UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

Merck Sharp & Dohme LLC Plaintiff, v. The Johns Hopkins University Defendant.	Civil Action No. _____ **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiff Merck Sharp & Dohme LLC ("Merck"), for its complaint against Defendant The Johns Hopkins University ("JHU"), alleges as follows:

Introduction

1. This action concerns patents emerging from a joint research collaboration by Merck and JHU regarding the use of Merck's breakthrough cancer drug pembrolizumab (also known as "pembro"), which Merck sells under the trade name Keytruda®. Merck and JHU partnered to design and conduct a clinical study administering Keytruda to cancer patients having tumors that had the genetic biomarker known as microsatellite instability-high ("MSI-H") or were mismatch repair deficient ("dMMR"). The clinical study was successful—including due to significant contributions made by Merck in the joint research collaboration.

2. After the conclusion of the study, JHU obtained issuance of United States patents citing the joint research study, but inaccurately claiming that the purported inventions arose prior to, and independent of, the collaboration with Merck. Further, JHU improperly exclusively licensed these patents to others. JHU then tried to use these patents to demand payment from Merck for use of Keytruda. JHU's activities in obtaining issuance of patents, which were

licensed to others, and then trying to enforce these patents against Merck, was in breach of JHU's covenants as part of its contract which Merck entered into in order to engage in the clinical study.

3. Merck therefore brings this action for breach of contract; declaratory judgment of noninfringement; and promissory estoppel.

The Parties

4. Plaintiff Merck is a global, research-driven pharmaceutical company that discovers, develops, manufactures, and markets a broad range of innovative products to improve health. Merck is an LLC organized and existing under the laws of the State of New Jersey with a principal place of business at 126 East Lincoln Avenue, Rahway, New Jersey, 07065. Merck, including through actions of its subsidiaries or other related entities, manufactures Keytruda for use per its United States Food and Drug Administration ("FDA") approved indications throughout the United States, and also markets, distributes, and sells Keytruda for such use.

5. Defendant JHU is a private university based in Baltimore, Maryland. JHU is a corporation existing under the laws of Maryland with its principal place of business located at Charles & 34th Street, Baltimore, MD, 21218.

Jurisdiction and Venue

6. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

7. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1332, and 1367.

8. JHU has continuous systematic contacts with Maryland and/or specific contacts with Maryland sufficiently related to this cause of action to warrant the exercise of personal jurisdiction by this court. JHU is a Maryland corporation and resides in Maryland, and the Merck and JHU contract is governed by Maryland law.

9. Venue is proper in this Court as to The Johns Hopkins University pursuant to 28 U.S.C. §§ 1391 because JHU is a Maryland corporation and thus resides in Maryland.

Keytruda

10. Keytruda was the first cancer drug of its kind, an anti-PD-1 antibody, approved by the FDA. Keytruda works by aiding the immune system to identify and destroy cancer cells. Keytruda was discovered and developed by scientists working for Merck and Merck's predecessors.

11. In 2010, Merck submitted an investigational new drug application to the FDA, followed by the initiation of a seminal phase 1 clinical trial in patients with advanced solid tumors. Keytruda, at the time referred to as MK-3475, was granted orphan drug designation for the treatment of advanced melanoma in late 2012 and was subsequently awarded breakthrough therapy designation for advanced melanoma in 2013.

12. Breakthrough therapy designation enables expedited clinical development, which in the case of Keytruda ultimately led to its accelerated approval in the USA in 2014 for the treatment of certain patients with unresectable or metastatic melanoma. Over time, Keytruda has been FDA approved for the treatment of over 19 different cancer indications, some spanning multiple types of cancers. It has been a life-saving and life-changing medicine for countless cancer patients.

13. Among the indications approved by the FDA for Keytruda is use "for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors . . . that have progressed following prior treatment and who have no satisfactory alternative treatment options." (Exhibit A at 1.) The Keytruda labeling further indicates that Keytruda is "for the treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC)." (Exhibit A at 1.)

14. The Keytruda labeling provides the following instructions with regard to these indications: "MSI-H or dMMR Cancer: 200 mg every 3 weeks or 400 mg every 6 weeks for adults; 2 mg/kg (up to 200 mg) every 3 weeks for pediatrics." (Exhibit A at 2.) The Keytruda labeling provides the following additional instructions: "MSI-H or dMMR CRC: 200 mg every 3 weeks or 400 mg every 6 weeks." (Exhibit A at 2.)

15. Among many other studies, the Keytruda labeling refers to the clinical study conducted in the joint research collaboration with JHU. (Exhibit A at 89.)

16. The Keytruda labeling does not instruct anyone to perform any sort of comparison of the treatment outcome of a given patient to another reference patient.

The Merck and JHU Joint Research Collaboration

17. In late 2012, JHU contacted Merck regarding the use of Merck's pembrolizumab product, Keytruda, for a clinical study of the efficacy of Keytruda in treating cancer patients in whom existed tumors that were MSI-H or dMMR.

18. On February 25, 2013, following initial discussions between JHU and Merck, JHU sent Merck a draft protocol for a study to treat cancer patients having tumors that were MSI-H, with Merck partially funding the study and providing supply of Merck's drug product. In that protocol, JHU suggested, among other things, using a particular dosage for Keytruda: 10

mg/kg every 21 days (i.e., every 3 weeks). JHU also suggested a particular frequency for scanning patients for tumor progression to determine whether the drug was reducing or eliminating the tumors: every 9 weeks. The timing of the scans was important to avoid false positive or negative results.

19. Based on proprietary data and experience with Keytruda, Merck scientists made various suggestions and edits to the protocol.

20. For example, on April 30, 2013, a Merck scientist, Amy Meister, based on information from other Merck scientists, communicated to JHU that the study should use a dose of 10 mg/kg every 2 weeks. The Merck scientists made this suggestion based on their experience, among other things, studying the treatment of melanoma patients with Keytruda. Amy Meister also communicated, based on Merck's scientists' suggestions, that a first scan should be performed at 12 weeks rather than 9 weeks, again based on Merck's experience with Keytruda.

21. On May 1, 2013, JHU sent Merck a revised protocol incorporating Merck's suggestion to provide a dosage of 10 mg/kg every 2 weeks. At that time, the revised protocol continued to call for scans every eight weeks. Merck's insistence that it was important for the first scan to be conducted at 12 weeks caused JHU to subsequently agree to a revised protocol following Merck's recommendations, *i.e.* with the dosing (10 mg/kg every 2 weeks) and a schedule for scans (beginning at week 12).

22. On June 10, 2013, the protocol was published at ClinicalTrials.gov (attached as Exhibit B). The published clinical study protocol described, among other things, treating patients with MSI high colorectal cancer and MSI high non-colorectal cancer with MK-3475. The published protocol called for, among other things, providing a dosage of 10 mg/kg of MK-

3475 every 2 weeks and measuring immune-related progression free survival (irPFS) and objective response rate (irORR), as well as the best overall response rate.

23. In August 2013, JHU and Merck entered into a formal, written contract to collaborate on the study. The contract is attached to this Complaint as Exhibit C ("Pembro Contract").

24. The Pembro Contract included several important provisions. For example, the contract provided:

> Ownership and rights to any new and patentable or unpatentable discovery, technology, or other intellectual property arising from the performance of the Protocol and Study shall be governed by the following provisions: Inventions made solely by the Principal Investigator or employees of Institution shall be the property of Institution (hereinafter "Institution Inventions"); and inventions made jointly by employees or agents of Merck and either the Principal Investigator or employees of Institution shall be the joint property of Merck and Institution (hereinafter "Joint Inventions"). Institution will promptly notify Merck in writing of any such inventions. Institution and Merck shall consult and agree upon the patent filing and prosecution strategy for all Joint Inventions.

(Exhibit C at § 12.B.)

25. In addition, under the Pembro Contract, Merck had

> an exclusive option to obtain an exclusive, worldwide license for commercial purposes, including the right to grant sub-licenses, to all Institution Inventions and to Institution's entire right, title and interest in and to all Joint Inventions. The parties agree to use good faith efforts to negotiate commercially reasonable terms for the exclusive license. Merck shall execute its option within six (6) months of Merck's receipt of written notice of said invention.

(Exhibit C at § 12.D.)

26. Further, the Pembro Contract stated that "all Study data and results generated during the course of the Study may be used fully by Merck for any legitimate business purpose without any additional payments being made to" JHU. (Exhibit C at § 9.A.)

27. The Pembro Contract is governed by Maryland law. (Exhibit C at § 15.)

28. In September 2013, the joint research study governed by the Pembro Contract began. Merck's scientists worked and made various contributions to help ensure the success of the study.

29. Over the course of the joint research collaboration, Merck contributed approximately $3.5 million to conduct the clinical study, in addition to supplying the actual drug Keytruda to the joint research study subjects.

The Pembro Patents

30. Without informing Merck, JHU began to file in the U.S. Patent and Trademark Office ("PTO") patent applications relating to the joint research collaboration. In 2021 and 2022, JHU obtained issuance of four patents: U.S. Patent No. 10,934,356 ("the '356 Patent," attached as Exhibit D), U.S. Patent No. 11,325,974 ("the '974 Patent," attached as Exhibit E), U.S. Patent No. 11,325,975 ("the '975 Patent," attached as Exhibit F), and U.S. Patent No. 11,339,219 ("the '219 Patent," attached as Exhibit G) (collectively, "the Pembro Patents").

31. JHU has included in the specifications of the Pembro Patents a discussion of the joint research collaboration with Merck. For instance, JHU describes a "phase 2 trial" that used a "study agent, pembrolizumab (Merck)" to treat three cohorts, which were divided based on MSI-H status and whether the cancer was a colorectal cancer. (Exhibit D at 8:9-11 (MSI-H markers were used to determine whether the cancers were mismatch repair deficient), 8:20-27, 8:45-47.) That is the same as the clinical trial protocol. The patent specification explains that pembrolizumab "was administered at 10 mg/kg intravenously every 14 days." (Exhibit D at 8:47-48.) That is the same as the clinical trial protocols after Merck made its suggestion. And the specification explains that "[r]adiologic assessments [of tumors] were made at 12 weeks and

every 8 weeks thereafter." (Exhibit D at 8:52-56.) That again is the same as the clinical trial protocol that had been revised based on Merck's suggestions. The specification also relies on results from the study. (*See, e.g.*, Exhibit D at 6:43-53, 9:23-39.)

32. JHU did not involve Merck in the drafting of the patent applications, their prosecution in the PTO, or in the selection of the language that appears in the claims of the Pembro Patents as purporting to define the inventions.[1]

33. The publicly available file history of the patents shows that the PTO repeatedly rejected the applications filed by JHU. For example, JHU faced repeated rejections for the use of "wherein" in certain claims requiring an improved outcome comparison. In attempting to overcome the Patent Office's rejections, JHU referred to the claim limitation, "wherein the patient exhibits an outcome that is improved as compared to a corresponding outcome that would be observed in a reference patient that has been administered pembrolizumab," and represented that, "this clause" was necessary to prevent the claim from "simply requir[ing] giving an effective amount of pembrolizumab to a patient," which would "effectively ignor[e] the unexpected relationship between MSI-high/MMR deficiency status and anti-PD-1 antibodies, as described in the specification." JHU argued that, to omit this clause from the presented claims, would "ignore a core concept disclosed in the specification: the unexpected relationship between MSI-high/MMR deficiency status and improved relative response to anti-PD-1 antibodies."

34. In February and June of 2020, JHU submitted two sworn declarations in support of its patents, endeavoring to explain under oath how the claimed inventions arose from the results of the joint research collaboration with Merck. In particular, on February 4, 2020, JHU

[1] Nothing in this Complaint should be construed to imply that the claims of the Pembro Patents satisfy all the requirements for patentability.

filed a first declaration by named inventor Dr. Andrew Pardoll (attached as Exhibit H), which explained that the study (with Merck) "allowed us to try to get at an answer to a question to which we did not know the answer—specifically whether or not patients with MSI-high or MMR deficient tumors would exhibit an improved response when treated with [pembrolizumab], compared with the more common [microsatellite stable] or MMR proficient colon cancers." (Exhibit H at ¶ 22.)

35. The Patent Office initially was unconvinced, and again rejected the pending claims on March 9, 2020 despite the declaration of Dr. Pardoll.

36. On June 8, 2020, JHU filed a second declaration (attached as Exhibit I), by Dr. Vijay Kuchroo, a professor at Harvard Medical School. Dr. Kuchroo emphasized the criticality of the data resulting from the study (with Merck). For instance, Dr. Kuchroo explained how, unlike the prior art, the patent applicants had actually "conducted . . . a study" (Exhibit I at ¶ 28) and, without such a study, "[a] person of ordinary skill in the art would not have reasonably expected" the claimed treatment (Exhibit I at ¶ 27).

37. On December 14, 2020, the Patent Office issued its first notice of allowance. The notice of allowance specifically relied on the declaration of Dr. Kuchroo, agreeing with Dr. Kuchroo's argument against the prior art. The notice of allowance emphasized the fact that the results of the clinical trial were essential to the granting of the patent.

38. The '356 Patent issued on March 2, 2021. JHU paid for accelerated prosecution of the other patents and they issued relatively shortly thereafter: the '974 and '975 Patents issued on May 10, 2022; and the '219 Patent issued on May 24, 2022.

39. The claims of the Pembro Patents expressly recite features that are tied to the effective dosage amounts and scanning features suggested by Merck's scientists. (*See, e.g.*,

Exhibit D at claim 1 ("administering an effective amount of pembrolizumab" and "determining that the patient exhibits an outcome that is improved"); Exhibit D at claim 17 ("wherein the outcome is assessed in the patient at 20 weeks after administering pembrolizumab"); Exhibit E at claim 1 ("administering an effective amount of pembrolizumab" and "wherein the patient exhibits an outcome that is improved"); Exhibit F at claim 1 ("administering an effective amount of an anti-PD-1 antibody" and "wherein the patient exhibits an outcome that is improved"); Exhibit G at claim 1 ("administering an effective amount of pembrolizumab" and "wherein the patient exhibits an outcome that is improved").

40. Instead of providing Merck with the possibility of an exclusive license (the contractually-required course of action even if JHU believed it had sole rights in the patents), JHU apparently enabled two other companies to obtain rights in the Pembro Patents without informing Merck.

41. In particular, two companies involved in the business of making tests, called Personal Genome Diagnostics ("PGDx") and QIAGEN, issued press releases in October 2016 and June 2017 with regard to technology directed to detecting biomarkers, which they stated that they had licensed from JHU. For example, PGDx's press release referred to "testing technology from Johns Hopkins University" in pending patents "to help identify candidates for immune checkpoint inhibition." In the press release, PGDx stated that it had incorporated the technology in certain assays (tests) and planned to include the technology in other assays. PGDx further announced that it "has exclusive rights to the MSI detection technology through mid-2017 and shared rights with another molecular diagnostics provider thereafter," and that it "also has the sole rights to sublicense the MSI detection technology." Similarly, QIAGEN announced that it had received a worldwide license from The Johns Hopkins University to "rights to genetic

biomarkers to assess microsatellite instability (MSI) and mismatch repair (MMR) in all sample and cell types." The QIAGEN press release further stated that the agreement would allow QIAGEN to "commercialize molecular testing solutions." The press releases did not identify particular patents, or discuss Merck medical treatments, or the collaboration between JHU and Merck.

42. In June 2017, PGDx communicated with Merck to discuss its purported license from JHU, and explained that the license was tied to a patent application filed by JHU.

43. In November 2017, Kim Folander, a Merck employee, spoke with Christy Wyskiel from JHU to inquire about these communications. Nonetheless, in light of the press releases by PGDx and QIAGEN, Folander inquired whether Merck was entitled to exercise an option under the contract. On December 5, 2017, Wyskiel represented that any future patent rights associated with the then-pending applications would not result from the joint research collaboration, and instead the inventions would have existed prior to the joint research collaboration and before Merck made any contributions. None of the applications filed by JHU had matured into patents at that time.

44. These representations, however, were inaccurate in view of subsequent prosecution of the patent applications and the subject matter of the claims of the Pembro Patents as issued—Dr. Pardoll and Dr. Kuchroo swore in their 2020 declarations that the invention arose during the collaboration as a result of the data received from the clinical trial, and the claims of the Pembro Patents issued in 2021 and 2022 expressly include suggestions conveyed by Merck scientists.

45. In March 2021, after JHU obtained issuance of the '356 Patent, JHU reached out to Merck to notify Merck that the '356 Patent issued and to ask Merck to take a license under the

patent. In a subsequent communication, on May 14, 2021, JHU represented that its "inventors are eager for Merck to formally recognize the value of their contributions to the commercial success of Keytruda." JHU then requested that Merck pay hundreds of millions of dollars, tied to Merck's sales of Keytruda. Merck did not agree to JHU's demands. JHU has since sought to expand the Pembro Patent portfolio.

46. Merck funds pharmaceutical research and development in part with revenues from Keytruda. JHU's representations and demands relating to the Pembro Patents has created a cloud of uncertainty, *inter alia*, with respect to what portion of the revenues from Keytruda Merck may invest into that research and development.

Count I
(Breach of Contract)

47. Merck repeats and realleges the allegations set forth in paragraphs 1-46 of the Complaint as if those allegations had been set forth herein.

48. Under § 12.B of the Pembro Contract, JHU had a duty to notify Merck "in writing" of any inventions arising from the protocol and study. JHU never notified Merck that any inventions arose therefrom. Based on JHU's representations in the Pardoll and Kuchroo declarations to the PTO in 2020, and the subject matter expressly claimed in the Pembro Patents, the claimed subject matter, in fact, arose from the protocol and study. Those representations and the corresponding patent claims make clear that, without the data generated by the joint research collaboration, there would have been no basis for JHU to obtain the Pembro Patents. The Pembro Patents plainly reflect "intellectual property arising from the performance of the Protocol and Study."

49. When Merck originally approached JHU, JHU's Wyskiel claimed that she spoke with the named inventors, and that any future rights associated with the Pembro Patents would not result from the joint research collaboration.

50. But when JHU submitted the Pardoll and Kuchroo declarations to the PTO in 2020, swearing to criticality of the data resulting from the collaboration as the basis for the claimed subject matter, and obtained the Pembro Patents based on these representations, JHU should have but did not inform Merck about the prior declarations and their relationship to JHU's obligations under the Pembro Contract.

51. The Pembro Contract gave Merck "an exclusive option to obtain an exclusive worldwide license for commercial purposes, including the right to grant sub-licenses; to all Institution Inventions and to Institution's entire right, title and interest in and to all Joint Inventions." (Exhibit C at § 12.D.) Because of JHU's breach, Merck was deprived of this contractual right with respect to the issued Pembro Patents.

52. Even if JHU promptly notified Merck, and it did not, Merck could never exercise its option to enter into an exclusive license with respect to the Pembro Patents because of JHU's prior licenses to PGDx and Qiagen, which were not disclosed to Merck.

53. Moreover, had the Pembro Patents been acknowledged to be a Joint Invention under the Pembro Contract, Merck would be (and is) a co-owner of all issued patents (and would have related rights/royalties regarding any licenses to PGDx and Qiagen), and any threats by JHU based on the Pembro Patents would be avoided.

54. The Pembro Contract was a valid and binding agreement. Merck performed its obligations under the Pembro Contract. Merck has been damaged as a result of JHU's breaches of the Pembro Contract.

Count II
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,934,356)

55. Merck repeats and realleges the allegations set forth in paragraphs 1-54 of the Complaint as if those allegations had been set forth herein.

56. The manufacture, use, sale, offer for sale, and importation into the United States of Keytruda does not infringe any claim of the '356 Patent.

57. For example, Claim 1 of the '356 Patent recites "determining that the patient exhibits an outcome that is improved as compared to a corresponding outcome that would be observed in a reference patient that has been administered pembrolizumab, wherein the reference patient has a tumor that does not exhibit a MSI-high or a MMR deficiency status." Merck does not perform this step, nor does Merck induce or have the intent to induce any others to perform this step.

58. Similarly, for example, Claims 11 and 19 of the '356 Patent recite "determining that the patient exhibits an outcome that is improved as compared to a corresponding outcome that would be observed in a reference patient that has been administered pembrolizumab, wherein reference patient has a tumor that does not exhibit an instability of the one or more microsatellite markers or a deficiency of the one or more mismatch repair markers." Merck does not perform this step, nor does Merck induce or have the intent to induce any others to perform this step.

59. Similarly, for example, Claim 23 of the '356 Patent recites "observing an objective response rate of about 12% to 96% in the population of cancer patients after administration of pembrolizumab." Merck does not perform this step, nor does Merck induce or have the intent to induce any others to perform this step.

60. In addition, the manufacture, use, sale, offer for sale, and importation into the United States of Keytruda is conduct protected by the contract. Under the contract with JHU, Merck has a right to use the data generated by the joint research collaboration for any legitimate business purpose, which includes helping patients and teaching FDA-approved indications.

61. An actual and justiciable controversy exists between Merck and JHU with respect to the '356 Patent, and Merck is entitled to a declaratory judgment that no claim of the '356 Patent is infringed by Merck's Keytruda products or conduct.

Count III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,325,974)

62. Merck repeats and realleges the allegations set forth in paragraphs 1-61 of the Complaint as if those allegations had been set forth herein.

63. The manufacture, use, sale, offer for sale, and importation into the United States of Keytruda does not infringe any claim of the '974 Patent.

64. For example, Claim 1 of the '974 Patent recites "wherein the patient exhibits an outcome that is improved as compared to a corresponding outcome that would be observed in a reference patient that has been administered pembrolizumab, wherein the reference patient has a tumor that does not exhibit an instability of the one or more microsatellite markers or a deficiency of the one or more mismatch repair markers." Merck does not perform this step, nor does Merck induce or have the intent to induce any others to perform this step.

65. In addition, the manufacture, use, sale, offer for sale, and importation into the United States of Keytruda is conduct protected by the contract. Under the contract with JHU, Merck has a right to use the data generated by the joint research collaboration for any legitimate business purpose, which includes helping patients and teaching FDA-approved indications.

66. An actual and justiciable controversy exists between Merck and JHU with respect to the ’974 Patent, and Merck is entitled to a declaratory judgment that no claim of the ’974 Patent is infringed by Merck’s Keytruda products or conduct.

Count IV
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,325,975)

67. Merck repeats and realleges the allegations set forth in paragraphs 1-66 of the Complaint as if those allegations had been set forth herein.

68. The manufacture, use, sale, offer for sale, and importation into the United States of Keytruda does not infringe any claim of the ’975 Patent.

69. For example, claim 1 of the ’975 Patent recites “wherein the patient exhibits an outcome that is improved as compared to a corresponding outcome that would be observed in a reference patient that has been administered the anti-PD-1 antibody, wherein the reference patient has a tumor that does not exhibit a MSI-high or a MMR deficiency status.” Merck does not perform this step, nor does Merck induce or have the intent to induce any others to perform this step.

70. Similarly, for example, claim 9 of the ’975 Patent recites “wherein the patient exhibits an outcome that is improved as compared to a corresponding outcome that would be observed in a reference patient that has been administered the anti-PD-1 antibody, wherein the reference patient has a tumor that does not exhibit a MSI-high status or is MMR proficient.” Merck does not perform this step, nor does Merck induce or have the intent to induce any others to perform this step.

71. In addition, the manufacture, use, sale, offer for sale, and importation into the United States of Keytruda is conduct protected by the contract. Under the contract with JHU,

Merck has a right to use the data generated by the joint research collaboration for any legitimate business purpose, which includes helping patients and teaching FDA-approved indications.

72. An actual and justiciable controversy exists between Merck and JHU with respect to the '975 Patent, and Merck is entitled to a declaratory judgment that no claim of the '975 Patent is infringed by Merck's Keytruda products or conduct.

Count V
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,339,219)

73. Merck repeats and realleges the allegations set forth in paragraphs 1-72 of the Complaint as if those allegations had been set forth herein.

74. The manufacture, use, sale, offer for sale, and importation into the United States of Keytruda does not infringe any claim of the '219 Patent.

75. For example, claim 1 of the '219 Patent recites "wherein the patient exhibits an outcome that is improved as compared to a corresponding outcome that would be observed in a reference patient that has been administered pembrolizumab, wherein the reference patient has a tumor that does not exhibit a MSI-high or a MMR deficiency status." Merck does not perform this step, nor does Merck induce or have the intent to induce any others to perform this step.

76. In addition, the manufacture, use, sale, offer for sale, and importation into the United States of Keytruda is conduct protected by the contract. Under the contract with JHU, Merck has a right to use the data generated by the joint research collaboration for any legitimate business purpose, which includes helping patients and teaching FDA-approved indications.

77. An actual and justiciable controversy exists between Merck and JHU with respect to the '219 Patent, and Merck is entitled to a declaratory judgment that no claim of the '219 Patent is infringed by Merck's Keytruda products or conduct.

Count VI
(Promissory Estoppel)

78. Merck repeats and realleges the allegations set forth in paragraphs 1-77 of the Complaint as if those allegations had been set forth herein.

79. JHU's failure to notify Merck of patents that arose from the joint research collaboration and offer a license right, in view of the representations made by JHU in the declarations of Dr. Pardoll and Dr. Kuchroo and the issuance of the claims of the Pembro Patents precludes JHU from asserting the Pembro Patents against Merck. Likewise, JHU's promise to allow Merck to use data from the joint research collaboration precludes JHU from asserting the Pembro Patents based on any alleged use by Merck of those data in connection with its Keytruda product. JHU reasonably expected Merck to contribute the pembrolizumab, and Merck's expertise therewith, to the joint research collaboration, and later, beyond the contract, to provide financial support for the joint research study. Merck in fact supported the joint research study with pembrolizumab, Merck's expertise with pembrolizumab, and approximately $3.5 million. The harm to Merck can only be avoided by JHU being precluded from asserting the Pembro Patents against Merck.

Prayer For Relief

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

A. Declare that JHU breached the Pembro Contract;

B. Award Merck damages for JHU's breach of the Pembro Contract;

C. Declare that JHU cannot assert the Pembro Patents against Merck, based on the Pembro Contract and the doctrine of promissory estoppel;

D. Declare that Merck's manufacture, use, sale, offer for sale, and/or importation of Keytruda® products do not infringe any claims of the Pembro Patents;

E. Determine that this is an exceptional case under 35 U.S.C. § 285;

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

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

* * *

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Merck hereby demands a trial by jury of all issues so triable.

/s/ Kwame J. Manley

Kwame J. Manley
PAUL HASTINGS LLP
2050 M Street NW
Washington, DC 20036
(202) 551-1962
kwamemanley@paulhastings.com

Bruce M. Wexler (*pro hac vice* forthcoming)
Preston K. Ratliff II (*pro hac vice* forthcoming)
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

Attorneys for Plaintiff Merck Sharp & Dohme LLC

Date: November 29, 2022