sue and recover for infringement thereof. On information and belief, Defendant BMS holds exclusive rights to the '105 patent and has rights to sue and recover for infringement thereof. *See supra* Paragraph 23.

39. The '776 patent issued from an application that was a continuation of an application that was a division of the application from which the '105 patent issued. As noted above in Paragraph 34, the application from which the '105 patent issued was a continuation of an application that was the U.S. national phase entry of the PCT Application.

40. The '776 patent contains one independent claim and eight dependent claims. The independent claim of the '776 patent is directed to methods of treating tumors in a patient by administering a therapeutic dose of a human or humanized anti-PD-1 monoclonal antibody (or antigen binding portion thereof) after the patient already had been administered an anti-CTLA-4 antibody (or antigen binding portion thereof) (claim 1). All of the dependent claims require,

among other things, that the anti-PD-1 antibody or antigen-binding portion thereof "cross-competes for binding to human PD-1" with one of four reference antibodies.

DEFENDANTS' PATENT ASSERTION ACTIVITIES

41. Defendants already have sued Merck for the alleged infringement by KEYTRUDA® of multiple patents claiming anti-PD-1 antibody technology, including a patent that is a foreign counterpart to the patents in suit. BMS acknowledges that it has "brought claims of infringement in a number of ongoing patent litigations against Merck & Co., Inc. (Merck) around the world with respect to patents directed to methods of treating cancer using a PD-1 antibody." *See* BMS Form 10-K for fiscal year ended December 31, 2015, *available at* http://investor.bms.com/investors/financial-information/sec-filings/default.aspx, at p. 101. In particular, BMS acknowledges that it has brought infringement claims against Merck directed at KEYTRUDA® in the United Kingdom, in the Netherlands, "in several other European countries, including France, Germany, Ireland, Spain and Switzerland," in the United States, and in Australia. *Id.*

Assertion of Australian Counterpart Patent

42. The Australian litigation, for example, concerns Australian Patent No. AU 2011203119 B2 ("the AU '119 patent"), which issued from the Australian national phase entry of the PCT Application. The AU '119 patent therefore is a foreign counterpart to the patents in suit (which also claim priority to the PCT Application). Independent claim 1 of the AU '119 patent is directed to a "monoclonal antibody, or antigen-binding portion thereof, which comprises" one of four sets of CDR amino acid sequences. These same four sets of CDR amino acid sequences are recited in, *inter alia*, independent claim 5 of the '105 patent, and three of the four sets appear in amino acid sequences recited in independent claim 2 of the '776 patent. Dependent claim 2 of the AU '119 patent is directed to a "monoclonal antibody, or antigen-

binding portion thereof" that comprises three of four sets of variable region amino acid sequences, which also appear in dependent claim 3 of the AU '119 patent. These same four sets of variable region amino acid sequences are recited in, *inter alia*, independent claims 1 and 10 of the '105 patent, and three of the four sets are recited in dependent claim 2 of the '776 patent.

43. The AU '119 patent is entitled "Human monoclonal antibodies to programmed death 1(PD-1) and methods for treating cancer using anti-PD-1 antibodies alone or in combination with other immunotherapeutics." It states on its face an Accepted Journal Date of March 8, 2012, and it lists the following inventors: Alan J. Korman, Bing Chen, Mohan Srinivasan, Josephine M. Cardarelli, Mark J. Selby, and Changyu Wang.

44. The face of the AU '119 patent lists Defendant Ono and Medarex, Inc. as applicants. Medarex, Inc. was acquired by Defendant BMS and later, following a name change, merged into Defendant Squibb. *See supra* Paragraph 22. BMS reports that it and Ono filed the infringement claim against Merck in Australia based on the AU '119 patent. *See* BMS Form 10-K for fiscal year ended December 31, 2015, *available at* http://investor.bms.com/investors/financial-information/sec-filings/default.aspx, at p. 101; *see also Merck Sharp & Dohme Corp. and Merck Sharp & Dohme (Australia) Pty Ltd. v. Ono Pharmaceutical Co. Ltd. and Medarex, L.L.C*, Matter No. NSD954/2014 (Federal Court of Australia), cross-claim filed March 20, 2015 (asserting that certain acts relating to KEYTRUDA® infringe claims 3, 5, 8–9, 11, and 14–17 of the AU '119 patent).

45. Regarding the Australian litigation concerning the AU '119 patent, BMS has stated: "Ono and BMS have similar and other patents and applications pending in the United States and other countries." *Id.* The phrase "similar and other patents" reasonably is understood to include the patents in suit (which are foreign counter parts to the AU '119 patent and claim

similar subject matter as the AU '119 patent). Particularly in view of the fact that Ono and BMS have sued Merck for infringement of the AU '119 patent, this statement suggests that Defendants also consider Merck's KEYTRUDA® to infringe the patents in suit.

European Counterpart Patent

46. The PCT Application (to which the patents in suit claim priority) itself issued as European Patent EP 2 161 336 B1 ("the EP '336 patent"). Independent claim 1 of the EP '336 patent is directed to an "isolated monoclonal antibody, or antigen-binding portion thereof," that "specifically binds human Programmed Death 1 (PD-1) protein" and that comprises certain variable region amino acid sequences. The same variable region amino acid sequences appear, *inter alia*, in independent claims 1 and 10 of the '105 patent.

47. The EP '336 patent is entitled "Human monoclonal antibodies to programmed death 1 (PD-1) and methods for treating cancer using anti-PD-1 antibodies alone or in combination with other immunotherapeutics." It states on its face that it issued on July 31, 2013, and it lists the following inventors: Alan J. Korman, Mohan Srinivasan, Changyu Wang, Mark J. Selby, Bing Chen, Josephine M. Cardarelli, and Haichun Huang.

48. The EP '336 patent lists ONO Pharmaceutical Co., Ltd. and Medarex, Inc. as assignees. Medarex, Inc. was acquired by Defendant BMS and later, following a name change, merged into Defendant Squibb. *See supra* Paragraph 22.

49. In the United Kingdom litigation, Merck asserted invalidity of the EP '336 patent, and during that litigation, BMS and Ono refused to concede that the claims of that patent would not be infringed by Merck's KEYTRUDA®.

50. Even when withdrawing the EP '336 patent from the United Kingdom litigation, Ono and BMS maintained their position that Merck's KEYTRUDA® would infringe the EP '336

patent. *See Merck Sharp & Dohme Limited and Ono Pharmaceutical Co. Limited; Medarex, LLC; Tasuku Honjo*, Claim HP-2014-000038 (United Kingdom High Court of Justice, Chancery Chambers), Amended Defence Received September 26, 2014, at ¶ 4B ("It is not admitted that the Claimant's proposed Pembrolizumab product does not fall within the scope of any claim, alternatively the scope of any valid claim of the 336 Patent. It is admitted that the Defendants have not given an acknowledgement to that effect.").

51. The fact that Ono and BMS refused to concede non-infringement of the EP '336 patent even when withdrawing it from the litigation further suggests that Defendants also consider Merck's KEYTRUDA® to infringe the patents in suit, which claim priority to the PCT Application from which the EP '336 patent issued.

Patent Assertion in the United States

52. As noted above in Paragraph 41, Defendants have brought infringement claims against Merck's KEYTRUDA®, asserting patents directed to anti-PD-1 antibody technology, in a multitude of countries, including the United States.

53. In particular, Defendants BMS, Squibb, and Ono, together with Tasuku Honjo, have accused KEYTRUDA® of patent infringement in three pending actions in the United States District Court for the District of Delaware: *Bristol-Myers Squibb Co., et al. v. Merck & Co., Inc., et al.*, Civil Action No. 14-1131; *Bristol-Myers Squibb Co., et al. v. Merck & Co., Inc., et al.*, Civil Action No. 15-560; and *Bristol-Myers Squibb Co., et al. v. Merck & Co., Inc., et al.*, Civil Action No. 15-572. The patents asserted in those actions, respectively, are U.S. Patent No. 8,728,474; U.S. Patent No. 9,067,999; and U.S. Patent No. 9,073,994. These three patents are generally directed to methods of treating cancer by administering an anti-PD-1 monoclonal antibody.

54. The fact that Defendants have sued Merck repeatedly in the United States, accusing the same product that is at issue here shows that Defendants are motivated to assert their patent rights against Merck's KEYTRUDA® in the United States.

55. The U.S. market for PD-1 immunotherapies like KEYTRUDA® has been projected as substantial in volume. *See, e.g.*, "Merck brings first PD-1 inhibitor to US market," in PMLive, September 5, 2014, *available at* http://www.pmlive.com/pharma_news/merck_brings_first_pd-1_inhibitor_to_us_market_597070. The economics of this industry and market therefore provide an increased incentive for Defendants to pursue additional claims against Merck in the United States based on the patents in suit.

56. Based upon Defendants' previous and ongoing claims of patent infringement by KEYTRUDA®, Merck has a reasonable apprehension that Defendants are likely to accuse KEYTRUDA® of infringing the claims of the '105 patent and the '776 patent, and that Defendants intend to do so imminently.

COUNT I
(Declaratory Judgment of Invalidity and Non-Infringement of the '105 Patent)

1. Merck incorporates by reference each of the preceding paragraphs of this Complaint as if fully set forth herein.

2. The claims of the '105 patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 101, 102, 103, and 112.

3. The manufacture, use, sale, offer for sale, and importation into the United States of KEYTRUDA® does not infringe any valid claim of the '105 patent.

4. An actual and justiciable controversy exists between Merck and Defendants with respect to the '105 patent, and Merck is entitled to a declaratory judgment that the '105 patent is invalid and not infringed by Merck's KEYTRUDA® products.

COUNT II
(Declaratory Judgment of Invalidity and Non-Infringement of the '776 Patent)

5. Merck incorporates by reference each of the preceding paragraphs of this Complaint as if fully set forth herein.

6. The claims of the '776 patent are invalid for failure to satisfy the requirements of 25 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 101, 102, 103, and 112.

7. The manufacture, use, sale, offer for sale, and importation into the United States of KEYTRUDA® does not infringe any valid claim of the '776 patent.

8. An actual and justiciable controversy exists between Merck and Defendants with respect to the '776 patent, and Merck is entitled to a declaratory judgment that the '776 patent is invalid and not infringed by Merck's KEYTRUDA® products.

PRAYER FOR RELIEF

WHEREFORE, Merck respectfully requests that this Court enter judgment in its favor and against Defendants Bristol-Myers Squibb Co., E. R. Squibb & Sons, L.L.C., and Ono Pharmaceutical Co., Ltd. and grant the following relief:

A. Declare that the claims of the '105 patent are invalid;

B. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of KEYTRUDA® products does not infringe any valid claims of the '105 patent;

C. Declare that the claims of the '776 patent are invalid;

D. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of KEYTRUDA® products does not infringe any valid claims of the '776 patent;

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

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

Dated: April 15, 2016

Respectfully submitted,

By: s/John E. Flaherty

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that, to the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: April 15, 2016

Respectfully submitted,

By: s/John E. Flaherty

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