UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DANA-FARBER CANCER INSTITUTE, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. _____
	)	
BRISTOL-MYERS SQUIBB, CO., E.R. SQUIBB & SONS, L.L.C., AND ONO PHARMACEUTICAL CO., LTD.,	)	
	)	
Defendants.	)	

COMPLAINT

Dana-Farber Cancer Institute, Inc. ("Dana-Farber"), for its complaint against Bristol-Myers Squibb Co. ("Bristol"), E.R. Squibb & Sons, L.L.C. ("Squibb") (together, "BMS"), and Ono Pharmaceutical Co., Ltd. ("Ono") (collectively, "Defendants"), alleges as follows:

INTRODUCTION

1. This is a civil action by Dana-Farber seeking equitable relief and damages to account for Defendants' unjust enrichment and unfair competition in exploiting patents co-owned by Dana-Farber while holding themselves out to Dana-Farber's potential licensees as the exclusive owners of the patents. The patents are directed to methods of cancer immunotherapy involving the administration of PD-1 or PD-L1 antibodies. As the United States District Court for the District of Massachusetts ("the Court") held in its May 17, 2019 decision in *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, Dana-Farber scientist Gordon Freeman is a joint inventor of those patents, and Dana-Farber is a co-owner. *See* Dkt. No. 389, Findings of Fact, Conclusions of Law, and Order, *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, No. 15-13443-PBS (D. Mass. May 17, 2019) (the "Decision").

2. Defendants have long known of Freeman's scientific contributions to those patents and Dana-Farber's rightful co-ownership of them. Yet by denying Dana-Farber's co-ownership of the patents, by obstructing and delaying correction of inventorship of the patents, and by holding themselves out as exclusive owners of the patents, they have been able to sue their competitors for patent infringement and negotiate lucrative licensing deals with them, unjustly enriching themselves through their receipt of more than $1.6 billion in licensing revenue. Defendants' actions unfairly deprived Dana-Farber of the opportunity to grant royalty-bearing licenses to potential licensees known to Defendants, and those actions robbed Dana-Farber of the licensing revenue Defendants unfairly seized for themselves. As set forth below, Dana-Farber seeks equitable remedies and money damages for Defendants' unjust enrichment and violations of the law of contracts, torts, and Massachusetts General Laws Chapter 93A.

THE PARTIES

3. Dana-Farber is a Massachusetts non-profit corporation with a place of business at 450 Brookline Avenue, Boston, Massachusetts 02215. Since its founding in 1947, Dana-Farber has been committed to providing adults and children suffering from cancer with the best treatments available today while also developing future therapies through cutting-edge research. As an affiliate of Harvard Medical School and a Comprehensive Cancer Center designated by the National Cancer Institute, Dana-Farber also provides training for new generations of physicians and scientists; designs programs that promote public health, particularly among high-risk and underserved populations; and disseminates innovative patient therapies and scientific discoveries across the United States and throughout the world, all with the goal of defeating cancer.

4. As a leader in basic, translational, clinical, and population science research, Dana-Farber prides itself on its emphasis on both research and patient care. Dana-Farber helps to

advance this mission through, among other things, licensing its intellectual property. Licensing partnerships help to support Dana-Farber's vital cancer research and patient care, and translate Dana-Farber's research discoveries into new products made widely available for diagnosing and treating cancer. Dana-Farber's licensing program also generates revenue for Dana-Farber that can be re-invested in future cancer research and patient care.

5. Dana-Farber is the assignee of Freeman's rights and interest as an inventor in the inventions claimed in U.S. Patent No. 7,595,048 (the "'048 patent"); U.S. Patent No. 8,168,179 (the "'179 patent"); U.S. Patent No. 8,728,474 (the "'474 patent"); U.S. Patent No. 9,067,999 (the "'999 patent"); U.S. Patent No. 9,073,994 (the "'994 patent"); and U.S. Patent No. 9,402,899 (the "'899 patent") (collectively, the "Patents").

6. On information and belief, Bristol is a corporation organized under the laws of the State of Delaware, with a principal place of business at 345 Park Avenue, New York, New York 10154.

7. On information and belief, Squibb is a limited liability company organized under the laws of the State of Delaware, with a principal place of business at Route 206 & Province Line Road, Princeton, New Jersey 08543.

8. On information and belief, 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. Named inventor Shiro Shibayama is, and at all relevant times was, an employee of Ono. BMS is the exclusive licensee of Ono's rights in the Patents.

JURISDICTION

9. This court has jurisdiction under 28 U.S.C. § 1332. The amount in controversy exceeds $75,000, exclusive of interest and costs.

10. Venue is proper in this judicial district under 28 U.S.C 1391(b).

11. This Court has personal jurisdiction over Bristol, Squibb, and Ono to adjudicate this action.

FACTUAL BACKGROUND

The Technology

12. This case stems from the pioneering work of Freeman and Clive Wood, Ph.D., former head of drug development at Genetics Institute, in a collaboration with Dr. Tasuku Honjo of Kyoto University that led to the development of cancer immunotherapy treatment methods claimed in the Patents.

13. The Patents disclose groundbreaking methods of "using the body's immune system to attack tumor cells, a type of treatment known as cancer immunotherapy." Decision at 11.

14. The Patents describe methods that target an "inhibitory receptor on T cells known as PD-1." *Id.* at 9. As the Court explained, immune cells communicate through receptor-ligand interactions. "The receptor receives a signal from outside the cell and then transmits the signal to the internal components of the cell to trigger a response. Ligands are proteins that bind to receptors to initiate signaling." *Id*. at 7.

15. As the Court explained, "[w]hen PD-1 binds to one of its ligands, PD-L1 or PD-L2, the T cell receives an inhibitory signal that prevents it from attacking the cell expressing PD-L1 or PD-L2." *Id.* at 9. In healthy cells, expression of those ligands "protects the cells from immune attack. Some tumor cells also express PD-L1 or PD-L2, allowing them to masquerade as healthy cells by activating PD-1 to send an inhibitory signal to T cells." *Id*.

Overview of the Patents

16. The Court found that Freeman and Wood collaborated with Honjo, a professor at Kyoto University, "from at least October 1999 until at least September 2000 through numerous meetings, joint authorship of scientific journal articles, written collaboration agreements, and sharing of experimental results and ideas." *Id.* at 5. The Court concluded that "all three made significant contributions to the inventions" claimed in the Patents. *Id*. Despite this, the Patents listed only Honjo; two of his current or former colleagues at Kyoto University, Nagahiro Minato and Yoshiko Iwai; and Ono scientist Shiro Shibayama as named inventors.

17. The Patents all claim priority to two Japanese patent applications, Japanese Patent Applications 2002-194491 and 2003-029846 (the "Japanese Patent Applications"). On July 3, 2002, Ono filed Japanese Patent Application 2002-194491. Ono then filed Japanese Patent Application 2003-029846 on February 6, 2003. The Japanese Patent Applications name Honjo, Iwai, and Minato as the sole inventors. Ono filed the Japanese Patent Applications secretly, without informing either Freeman or Wood.

18. On July 2, 2003, without informing Freeman or Wood, Ono secretly filed PCT Application No. PCT/JP03/08420 (the "PCT Application"), a utility application that claims priority to the Japanese Patent Applications. The PCT Application names Honjo, Iwai, Minato, and Shibayama as sole inventors.

19. On September 29, 2009, the United States Patent and Trademark Office (USPTO) issued the '048 patent. The '048 patent issued from U.S. Patent Application No. 10/519,925 filed on January 3, 2005. The '048 patent claims priority to the Japanese Patent Applications. The '048 patent as issued named Honjo, Iwai, Minato, and Shibayama as sole inventors and

originally was co-assigned to Honjo and Ono. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the ’048 patent to name Freeman and Wood as co-inventors.

20. On May 1, 2012, the United States Patent Office issued the ’179 patent. The ’179 patent issued from U.S. Patent Application No. 12/538,698 filed on August 10, 2009. The ’179 patent claims priority to the Japanese Patent Applications. The ’179 patent as issued named Honjo, Iwai, Minato, and Shibayama as sole inventors and originally was co-assigned to Honjo and Ono. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the ’179 patent to name Freeman and Wood as co-inventors.

21. On May 20, 2014, the United States Patent Office issued the ’474 patent. The ’474 patent issued from U.S. Patent Application No. 12/959,307 filed on December 2, 2010. The ’474 patent claims priority to the Japanese Patent Applications. The ’474 patent as issued named Honjo, Iwai, Minato, and Shibayama as sole inventors and originally was co-assigned to Honjo and Ono. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the ’474 patent to name Freeman and Wood as co-inventors.

22. On June 30, 2015, the United States Patent Office issued the ’999 patent. The ’999 patent issued from U.S. Patent Application No. 14/638,985 filed on March 4, 2015. The ’999 patent claims priority to the Japanese Patent Applications. The ’999 patent as issued named Honjo, Iwai, Minato, and Shibayama as sole inventors and originally was co-assigned to Honjo and Ono. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the ’999 patent to name Freeman and Wood as co-inventors.

23. On July 7, 2015, the United States Patent Office issued the ’994 patent. The ’994 patent issued from U.S. Patent Application No. 14/550,585 filed on November 21, 2014. The ’994 patent claims priority to the Japanese Patent Applications. The ’994 patent as issued named

Honjo, Iwai, Minato, and Shibayama as sole inventors and originally was co-assigned to Honjo and Ono. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the ’994 patent to name Freeman and Wood as co-inventors.

24. On August 2, 2016, the United States Patent Office issued the ’899 patent. The ’899 patent issued from U.S. Patent Application No. 14/245,692 filed on April 4, 2014. The ’899 patent also claims priority to the Japanese Patent Applications. The ’899 patent as issued named Honjo, Iwai, Minato, and Shibayama as sole inventors and originally was co-assigned to Honjo and Ono. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the ’899 patent to name Freeman and Wood as co-inventors.

25. Each of the Patents expires in 2023 or 2024.

Dana-Farber’s Action to Correct Inventorship

26. On September 25, 2015, Dana-Farber filed an action in the District of Massachusetts for correction of inventorship of the Patents. *See* Dkt. No. 1, Compl., *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, No. 15-13443-PBS (D. Mass. Sept. 25, 2015).

27. As Dana-Farber stated in its Complaint, it sought “to confirm its ability to grant non-exclusive licenses to companies interested in developing cancer immunotherapies directed to the PD-1/PD-L1 pathway, in order to ensure broad patient access to the cancer treatments claimed in the Patents.” *Id.*, ¶ 56; Dkt. No. 98, Am. Compl., ¶ 64, *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, No. 15-13443-PBS (D. Mass. Jan. 3, 2017).

28. Following a nine-day bench trial, the Court issued its findings of fact and conclusions of law on May 17, 2019. In that decision, the Court concluded that Dana-Farber

presented clear and convincing evidence demonstrating that Freeman and Wood are joint inventors of the Patents.

29. The Court found:

> I find Dana-Farber has presented clear and convincing evidence that Dr. Freeman and Dr. Wood are joint inventors of the six Honjo patents. Dr. Honjo collaborated extensively with both Dr. Freeman and Dr. Wood from at least October 1999 until at least September 2000 through numerous meetings, joint authorship of scientific journal articles, written collaboration agreements, and sharing of experimental results and ideas. Indeed, Dr. Honjo himself referred to his work with Dr. Freeman and Dr. Wood as a collaboration on at least six occasions. While the relationship among these three brilliant scientists eventually soured, all three made significant contributions to the inventions. After a review of the extensive record and evaluation of the credibility of the witnesses, I conclude that both Dr. Freeman's and Dr. Wood's contributions were significant in light of the dimension of the full inventions claimed in the six Honjo patents, which are all premised on blocking the inhibitory interaction of the PD-1/PD- L1 pathway to treat tumors that express PD-L1 or PD-L2.

Decision at 5.

30. The Court further found:

> Dr. Freeman and Dr. Wood made significant contributions to conception of the inventions claimed in the Honjo patents through their discovery of PD-L1 and PD-L2, their discoveries of blocking antibodies, Dr. Wood's discovery of the inhibitory interaction between PD-1 and PD-L1, and Dr. Freeman's discovery of the expression of PD-L1 on tumor cells. Accordingly, Dana-Farber has proven by clear and convincing evidence that Dr. Freeman and Dr. Wood are joint inventors of the six Honjo patents.

Id. at 104.

31. As the Court recognized, "Here, there is no doubt Dr. Freeman, Dr. Wood, and Dr. Honjo collaborated sufficiently to qualify as joint inventors as early as October 1999, almost three years before Dr. Honjo filed his first patent application and a year before the conception

date. Dr. Freeman and Dr. Wood shared their confidential experimental results on PD-L1 with Dr. Honjo a year before publishing them." *Id.* at 85.

32. The Court concluded that Freeman and Wood's contributions to the Patents include their "joint discovery and characterization of PD-L1." *Id*. at 78. As the Court found, the "fact remains that it was Dr. Freeman and Dr. Wood, not Dr. Iwai, who discovered PD-L1 and provided it to Dr. Honjo." *Id.* at 80.

33. The Court found that "Dr. Freeman and Dr. Wood discovered that anti-PD-1 and anti-PD-L1 antibodies can block the pathway's inhibitory signal. Dr. Wood conducted an experiment using one of Dr. Honjo's anti-PD-1 antibodies that showed blockage of the PD-1/PD-L1 pathway, and both Dr. Freeman and Dr. Wood developed their own anti-PD-L1 blocking antibodies. They communicated these results to Dr. Honjo at multiple collaboration meetings before the date of conception." *Id.* at 83.

34. As the Court further concluded, it was Freeman who "discover[ed] that PD-L1 is highly expressed on human tumor cells." *Id.* at 94. The Court stated:

> While an anti-PD-1 or anti-PD-L1 antibody may enhance an immune response against a tumor by blocking inhibitory signaling triggered by PD-L1 on a nontumor cell, conception of the invention was inextricably linked to the expression of PD-L1 on human tumors. Even [Defendants' expert] admitted that Dr. Honjo and Dr. Iwai would not have designed their in vivo experiments the way they did if they did not know that human tumors express PD-L1. Dr. Freeman was the first to make that discovery.

Id. at 95.

35. Freeman's experimental work contributing to the Patents was performed in his Dana-Farber laboratory in Boston, Massachusetts.

36. Freeman and Wood's contributions were known to Ono. Indeed, Ono participated in multiple collaboration meetings with Freeman and Wood from the outset of their

collaboration. At least two of those meetings took place in Cambridge, Massachusetts. In those meetings, Freeman confidentially shared research data from his laboratory at Dana-Farber. Many of the documentary notes and meeting minutes confirming Freeman and Wood's contributions come from Ono's files.

37. As Defendants acknowledged at trial, much of the evidence of Freeman's contributions is undisputed. Despite Defendants' knowledge of Freeman and Wood's inventive contributions as reflected in hundreds of contemporaneous documents and later sworn deposition testimony, and after being served with Dana-Farber's Complaint, they refused to correct inventorship of the Patents to make Dana-Farber a co-owner.

Defendants' Assertion of the Patents Against Merck

38. On September 4, 2014, the U.S. Food and Drug Administration (the "FDA") approved Merck & Co.'s ("Merck") PD-1 blocking antibody Keytruda® (pembrolizumab) for the treatment of "patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF Inhibitor."

39. That same day, Defendants and Honjo filed a patent infringement lawsuit in the District of Delaware against Merck, BMS's primary competitor in the area of PD-1-related cancer immunotherapy. Defendants did not seek Dana-Farber's consent to sue Merck for patent infringement, knowing that if they had recognized Dana-Farber as a co-owner of the asserted patent, they would not have had standing to sue Merck for patent infringement.

40. Under U.S. patent laws, all co-owners of a patent must join as plaintiffs to have standing to sue for patent infringement.

41. Defendants' lawsuit against Merck alleged that "[b]y virtue of obtaining approval to market and sell pembrolizumab [Keytruda®] as a treatment for certain patients with

melanoma, Merck has the specific intent to cause infringement of the 474 patent or, at a minimum, Merck has been willfully blind to the infringement of the 474 patent that will inevitably result." Compl., ¶ 22, *Bristol-Myers Squibb Co. v. Merck & Co. Inc.*, No. 14-01131-GMS (D. Del. Sept. 4, 2014).

42. On December 22, 2014, the FDA approved BMS's PD-1 antibody Opdivo® (nivolumab) for the same indication as Keytruda®.

43. The FDA has since approved both Keytruda® and Opdivo® for additional cancer indications.

44. In 2015, Defendants filed two additional patent infringement lawsuits against Merck based on its alleged infringement of the '994 patent and the '999 patent through its manufacture and sale of Keytruda®. The cases were consolidated in the District of Delaware for discovery. Defendants again did not seek Dana-Farber's consent to sue Merck for patent infringement, knowing that if they had recognized Dana-Farber as a co-owner of the asserted patent, they would not have had standing to sue Merck for patent infringement.

45. Defendants were represented in the Merck case in Delaware by the same lead attorneys from the law firm of Akin Gump who also served as lead counsel for Defendants in Dana-Farber's correction of inventorship case in Massachusetts

46. Defendants had standing to sue Merck only because, at the time, they and their co-defendant Honjo were the only parties with ownership rights in the Patents. In other words, but for the omission of Freeman as a named inventor on the '474, '999, and '994 Patents, Defendants could not have sued Merck for patent infringement without Dana-Farber's participation and consent. Defendants thus benefited from their efforts to prolong and delay the correction of inventorship of the Patents.

47. In suing Merck for patent infringement in Delaware, Defendants and Honjo falsely and unfairly held themselves out as the sole owners of the Patents.

48. On January 1, 2017, more than a year after Dana-Farber sued for correction of inventorship but before this Court's order correcting inventorship, Defendants used their litigation leverage against Merck to negotiate a highly profitable settlement of the Merck litigation. Under the terms of the settlement, Merck obtained a license to the Patents in exchange for an upfront payment of $625 million plus an ongoing royalty of 6.5% on worldwide sales of Merck's PD-1 product Keytruda®.

49. On information and belief, Merck has reported cumulative revenue of at least $13.1 billion from its sales of Keytruda®.

50. On information and belief, since January 1, 2017, Merck has paid BMS and Ono approximately $1 billion in royalties in addition to Merck's upfront payment of $625 million.

51. In order to have standing to bring the three patent infringement actions against Merck, and to settle those actions on terms that have enriched Defendants to the extent of more than $1.6 billion in licensing fees and royalties, Defendants falsely represented and warranted that they and Honjo together were the sole patent owners. These actions deprived Dana-Farber of the opportunity to grant a royalty-bearing license to Merck and/or to share in the proceeds of Defendants' settlement with Merck.

52. Defendants unfairly and unjustly exploited and profited from their refusal to correct inventorship of the Patents in 2015 or thereafter and their refusal to provide Dana-Farber co-ownership rights in the Patents.

Defendants' Additional Lawsuits Asserting Infringement of the '899 Patent

53. In 2016, the FDA approved Tecentriq®, an anti-PD-L1 antibody developed by Genentech, for the treatment of urothelial carcinoma. In 2017, the FDA approved Bavencio®, an anti-PD-L1 antibody developed by Pfizer and EMD Serono, Inc., for the treatment of metastatic Merkel cell carcinoma. In 2017, the FDA approved Imfinzi®, an anti-PD-L1 antibody developed by AstraZeneca, for bladder cancer and some types of lung cancer.

54. In 2017, while Dana-Farber's action to correct inventorship was pending in Massachusetts federal court, Defendants and Honjo filed additional patent infringement actions in the District of Delaware against Pfizer, AstraZeneca, and Genentech, asserting infringement of the '899 patent. As the Defendants and Honjo stated in their complaint against Genentech, "The claims of the '899 patent are generally directed to methods of treating cancer by administering an anti-PD-L1 monoclonal antibody that inhibits the interaction between PD-1 and PD-L1." Compl., ¶ 22, *Bristol-Myers Squibb Co. v. Genentech, Inc.*, No. 17-01027-GMS (D. Del. July 26, 2017).

55. Had Freeman been named as an inventor on the '899 patent, Dana-Farber would have been a co-owner of the '899 patent, and Defendants would not have had standing to sue Genentech, Pfizer, and Astra-Zeneca for infringement of the '899 patent.

56. On February 4, 2019, on the eve of trial in Massachusetts on Dana-Farber's complaint for correction of inventorship, Defendants entered into a settlement agreement with Pfizer, announced in court in Boston on February 5, 2019.

57. On information and belief, Defendants' settlements with Merck and Pfizer were designed to hinder and obstruct Dana-Farber's correction of inventorship case, including,

without limitation, by interfering with the availability of corroborating witnesses to appear at trial.

58. Defendants' conduct with respect to these settlements was calculated to harm Dana-Farber in Massachusetts and obstruct correction of inventorship of the Patents to make Dana-Farber a co-owner.

Defendants Grant an Additional License of the Patents by Falsely Representing Themselves as Exclusive Owners

59. Regeneron, Pharmaceuticals, Inc. ("Regeneron") is a biopharmaceutical company located in Tarrytown, New York.

60. Sanofi-aventis U.S. LLC is a U.S. subsidiary of the French multinational pharmaceutical company Sanofi. Sanofi-aventis U.S. LLC is headquartered in Bridgewater, NJ 08807.

61. On September 28, 2018, the FDA approved Regeneron and sanofi-aventis U.S. LLC's co-marketed product Libatyo®, an anti-PD-1 antibody, for the treatment of metastatic cutaneous squamous cell carcinoma ("CSCC") or locally advanced CSCC for patients who are not candidates for curative surgery or curative radiation. Libatyo® was the third anti-PD-1 antibody approved by the FDA.

62. In August 2018, nearly three years after Dana-Farber sued Defendants to correct inventorship, Defendants negotiated a license agreement with Regeneron and Sanofi. Under this agreement, Regeneron and Sanofi obtained non-exclusive rights in the Patents in exchange for an up-front payment of $20 million and royalties of 8.0% on worldwide sales of their PD-1 product through December 31, 2023.

63. On information and belief, Defendants used the threat of patent infringement litigation against Regeneron and Sanofi as leverage to negotiate the license agreement. But for

Defendants' refusal to provide Dana-Farber co-ownership rights in the Patents, Defendants would have not have standing to sue Regeneron and Sanofi for infringement of the Patents and would not have been able to use the threat of patent litigation to negotiate a license agreement with Regeneron and Sanofi.

64. In entering into the license agreement with Regeneron and Sanofi in 2018 and falsely holding themselves out as exclusive owners of the Patents, Defendants unfairly and unjustly benefited from Defendants' refusal to provide Dana-Farber its rights as a co-owner of the Patents.

65. On information and belief, to date Defendants have received in excess of $22 million in licensing fees and royalties from Sanofi and Regeneron.

Defendants Interfere With Dana-Farber's Licensing Opportunity With Another Prospective Licensee

66. On May 29, 2019, following the Court's May 17, 2019 decision ordering correction of inventorship, representatives from a Massachusetts-based biopharmaceutical company approached Dana-Farber to propose that Dana-Farber grant it a non-exclusive license to the Patents. The prospective licensee has an ongoing business relationship with Dana-Farber related to the subject matter of the Patents.

67. Two days later, on Friday, May 31, 2019, the prospective licensee sent Dana-Farber an email outlining the principal terms of its proposed license, including specific royalty terms.

68. On June 10, 2019, the prospective licensee abruptly informed Dana-Farber that it no longer wished to pursue a license from Dana-Faber.

69. On information and belief, the prospective licensee's withdrawal of its offer resulted from communications to it from representatives of BMS.

70. On information and belief, Defendants knowingly interfered with Dana-Farber's prospective licensing opportunity and induced the prospective licensee not to enter into a licensing agreement with Dana-Farber.

Defendants' Delaying Tactics

71. Between September 2015 and May 2019, Defendants intentionally hindered and delayed correction of inventorship of the Patents. On information and belief, the purpose of Defendants' delaying tactics was to allow Defendants to maintain standing to pursue patent infringement litigation against potential third party licensees, to prevent Dana-Farber from licensing the Patents non-exclusively to potential licensees, and to interfere with Dana-Farber's ability to realize licensing revenue as a co-owner of the Patents.

Defendants Have Unjustly and Unfairly Profited from Dana-Farber's Inventions

72. Defendants have derived substantial economic benefit from their failure and refusal to correct inventorship of the Patents and provide Dana-Farber its rights as a co-owner, including the right independently to grant licenses to companies developing and marketing products to treat cancer by the administration of PD-1 and PD-L1 antibodies.

73. To date, numerous biotechnology companies have developed or are developing antibodies against PD-1 and PD-L1 for treatment of cancer, including Merck, Regeneron, Novartis, Tesaro (a GSK company), Roche-Genentech, Pfizer, and AstraZeneca. Other companies are investigating additional PD-1 and PD-L1 therapies covered by one or more of the Patents.

74. Dana-Farber has previously licensed other patents it owns or co-owns relating to modulation of the PD-1/PD-L1 pathway to treat disease. Among the many companies it has licensed are BMS, Merck, Genentech, Novartis, AstraZeneca, Boehringer Ingelheim,

Amplimmune, and EMD Serono. Dana-Farber's ownership objective is and always has been ensuring broad patient access to the cancer treatments claimed in the Patents. Dana-Farber licenses its innovative research broadly to help support its mission as a worldwide leader in cancer research and to help encourage the translation of its scientific discoveries into drug development. Dana-Farber thus is in the business of non-exclusively licensing technology related to the PD-1/PD-L1 pathway.

75. Upon information and belief, BMS and Ono were aware of these past licensing relationships. BMS and Ono were also aware at least since 2015 of Dana-Farber's intent "to grant non-exclusive licenses to companies interested in developing cancer immunotherapies directed to the PD-1/PD-L1 pathway, in order to ensure broad patient access to the cancer treatments claimed in the Patents." Dkt. No. 1, Compl., ¶ 56 *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, No. 15-13443-PBS (D. Mass. Sept. 25, 2015); Dkt. No. 98, Am. Compl., ¶ 64, *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, No. 15-13443-PBS (D. Mass. Jan. 3, 2017).

76. Dana-Farber's licensing agreements are well-known among pharmaceutical companies. Indeed, Dana-Farber describes many of its technologies available for licensing on its website.

77. But for Defendants' actions in refusing to provide Dana-Farber co-ownership rights in the Patents after Dana-Farber filed suit for correction of inventorship in 2015, Dana-Farber would have granted royalty-bearing licenses to multiple companies developing and/or marketing PD-1 or PD-L1 antibodies for treatment of cancer, including, without limitation, one or more of the companies identified in paragraph 74, above.

78. As an example of the value Dana-Farber derives from its PD-/PD-L1 related licensing efforts, in August 2016, Dana-Farber entered into an agreement with CPPIB Credit Europe S.à r.l., a wholly owned subsidiary of Canada Pension Plan Investment Board to monetize a portion of its interest in royalties defined by certain licensing agreements related to its PD-L1 intellectual property. CPPIB has paid Dana-Farber $168 million pursuant to this monetization agreement.

79. Defendants' actions seeking to hinder, delay and obstruct Dana-Farber from securing its co-ownership rights, while simultaneously licensing the Patents to Dana-Farber's business partners and prospective licensees, have interfered with Dana-Farber's business relationships and had the effect of preventing Dana-Farber from entering into licensing agreements with its prospective business partners and receiving licensing revenues.

80. As of the date of this Complaint, Dana-Farber has received none of the substantial economic benefits realized by Defendants through their exploitation of Freeman's work and refusal to recognize Dana-Farber's co-ownership rights in the Patents.

81. Defendants have been unjustly enriched by the settlement, licensing, royalties, and/or other fees they have obtained from third parties in connection with the Patents as described herein, and Dana-Farber has suffered substantial damages by reason of Defendants' conduct described herein.

Count I
(Unjust Enrichment - Contract)

82. Dana-Farber repeats and realleges the allegations set forth in paragraphs 1 through 81 of the Complaint as if those allegations have been set forth herein.

83. Dana-Farber conferred benefits upon Defendants, including at least the confidential information, data, discoveries and/or materials that Freeman confidentially and in

good faith shared with Honjo during their collaboration between 1999 and 2002 pursuant to oral and written agreements. Defendants were aware of the benefit of these many contributions.

84. Ono and, later, BMS, accepted the benefits conferred upon them by Dana-Farber. Defendants have exploited the benefit of Dana-Farber and Freeman's confidential discoveries, ideas, and materials while falsely holding themselves out as the exclusive owners of the Patents, enabling them to assert, or threaten to assert, the Patents against their competitors and through licensing of the Patents in exchange for more than $1.6 billion in licensing revenues. To date, Defendants have not shared any of these benefits with Dana-Farber.

85. The retention of these benefits by Defendants has been and continues to be unjust, unfair, and inequitable. By reason of Defendants' conduct, Dana-Farber was prevented from realizing its rights and benefits as a co-owner and has foregone licensing opportunities.

86. Defendants have derived, and will continue to derive, substantial revenue from their licensing of the Patents and through their settlement of litigation with Merck and their licensing to Regeneron and Sanofi without any compensation to Dana-Farber. Defendants have deprived Dana-Farber of the economic advantages it would have enjoyed had it not been for Defendants' unfair, inequitable, and wrongful conduct.

87. Defendants have been unjustly enriched at Dana-Farber's expense by their continued profit from the Patents, and by their refusal to recognize Dana-Farber's rights as a co-owner of the Patents.

Count II
(Constructive Trust)

88. Dana-Farber repeats and realleges the allegations set forth in paragraphs 1 through 87 of the Complaint as if those allegations have been set forth herein.

89. Defendants have derived substantial financial benefits from their patent infringement action against Merck and their subsequent settlement and license agreement with Merck in 2017. Defendants did not join Dana-Farber as a co-owner of the asserted patents in that action or seek Dana-Farber's consent to bring suit against Merck.

90. Defendants have been unjustly enriched at Dana-Farber's expense by their continued profit from Patents derived from the research and materials that Dana-Farber and Freeman shared with them, and by their refusal to provide Dana-Farber its rights as a co-owner of the Patents.

91. As an equitable remedy, the Court should impose a constructive trust for the benefit of Dana-Farber to receive its share of the proceeds from Defendants' settlement with Merck, Defendants' agreement with Regeneron and Sanofi, and any license agreement with Astra-Zeneca, Genentech, or other prospective licensee or company that develops a PD-1 or PD-L1 therapy for treatment of cancer.

Count III
(Tortious Interference with Prospective Business Relations)

92. Dana-Farber repeats and realleges the allegations set forth in paragraphs 1 through 91 of the Complaint as if those allegations have been set forth herein.

93. Dana-Farber has had present and/or prospective business relationships for licensing intellectual property related to the PD-1/PD-L1 pathway with companies developing and marketing cancer immunotherapy drugs related to the PD-1/PD-L1 pathway. Those business relationships include, but are not limited to, relationships with Merck, Genentech, AstraZeneca, and EMD Serono.

94. On information and belief, BMS and Ono knowingly induced at least Merck, Regeneron/Sanofi, and another prospective licensee not to enter into a business relationship with

Dana-Farber to license technology directed to the use of the antibodies to block the PD-L1/PD-1 pathway for treatment of cancer, as claimed in the Patents.

95. Defendants possessed an improper motive or means. Among other things, Defendants held themselves out to prospective licensees as the sole owners of the Patents and were able to do so only by hindering, delaying, and obstructing correction of inventorship of the Patents.

96. Dana-Farber suffered substantial economic harm by the loss of the foregoing business opportunities.

Count IV
(Unfair Trade Practices)

97. Dana-Farber repeats and realleges the allegations set forth in paragraphs 1 through 96 of the Complaint as if those allegations have been set forth herein.

98. Dana-Farber, BMS, and Ono, as owners, licensees, and/or licensors of intellectual property were engaged in trade or commerce within the meaning of Mass. G.L. ch. 93A, §§ 2 and 11 at all times relevant to this Complaint.

99. BMS and Ono committed unfair and/or deceptive trade practices within the meaning of Mass. G. L. ch. 93A, §§ 2 and 11 by depriving Dana-Farber of its lawful rights as a co-owner of the patents and interfering with Dana-Farber's business relationships with potential licensees, including potential licensees operating in Massachusetts.

100. BMS and Ono's employment of said trade practices was a knowing and/or willful violation of Mass. G. L. ch. 93A § 2 and 11.

101. Dana-Farber was injured by BMS's and Ono's unfair and/or deceptive conduct.

102. The unfair and/or deceptive acts by Defendants occurred primarily and substantially within Massachusetts.

PRAYERS FOR RELIEF

WHEREFORE, Dana-Farber Cancer Institute, Inc. respectfully requests that this Court:

a. Enter judgment for Dana-Farber and against Defendants on Counts I-IV of this Complaint;

b. Order BMS or Ono to disgorge some or all of the settlement proceeds, licensing fees, royalties and other benefits that BMS and Ono and their agents, beneficiaries, assignees, licensees, and successors have derived as a result of any and all litigation, agreements, and/or representations they undertook, entered into, or otherwise made concerning the Patents;

c. Impose a constructive trust upon BMS and Ono for the benefit of Dana-Farber for some or all of the settlement proceeds, licensing fees, royalties and other benefits that BMS and Ono and their agents, beneficiaries, assignees, licensees, and successors have derived as a result of any and all litigation, agreements, and/or representations they undertook, entered into, or otherwise made concerning the Patents, and upon imposing such trust, order BMS or Ono to transfer such fees or proceeds as BMS or Ono currently have in their possession;

d. Award Dana-Farber monetary damages in an amount to be proven at trial for the economic injury it has sustained as a consequence of Defendants' actions;

e. Award Dana-Farber treble the amount of any award of proceeds, profits or damages and award reasonable attorneys' fees and costs under Mass. G.L. Ch. 93A, § 11;

f. Alternatively, in the exercise of equitable discretion, award Dana-Farber its reasonable attorneys' fees and costs incurred in connection with this action; and

g. Grant Dana-Farber such other and further relief that this Court deems just and proper.

Respectfully submitted,

DANA-FARBER CANCER INSTITUTE, INC.
By its attorneys,

/s/ Donald R. Ware

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