UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY, E. R. SQUIBB & SONS, L.L.C., and ONO PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v.

AMGEN INC.,

Defendant.

C.A. No. 26-cv-1134-UNA

JURY TRIAL DEMANDED

[redacted]

COMPLAINT

Bristol-Myers Squibb Company ("BMS"), E. R. Squibb & Sons, L.L.C. ("Squibb"), and Ono Pharmaceutical Co., Ltd. ("Ono") (collectively, "Plaintiffs") for their complaint for patent infringement against Amgen Inc. hereby allege as follows:

INTRODUCTION

1. Plaintiffs develop, manufacture, and sell OPDIVO®—one of the most important advances in the history of cancer treatment. In 2014, OPDIVO® became the first anti-PD-1 therapy approved anywhere in the world, ushering in a new era of cancer care by harnessing the patient's immune system to fight cancer at a time when many in the scientific community doubted such an approach could succeed. OPDIVO® paved the way for every anti-PD-1 therapy that followed and helped make immunotherapy a cornerstone of modern oncology—achievements that stem directly from Plaintiffs' pioneering research. This action seeks to enforce the patent rights that protect the science behind that breakthrough: years of painstaking research, rigorous clinical testing, and innovation that advanced not only a single drug, but the entire field of cancer immunotherapy.

2. Plaintiffs seek, among other things, an order enjoining Amgen from manufacturing and selling a biosimilar version of OPDIVO® while Plaintiffs' composition of matter patent remains in force. That patent covers the drug itself—the active ingredient that makes OPDIVO® what it is—and represents the core of the protection Plaintiffs lawfully earned through years of research and billions of dollars of investment that made this groundbreaking medicine possible. Plaintiffs further seek an order enjoining Amgen from selling its biosimilar version for administration in ways covered by BMS's method of treatment patents. Together, these patents protect the exclusivity Plaintiffs attained through extensive scientific research and innovation. Amgen did not independently develop its proposed OPDIVO® biosimilar. Instead, it seeks to commercialize that product before Plaintiffs' patents have expired—threatening the exclusivity that supports Plaintiffs' continued investment in the next generation of cancer medicines.

3. To understand what OPDIVO® does requires a brief explanation of how cancer evades the body's natural defenses. The human immune system relies on T cells to detect and destroy abnormal cells, including cancer cells. But the immune system has a built-in safeguard: a receptor on T cells called PD-1 that acts as a "brake" on the immune system, signaling T cells to stand down once the immune response has done its job so that immune cells do not attack healthy tissues. Cancer cells take advantage of this safeguard. By engaging the PD-1 pathway, cancer cells apply the brakes on the immune response before it can eliminate the cancer cells—effectively shielding them from attack. OPDIVO®'s active ingredient, nivolumab, is a recombinant (genetically engineered) human antibody designed to solve this problem. Nivolumab binds directly to PD-1 and releases the brake on T cells, permitting them to remain active and attack cancer cells.

4. When Plaintiffs began clinical trials on nivolumab in 2006, the prevailing view among oncologists was that immunotherapy would not work to treat cancer. Plaintiffs persisted even after others abandoned their programs, investing years of research and billions of dollars into demonstrating that blocking the PD-1 pathway could unleash the immune system against cancers that resisted prior treatments. In July 2014, Japan approved OPDIVO® for the treatment of advanced melanoma, making it the first anti-PD-1 therapy approved anywhere in the world. Five months later, in December 2014, the FDA approved OPDIVO® for the treatment of advanced melanoma based on results from a large-scale, multi-center, international Phase III trial. Since then, Plaintiffs have conducted dozens of additional clinical trials and expanded the approved uses for OPDIVO® from a single indication to more than twenty-five. OPDIVO® is now a leading medicine used to treat patients suffering from, *inter alia*, melanoma, non-small cell lung cancer, renal cell carcinoma, and hepatocellular carcinoma. It is estimated that, to date, more than 1 million patients worldwide have been administered OPDIVO®.

5. Plaintiffs' scientists and researchers also discovered groundbreaking ways to administer OPDIVO® in combination therapies for cancers that were difficult or impossible to treat with a single product. As a result of these efforts, patients now receive OPDIVO® in combination with other medicines, including chemotherapy and YERVOY® (ipilimumab)—another immunotherapeutic antibody developed by Plaintiffs—for the treatment of a range of cancers, including advanced and metastatic cancers for which few effective treatments previously existed.

6. The U.S. Patent and Trademark Office recognized these contributions by awarding Plaintiffs multiple patents—including a composition of matter patent that covers nivolumab, as well as patents covering the methods of treating different types of cancer using OPDIVO® that Plaintiffs invented through their extensive clinical research program. Plaintiffs continue to

innovate and have filed additional applications as they continue to invest in clinical trials to discover additional ways of using OPDIVO® to treat even more patients with different types of cancer.

7. OPDIVO® is one of Plaintiffs' largest-selling products and is among the top-selling medicines in the pharmaceutical industry. And the exclusivity that the patent system provides is the engine of Plaintiffs' continued innovation: the revenues earned from OPDIVO® directly fund a research and development pipeline that includes, *inter alia*, novel antibodies, cell therapies, and next-generation biologics for the treatment of cancer, cardiovascular disease, and autoimmune disorders. Plaintiffs collectively employ thousands of scientists and physicians whose work depends on the sustained revenue streams that patent exclusivity makes possible. Premature erosion of that exclusivity undermines the incentive structure the patent laws are designed to protect and will inflict irreparable damage on Plaintiffs.

8. Rather than undertake the years of research and billions of dollars of investment required to develop its own anti-PD-1 therapy, Amgen filed an abbreviated Biologics License Application ("aBLA")—an application based primarily on Plaintiffs' extensive clinical research—with the FDA under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. §§ 262(k)-(*l*), seeking approval to commercialize ABP 206, a biosimilar version of OPDIVO® (the "Proposed Amgen Nivolumab Biosimilar"). When Amgen filed its aBLA, it committed an act of patent infringement under 35 U.S.C. § 271(e). Plaintiffs bring this action to hold Amgen accountable for that infringement and to preserve the exclusivity on which their continued research and development depends.

THE PARTIES

9. BMS is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at Route 206 & Province Line Road, Princeton, New Jersey 08543.

10. Squibb is a limited liability company organized and existing under the laws of the state of Delaware, with a principal place of business at Route 206 & Province Line Road, Princeton, New Jersey 08543.

11. Ono is a corporation organized under the laws of Japan, with a principal place of business at 1-8-2 Kyutaromachi, Chuo-ku, Osaka 541-8564, Japan.

12. Amgen is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

13. On information and belief, Amgen and its subsidiaries, affiliates, and agents will function as an integrated organization and a single business enterprise in the manufacture, importation, sale, and/or offer for sale of the Proposed Amgen Nivolumab Biosimilar in the United States.

JURISDICTION AND VENUE

14. This is an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and the BPCIA, including 42 U.S.C. § 262(*l*).

15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

16. This Court has personal jurisdiction over Amgen because Amgen is a corporation organized and existing under the laws of Delaware.

17. Furthermore, this Court has personal jurisdiction over Amgen because, on information and belief, Amgen (a) has regularly and systematically transacted business in Delaware, including, but not limited to, manufacturing and marketing biologics that are sold and distributed in Delaware; (b) has engaged in substantial and continuing contacts with Delaware; and (c) through its intended launch of the Proposed Amgen Nivolumab Biosimilar will commit acts of patent infringement in Delaware. Amgen has also availed itself of the rights and benefits of Delaware law, including by engaging in patent litigation in this District. *See, e.g.*, *Amgen Inc. v. Hospira, Inc.*, No. 20-cv-561-CFC (D. Del. Apr. 24, 2020); *Amgen Inc. v. Hospira, Inc.*, No. 20-cv-201-CFC (D. Del. Feb. 11, 2020); *Amgen Inc. v. Hospira, Inc.*, No. 18-cv-1064-CFC (D. Del. July 18, 2018); *Amgen Inc. v. Coherus Biosciences, Inc.*, No. 17-cv-546-LPS (D. Del. May 10, 2017).

18. On information and belief, Amgen submitted an aBLA to the FDA pursuant to 42 U.S.C. § 262(k) seeking approval to market the Proposed Amgen Nivolumab Biosimilar throughout the United States, including in this District.

19. On information and belief, Amgen intends to commercially market its Proposed Amgen Nivolumab Biosimilar throughout the United States, including in this District.

20. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400 because Amgen, a Delaware corporation subject to personal jurisdiction in the judicial district of Delaware, resides in this District.

CONDUCT OF THE BPCIA "PATENT DANCE"

21. Enacted in 2010 as part of the Affordable Care Act, the BPCIA provides an abbreviated regulatory approval pathway for biosimilars, letting applicants rely on the extensive clinical testing previously conducted, at great expense, by the innovator company that developed the medicine the applicant wants to copy. The BPCIA also provides for an extensive, pre-launch

process designed to ensure that the manufacture and sale of the proposed biosimilar do not infringe any patents the innovator has been awarded to protect its inventions.

22. This structured framework for resolving patent disputes is known as the "patent dance." It begins with the biosimilar applicant providing the innovator, or "reference product sponsor," with the information necessary to assess whether the approval and launch of the proposed biosimilar would infringe patents protecting the innovator's inventions. 42 U.S.C. § 262(*l*)(1), (2). The required production includes a copy of the applicant's "aBLA" along with "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." *Id*. Based on this information, the innovator must identify the patent or patents for which a claim of patent infringement could reasonably be asserted against the biosimilar applicant with respect to the proposed biosimilar product, the proposed uses for which the applicant was seeking approval, and the processes by which the applicant proposed to make it. *Id*. § 262(*l*)(3).

23. On [redacted], Amgen purported to comply with this obligation by providing BMS—the reference product sponsor because it holds the FDA license to OPDIVO®—an electronic link to certain documents and information. After reviewing these materials, BMS promptly identified and requested missing Amgen information that it needed to fully assess whether the Proposed Amgen Nivolumab Biosimilar would infringe certain of Plaintiffs' patents. In particular, BMS identified missing details of Amgen's manufacturing process that were necessary to determine whether Amgen intended to use innovations for which Plaintiffs had secured patents.

24. Amgen initially refused BMS's request. Only after BMS pressed a second time did Amgen agree to make a small supplemental production—but it still refused to provide crucial

information regarding its manufacturing process for the Proposed Amgen Nivolumab Biosimilar. Amgen's failure to comply with 42 U.S.C. § 262(*l*)(2)(A) has impaired BMS's ability to enforce its rights in the manner the BPCIA provides.

25. Notwithstanding Amgen's failure to provide the required information, on [redacted], BMS provided Amgen with a list of twenty-four patents for which BMS believed an infringement claim might reasonably be asserted against Amgen. BMS supplemented this list with two additional patents that issued on May 12, 2026 and on July 21, 2026.

26. Amgen responded pursuant to 42 U.S.C. § 262(*l*)(3)(B) with a statement that it did not infringe [redacted] of the identified patents and/or stating why those patents were allegedly invalid. Amgen did not contest the enforceability of any of Plaintiffs' identified patents. Amgen also did not provide any additional evidence to support its purported non-infringement positions including, for example, additional information regarding its manufacturing process that might resolve the concern that the process for which Amgen is seeking FDA approval incorporates components or steps claimed in Plaintiffs' patents.

27. BMS responded pursuant to 42 U.S.C. § 262(*l*)(3)(C) with detailed contentions explaining how the Proposed Amgen Nivolumab Biosimilar infringed the identified patents, and why those patents are valid. BMS also requested Amgen's position regarding which patents should be the subject of a patent infringement action.

28. Ten days later, Amgen acknowledged receipt of BMS's detailed statements and proposed that the parties wait eleven more days to begin negotiating which patents should be litigated in an immediate patent infringement action under 42 U.S.C. § 262(*l*)(6).

29. BMS requested that, consistent with 42 U.S.C. § 262(*l*)(4)(A), the parties commence negotiations immediately. Following a series of exchanges, the parties agreed that the

following patents would be litigated in a first-wave litigation: U.S. Patent Nos. 8,008,449 ("the '449 Patent"); 9,856,320 ("the '320 Patent"); 10,072,082 ("the '082 Patent"); 12,590,154 ("the '154 Patent"); 12,624,107 ("the '107 Patent"); 12,590,153 ("the '153 Patent"); and 12,479,917 ("the '917 Patent") (collectively, the "Patents-in-Suit").

30. Plaintiffs file this action for patent infringement with respect to the agreed-upon patents under Section 262(*l*)(4), within 30 days after such agreement, pursuant to 42 U.S.C. § 262(*l*)(6)(A).

THE PATENTS-IN-SUIT

The '449 Patent

31. The '449 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" and issued on August 30, 2011. A true and correct copy of the '449 Patent is attached hereto as Exhibit A.

32. The '449 Patent issued from U.S. Patent Application No. 11/913,217. It claims priority through PCT/JP2006/309606 to U.S. Provisional Application No. 60/679,466, filed on May 9, 2005; U.S. Provisional Application No. 60/738,434, filed on November 21, 2005; and U.S. Provisional Application No. 60/748,919, filed on December 8, 2005. The '449 Patent names Alan J. Korman, Mohan Srinivasan, Changyu Wang, Mark J. Selby, Bingliang Chen, Josephine M. Cardarelli, and Haichun Huang as inventors.

33. The '449 Patent is assigned to Squibb and Ono. Squibb granted BMS an exclusive license to the '449 Patent.

34. The '449 Patent discloses and claims the amino acid sequence of nivolumab.

35. The '449 Patent contains twenty-three claims, six of which are independent claims. Claim 3 recites:

> An isolated monoclonal antibody, or antigen-binding portion thereof, comprising a heavy chain variable region and a light chain variable region, wherein the heavy chain variable region and light chain variable region are selected from the group consisting of:
>
> a) a heavy chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 1; and a light chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 8;
>
> b) a heavy chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 2; and a light chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 9;
>
> c) a heavy chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 3; and a light chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 10;
>
> d) a heavy chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 4; and a light chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 11;
>
> e) a heavy chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 5; and a light chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 12;
>
> f) a heavy chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 6; and a light chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 13; and
>
> g) a heavy chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 7; and a light chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 14,
>
> wherein the antibody or antigen-binding portion thereof specifically binds to PD-1.

Claim 20 recites:

> The antibody, or antigen-binding portion thereof of claim 3, which comprises:
>
> (a) a heavy chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 4; and
>
> (b) a light chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 11.

36. Amgen has known about the ’449 Patent since at least as early as July 10, 2025, when Amgen discussed the ’449 Patent in its Opposition to Patent Owner’s Request for

Discretionary Denial in IPR2025-00601 and IPR2025-00602. On information and belief, Amgen has known about the '449 Patent for many years before that, including at least as early as the approximate time it committed to its pursuit of a biosimilar of OPDIVO®.

37. The '449 Patent was identified in the letter BMS sent to Amgen on [redacted] as a patent for which BMS believes a claim of patent infringement could reasonably be asserted against Amgen if Amgen engaged in the making, using, offering to sell, selling, or importing into the United States of the Proposed Amgen Nivolumab Biosimilar.

The '320 Patent

38. The '320 Patent is entitled "Cancer Immunotherapy by Disrupting PD-1/PD-L1 Signaling" and issued on January 2, 2018. A true and correct copy of the '320 Patent is attached hereto as Exhibit B.

39. The '320 Patent issued from U.S. Patent Application No. 14/400,667. It claims priority to U.S. Provisional Application No. 61/647,442, filed on May 15, 2012, and U.S. Provisional Application No. 61/790,747, filed on March 15, 2013. The '320 Patent names John P. Cogswell, Stacie M. Goldberg, Ashok K. Gupta, Maria Jure-Kunkel, Xi-Tao Wang, and Jon M. Wigginton as inventors.

40. The '320 Patent is assigned to BMS.

41. The '320 Patent contains twenty-two claims, two of which are independent claims. Claim 5 recites:

> A method of treating a human subject afflicted with a cancer comprising administering to the subject 1 mg/kg of an anti-PD-1 antibody and 3 mg/kg of an anti-CTLA-4 antibody every 3 weeks for 4 doses, followed by subsequently administering the anti-PD-1 antibody alone at a dosing frequency of once every 2 weeks.

42. Amgen has known about the '320 Patent since at least as early as February 28, 2025, when Amgen filed a request for *inter partes* review of the '320 Patent, which was discretionarily denied.

43. The '320 Patent was identified in the letter BMS sent to Amgen on [redacted] as a patent for which BMS believes a claim of patent infringement could reasonably be asserted against Amgen if Amgen engaged in the making, using, offering to sell, selling, or importing into the United States of the Proposed Amgen Nivolumab Biosimilar.

The '082 Patent

44. The '082 Patent is entitled "Cancer Immunotherapy by Disrupting PD-1/PD-L1 Signaling" and issued on September 11, 2018. A true and correct copy of the '082 Patent is attached hereto as Exhibit C.

45. The '082 Patent issued from U.S. Patent Application No. 14/950,748. It claims priority to U.S. Provisional Application No. 61/647,442, filed on May 15, 2012, and U.S. Provisional Application No. 61/790,747, filed on March 15, 2013. The '082 Patent names John P. Cogswell, Stacie M. Goldberg, Ashok K. Gupta, Maria Jure-Kunkel, Xi-Tao Wang, and Jon M. Wigginton as inventors.

46. The '082 Patent is assigned to BMS.

47. The '082 Patent contains twenty-eight claims, two of which are independent claims. Claim 1 recites:

> 1. A method for treating a human subject afflicted with cancer using an immunotherapy, which method comprises:
>
> (a) selecting a human subject who is a suitable candidate for immunotherapy, wherein the selecting comprises:
>
> assessing the proportion of cells in a test tissue sample that express PD-L1 on the cell surface as determined by immunohistochemistry (IHC) using an anti-PD-L1 antibody, wherein the test tissue sample is obtained from a tumor of the subject

and wherein the proportion of cells that express PD-L1 on the cell surface is ≥1%; and

(b) administering a composition comprising a therapeutically effective amount of an anti-PD-1 antibody to the subject;

wherein the anti-PD-L1 antibody comprises:

(a) a heavy chain (HC) complementarity determining region (CDR) 1 comprising the amino acid sequence set forth in the HC-CDR1 of SEQ ID NO: 35;

(b) an HC-CDR2 comprising the amino acid sequence set forth in the HC-CDR2 of SEQ ID NO: 35;

(c) an HC-CDR3 comprising the amino acid sequence set forth in the HC-CDR3 of SEQ ID NO: 35;

(d) a light chain (LC) CDR1 comprising the amino acid sequence set forth in the LC-CDR1 of SEQ ID NO: 36;

(e) an LC-CDR2 comprising the amino acid sequence set forth in the LC-CDR2 of SEQ ID NO: 36; and

(f) an LC-CDR3 comprising the amino acid sequence set forth in the LC-CDR3 of SEQ ID NO: 36.

48. The ’082 Patent was identified in the letter BMS sent to Amgen on [redacted] as a patent for which BMS believes a claim of patent infringement could reasonably be asserted against Amgen if Amgen engaged in the making, using, offering to sell, selling, or importing into the United States of the Proposed Amgen Nivolumab Biosimilar.

The ’154 Patent

49. The ’154 Patent is entitled “Cancer Immunotherapy by Disrupting PD-1/PD-L1 Signaling” and issued on March 31, 2026. A true and correct copy of the ’154 Patent is attached hereto as Exhibit D.

50. The ’154 Patent issued from U.S. Patent Application No. 19/193,652, which is a continuation of U.S. Patent Application No. 18/662,447, which is a continuation of U.S. Patent

Application No. 18/052,099, now abandoned, which is a continuation of U.S. Patent Application No. 16/827,580, now abandoned, which is a continuation of U.S. Patent Application No. 16/231,211, which issued as U.S. Patent No. 10,604,575, which is a division of U.S. Patent Application No. 16/006,365, which issued as U.S. Patent No. 10,316,090, which is a continuation of U.S. Patent Application No. 14/950,748, which issued as U.S. Patent No. 10,072,082, which is a division of U.S. Patent Application No. 13/892,671, which issued as U.S. Patent No. 9,212,224. The '154 Patent claims priority to U.S. Provisional Application No. 61/647,442, filed on May 15, 2012, and U.S. Provisional Application No. 61/790,747, filed on March 15, 2013. The '154 Patent names John P. Cogswell, Stacie M. Goldberg, Ashok K. Gupta, Maria Jure-Kunkel, Xi-Tao Wang, and Jon M. Wigginton as inventors.

51. The '154 Patent is assigned to BMS.

52. The '154 Patent contains twenty claims, two of which are independent claims. Claim 1 recites:

> 1. A method of treating a hepatocellular carcinoma (HCC) in a human subject in need thereof, comprising administering to the subject 1 mg/kg of nivolumab and 3 mg/kg of ipilimumab every 3 weeks for 4 cycles, followed by subsequently administering the nivolumab alone.

53. The '154 Patent was identified in the letter BMS sent to Amgen on [redacted] as a patent for which BMS believes a claim of patent infringement could reasonably be asserted against Amgen if Amgen engaged in the making, using, offering to sell, selling, or importing into the United States of the Proposed Amgen Nivolumab Biosimilar.

The '107 Patent

54. The '107 Patent is entitled "Cancer Immunotherapy by Disrupting PD-1/PD-L1 Signaling" and issued on May 12, 2026. A true and correct copy of the '107 Patent is attached hereto as Exhibit E.

55. The ’107 Patent issued from U.S. Patent Application No. 19/193,595, which is a continuation of U.S. Patent Application No. 18/662,447, which is a continuation of U.S. Patent Application No. 18/052,099, now abandoned, which is a continuation of U.S. Patent Application No. 16/827,580, now abandoned, which is a continuation of U.S. Patent Application No. 16/231,211, which issued as U.S. Patent No. 10,604,575, which is a division of U.S. Patent Application No. 16/006,365, which issued as U.S. Patent No. 10,316,090, which is a continuation of U.S. Patent Application No. 14/950,748, which issued as U.S. Patent No. 10,072,082, which is a division of U.S. Patent Application No. 13/892,671, which issued as U.S. Patent No. 9,212,224. The ’107 Patent claims priority to U.S. Provisional Application No. 61/647,442, filed on May 15, 2012, and U.S. Provisional Application No. 61/790,747, filed on March 15, 2013. The ’107 Patent names John P. Cogswell, Stacie M. Goldberg, Ashok K. Gupta, Maria Jure-Kunkel, Xi-Tao Wang, and Jon M. Wigginton as inventors.

56. The ’107 Patent is assigned to BMS.

57. The ’107 Patent contains six claims, one of which is an independent claim. Claim 1 recites:

> 1. A method of treating a renal cell carcinoma in a human subject in need thereof, comprising administering to the subject 3 mg/kg of nivolumab and 1 mg/kg of ipilimumab every 3 weeks for 4 cycles, followed by subsequently administering the nivolumab alone.

58. The ’107 Patent was identified in the letter BMS sent to Amgen on [redacted] as a patent for which BMS believes a claim of patent infringement could reasonably be asserted against Amgen if Amgen engaged in the making, using, offering to sell, selling, or importing into the United States of the Proposed Amgen Nivolumab Biosimilar.

The '153 Patent

59. The '153 Patent is entitled "Treatment of PD-L1-negative Melanoma Using an Anti-PD-1 Antibody and an Anti-CTLA-4 Antibody" and issued on March 31, 2026. A true and correct copy of the '153 Patent is attached hereto as Exhibit F.

60. The '153 Patent issued from U.S. Patent Application No. 17/523,702, which is a continuation of U.S. Patent Application No. 16/240,316, now abandoned, which is a continuation of U.S. Patent Application No. 15/141,769, which issued as U.S. Patent No. 10,174,113. The '153 Patent claims priority to U.S. Provisional Application No. 62/153,973, filed on April 28, 2015. The '153 Patent names Arvin Yang as the inventor.

61. The '153 Patent is assigned to BMS.

62. The '153 Patent contains eleven claims, one of which is an independent claim. Claim 1 recites:

> A method for treating a melanoma tumor in a patient in need thereof comprising administering to the patient:
>
> (a) about 1 mg/kg nivolumab and 3 mg/kg ipilimumab every three weeks for about 4 doses; followed by
>
> (b) a dose of nivolumab, wherein the dose is a flat dose of about 240 mg or about 480 mg.

63. The '153 Patent was identified in the letter BMS sent to Amgen on [redacted] as a patent for which BMS believes a claim of patent infringement could reasonably be asserted against Amgen if Amgen engaged in the making, using, offering to sell, selling, or importing into the United States of the Proposed Amgen Nivolumab Biosimilar.

The '917 Patent

64. The '917 Patent is entitled "Methods of Treating NSCLC Comprising Administering Platinum Doublet Chemotherapy Followed by an Anti-PD-1 Antibody and an Anti-

CTLA-4 Antibody" and issued on November 25, 2025. A true and correct copy of the '917 Patent is attached hereto as Exhibit G.

65. The '917 Patent issued from U.S. Patent Application No. 17/287,838. It claims priority through PCT/US2019/057672 to U.S. Provisional Application No. 62/749,393, filed on October 23, 2018. The '917 Patent names Sabine Maier, Abderrahim Oukessou, Nicholas Allan Botwood, Kelly L. Covello, Michael V. Mandola, and Stephen R. Lane as inventors.

66. The '917 Patent is assigned to BMS.

67. The '917 Patent contains twenty claims, two of which are independent claims. Claim 1 recites:

> A method of treating a tumor in a subject afflicted with a non-small cell lung carcinoma (NSCLC), comprising:
>
> (1) administering to the subject (i) a platinum doublet chemotherapy comprising carboplatin and paclitaxel, (ii) a flat dose of about 360 mg of an anti-PD-1 antibody or antigen binding portion thereof, and (iii) a dose of about 1 mg/kg of an anti-CTLA-4 antibody or antigen binding portion thereof on day 1 of a first 3-week cycle, and administering to the subject (i) the platinum based doublet chemotherapy and (ii) a flat dose of about 360 mg of the anti-PD-1 antibody on day 1 of a second 3 week cycle; and
>
> (2) administering to the subject (i) a flat dose of about 360 mg of the anti-PD-1 antibody once about every 3 weeks and (ii) a dose of about 1 mg/kg of the anti-CTLA-4 antibody once about every 6 weeks.

68. The '917 Patent was identified in the letter BMS sent to Amgen on [redacted] as a patent for which BMS believes a claim of patent infringement could reasonably be asserted against Amgen if Amgen engaged in the making, using, offering to sell, selling, or importing into the United States of the Proposed Amgen Nivolumab Biosimilar.

COUNT I: INFRINGEMENT OF THE '449 PATENT

69. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

70. On information and belief, by submitting its aBLA to the FDA, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

71. Amgen committed an act or acts of infringement with respect to the '449 Patent under 35 U.S.C. § 271(e)(2)(C) when it submitted its aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

72. On information and belief, Amgen intends to manufacture, use, offer for sale, sell, and/or import its Proposed Amgen Nivolumab Biosimilar before the expiration of the '449 Patent.

73. Amgen has provided information to BMS pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the composition, indications, dosage, and methods of use for the Proposed Amgen Nivolumab Biosimilar. Based on this confidential information, Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe, actively induce infringement by others, or contribute to the infringement by others of [redacted] of the '449 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c), either literally or under the doctrine of equivalents.

74. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), BMS provided Amgen with a detailed statement describing with respect to the '449 Patent, on a claim-by-claim basis, the factual and legal bases of BMS's opinion that the '449 Patent will be infringed by the commercial marketing of the Proposed Amgen Nivolumab Biosimilar that is the subject of Amgen's aBLA. BMS's

detailed statement includes, refers to, and relies on confidential information Amgen provided to BMS pursuant to 42 U.S.C. § 262(*l*)(2).

75. According to Amgen's aBLA, [redacted]

76. On information and belief, Amgen's commercial manufacture, use, offer for sale, sale, and/or import into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '449 Patent will infringe, either literally or under the doctrine of equivalents, one or more claims of the '449 Patent under 35 U.S.C. §§ 271(a), including [redacted]

77. Amgen has known about the '449 Patent since at least as early as July 10, 2025. On information and belief, Amgen will encourage others to make, use, sell, offer for sale, and/or import the Proposed Amgen Nivolumab Biosimilar before the expiration of the '449 Patent. Amgen knows and/or is willfully blind to the fact that through this intentional conduct, it will infringe one or more claims of the '449 Patent, either literally or under the doctrine of equivalents. On information and belief, Amgen will actively induce direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Amgen Nivolumab Biosimilar with proposed labeling that instructs and encourages

healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar. Amgen will induce infringement of one or more claims of the '449 Patent under 35 U.S.C. § 271(b), including [redacted].

78. On information and belief, Amgen will offer to sell and sell the Proposed Amgen Nivolumab Biosimilar before the expiration of the '449 Patent. The Proposed Amgen Nivolumab Biosimilar constitutes a material part of the invention of the '449 Patent. Amgen knows and/or is willfully blind to the fact that the Proposed Amgen Nivolumab Biosimilar is especially made or especially adapted for use in an infringement of the '449 Patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Therefore, Amgen will contributorily infringe one or more claims of the '449 Patent under 35 U.S.C. § 271(c), including [redacted].

79. On information and belief, Amgen's infringement of the '449 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '449 Patent.

80. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '449 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and (D).

81. Plaintiffs have been injured by Amgen's infringement and to the extent Amgen manufactures, uses, offers for sale, or sells within the United States and/or imports into the United States, the Proposed Amgen Nivolumab Biosimilar before the expiration of the '449 Patent, it will

cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '449 PATENT

82. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

83. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(a), (b) and/or (c). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Amgen's threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar before expiration of the '449 Patent.

84. As set forth in Count I, incorporated by reference in its entirety herein, Amgen's commercial manufacture, use, offer for sale, sale, and/or import into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '449 Patent will infringe, either literally or under the doctrine of equivalents, one or more claims of the '449 Patent under 35 U.S.C. § 271(a), (b) and/or (c), including [redacted].

85. On information and belief, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to manufacture and sell the Proposed Amgen Nivolumab Biosimilar, a proposed biosimilar version of Plaintiffs' OPDIVO®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar.

86. On information and belief, Amgen intends to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Amgen

Nivolumab Biosimilar upon FDA approval of Amgen's aBLA and prior to the expiration of the '449 Patent.

87. Amgen has knowledge of or is willfully blind to the existence of the '449 Patent, including due to Amgen's identification of the '449 Patent during *inter partes* review proceedings, BMS's disclosure of the '449 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), BMS's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

88. An actual controversy has arisen and now exists between the parties concerning whether Amgen's making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar or Amgen's active inducement thereof before the expiration of the '449 Patent will infringe one or more claims of the '449 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

89. Plaintiffs are entitled to a declaratory judgment that Amgen will infringe, directly and/or indirectly, one or more claims of the '449 Patent by making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar before the expiration of the '449 Patent.

90. On information and belief, Amgen's infringement of the '449 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '449 Patent.

91. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United

States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '449 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 283.

92. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '449 Patent will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT III: INFRINGEMENT OF THE '320 PATENT

93. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

94. On information and belief, by submitting its aBLA to the FDA, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

95. Amgen committed an act or acts of infringement with respect to the '320 Patent under 35 U.S.C. § 271(e)(2)(C) when it submitted its aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

96. On information and belief, Amgen intends to manufacture, use, offer for sale, sell, and/or import its Proposed Amgen Nivolumab Biosimilar before the expiration of the '320 Patent.

97. Amgen has provided information to BMS pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the composition, indications, dosage, and methods of use for the Proposed Amgen Nivolumab Biosimilar. Based on this confidential information, Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Amgen Nivolumab

Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others or contribute to the infringement by others of [redacted] of the '320 Patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

98. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), BMS provided Amgen with a detailed statement describing with respect to the '320 Patent, on a claim-by-claim basis, the factual and legal bases of BMS's opinion that the '320 Patent will be infringed by the commercial marketing of the Proposed Amgen Nivolumab Biosimilar that is the subject of Amgen's aBLA. BMS's detailed statement includes, refers to, and relies on confidential information Amgen provided to BMS pursuant to 42 U.S.C. § 262(*l*)(2).

99. According to Amgen's aBLA, [redacted]

100. On information and belief, healthcare providers using the Proposed Amgen Nivolumab Biosimilar in accordance with Amgen's proposed labeling instructions will administer the Proposed Amgen Nivolumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '320 Patent, including [redacted].

101. Amgen has known about the '320 Patent since at least as early as February 28, 2025. On information and belief, Amgen will encourage others to make, use, sell, offer for sale, and/or import the Proposed Amgen Nivolumab Biosimilar before the expiration of the '320 Patent.

By including the instructions for use in its proposed label for the Proposed Amgen Nivolumab Biosimilar, Amgen knows and/or is willfully blind to the fact that through this intentional conduct, it will infringe one or more claims of the '320 Patent, either literally or under the doctrine of equivalents.

102. On information and belief, Amgen will actively induce direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Amgen Nivolumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar. Amgen will induce infringement of one or more claims of the '320 Patent under 35 U.S.C. § 271(b), including [redacted].

103. On information and belief, Amgen will offer to sell and sell the Proposed Amgen Nivolumab Biosimilar before the expiration of the '320 Patent. The Proposed Amgen Nivolumab Biosimilar constitutes a material part of the invention of the '320 Patent. Amgen knows and/or is willfully blind to the fact that the Proposed Amgen Nivolumab Biosimilar is especially made or especially adapted for use in an infringement of the '320 Patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Therefore, Amgen will contributorily infringe one or more claims of the '320 Patent under 35 U.S.C. § 271(c), including [redacted].

104. On information and belief, Amgen's infringement of the '320 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '320 Patent.

105. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '320 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and (D).

106. Plaintiffs have been injured by Amgen's infringement and to the extent Amgen manufactures, uses, offers for sale, or sells within the United States and/or imports into the United States, the Proposed Amgen Nivolumab Biosimilar before the expiration of the '320 Patent, it will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '320 PATENT

107. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

108. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(a), (b) and/or (c). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Amgen's threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar before expiration of the '320 Patent.

109. As set forth in Count III, incorporated by reference in its entirety herein, Amgen's commercial manufacture, use, offer for sale, sale, and/or import into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '320 Patent will infringe,

either literally or under the doctrine of equivalents, one or more claims of the '320 Patent under 35 U.S.C. § 271(b) and/or (c), including [redacted]

110. On information and belief, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to manufacture and sell the Proposed Amgen Nivolumab Biosimilar, a proposed biosimilar version of Plaintiffs' OPDIVO®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar.

111. On information and belief, Amgen intends to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Amgen Nivolumab Biosimilar upon FDA approval of Amgen's aBLA and prior to the expiration of the '320 Patent.

112. Amgen has knowledge of or is willfully blind to the existence of the '320 Patent, including due to Amgen's previous *inter partes* review challenge to the '320 Patent, BMS's disclosure of the '320 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), BMS's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

113. An actual controversy has arisen and now exists between the parties concerning whether Amgen's making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar or Amgen's active inducement thereof before the expiration of the '320 Patent will infringe one or more claims of the '320 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

114. Plaintiffs are entitled to a declaratory judgment that Amgen will infringe, directly and/or indirectly, one or more claims of the '320 Patent by making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar before the expiration of the '320 Patent.

115. On information and belief, Amgen's infringement of the '320 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '320 Patent.

116. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '320 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 283.

117. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '320 Patent will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT V: INFRINGEMENT OF THE '082 PATENT

118. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

119. On information and belief, by submitting its aBLA to the FDA, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

120. Amgen committed an act or acts of infringement with respect to the '082 Patent under 35 U.S.C. § 271(e)(2)(C) when it submitted its aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

121. On information and belief, Amgen intends to manufacture, use, offer for sale, sell, and/or import its Proposed Amgen Nivolumab Biosimilar before the expiration of the '082 Patent.

122. Amgen has provided information to BMS pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the composition, indications, dosage, and methods of use for the Proposed Amgen Nivolumab Biosimilar. Based on this confidential information, Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others or contribute to the infringement by others of [redacted] of the '082 Patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

123. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), BMS provided Amgen with a detailed statement describing with respect to the '082 Patent, on a claim-by-claim basis, the factual and legal bases of BMS's opinion that the '082 Patent will be infringed by the commercial marketing of the Proposed Amgen Nivolumab Biosimilar that is the subject of Amgen's aBLA. BMS's detailed statement includes, refers to, and relies on confidential information Amgen provided to BMS pursuant to 42 U.S.C. § 262(*l*)(2).

124. According to Amgen's aBLA, [redacted]

[redacted].

125. On information and belief, healthcare providers using the Proposed Amgen Nivolumab Biosimilar in accordance with Amgen's proposed labeling instructions will administer the Proposed Amgen Nivolumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '082 Patent, including [redacted]

126. Amgen has known about the '082 Patent since at least as early as [redacted]. On information and belief, Amgen will encourage others to make, use, sell, offer for sale, and/or import the Proposed Amgen Nivolumab Biosimilar before the expiration of the '082 Patent. By including the instructions for use in its proposed label for the Proposed Amgen Nivolumab Biosimilar, Amgen knows and/or is willfully blind to the fact that through this intentional conduct, it will infringe one or more claims of the '082 Patent, either literally or under the doctrine of equivalents.

127. On information and belief, Amgen will actively induce direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Amgen Nivolumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar. Amgen will induce infringement of one or more claims of the '082 Patent under 35 U.S.C. § 271(b), including [redacted].

128. On information and belief, Amgen will offer to sell and sell the Proposed Amgen Nivolumab Biosimilar before the expiration of the '082 Patent. The Proposed Amgen Nivolumab Biosimilar constitutes a material part of the invention of the '082 Patent. Amgen knows and/or is willfully blind to the fact that the Proposed Amgen Nivolumab Biosimilar is especially made or especially adapted for use in an infringement of the '082 Patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Therefore, Amgen will contributorily infringe one or more claims of the '082 Patent under 35 U.S.C. § 271(c), including [redacted].

129. On information and belief, Amgen's infringement of the '082 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '082 Patent.

130. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '082 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and (D).

131. Plaintiffs have been injured by Amgen's infringement and to the extent Amgen manufactures, uses, offers for sale, or sells within the United States and/or imports into the United States, the Proposed Amgen Nivolumab Biosimilar before the expiration of the '082 Patent, it will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '082 PATENT

132. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

133. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(a), (b) and/or (c). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Amgen's threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar before expiration of the '082 Patent.

134. As set forth in Count V, incorporated by reference in its entirety herein, Amgen's commercial manufacture, use, offer for sale, sale, and/or import into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '082 Patent will infringe, either literally or under the doctrine of equivalents, one or more claims of the '082 Patent under 35 U.S.C. § 271(b) and/or (c), including [redacted].

135. On information and belief, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to manufacture and sell the Proposed Amgen Nivolumab Biosimilar, a proposed biosimilar version of Plaintiffs' OPDIVO®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar.

136. On information and belief, Amgen intends to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Amgen Nivolumab Biosimilar upon FDA approval of Amgen's aBLA and prior to the expiration of the '082 Patent.

137. Amgen has knowledge of or is willfully blind to the existence of the '082 Patent, including due to BMS's disclosure of the '082 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), BMS's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

138. An actual controversy has arisen and now exists between the parties concerning whether Amgen's making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar or Amgen's active inducement thereof before the expiration of the '082 Patent will infringe one or more claims of the '082 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

139. Plaintiffs are entitled to a declaratory judgment that Amgen will infringe, directly and/or indirectly, one or more claims of the '082 Patent by making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar before the expiration of the '082 Patent.

140. On information and belief, Amgen's infringement of the '082 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '082 Patent.

141. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '082 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 283.

142. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '082 Patent will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT VII: INFRINGEMENT OF THE '154 PATENT

143. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

144. On information and belief, by submitting its aBLA to the FDA, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

145. Amgen committed an act or acts of infringement with respect to the '154 Patent under 35 U.S.C. § 271(e)(2)(C) at least as of its issuance date of March 31, 2026 by virtue of having submitted its aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

146. On information and belief, Amgen intends to manufacture, use, offer for sale, sell, and/or import its Proposed Amgen Nivolumab Biosimilar before the expiration of the '154 Patent.

147. Amgen has provided information to BMS pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the composition, indications, dosage, and methods of use for the Proposed Amgen Nivolumab Biosimilar. Based on this confidential information, Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others or contribute to the infringement

by others of [redacted] of the '154 Patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

148. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), BMS provided Amgen with a detailed statement describing with respect to the '154 Patent, on a claim-by-claim basis, the factual and legal bases of BMS's opinion that the '154 Patent will be infringed by the commercial marketing of the Proposed Amgen Nivolumab Biosimilar that is the subject of Amgen's aBLA. BMS's detailed statement includes, refers to, and relies on confidential information Amgen provided to BMS pursuant to 42 U.S.C. § 262(*l*)(2).

149. According to Amgen's aBLA, [redacted].

150. On information and belief, healthcare providers using the Proposed Amgen Nivolumab Biosimilar in accordance with Amgen's proposed labeling instructions will administer the Proposed Amgen Nivolumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '154 Patent, including [redacted].

151. Amgen has known about the '154 Patent since at least as early as [redacted]. On information and belief, Amgen will encourage others to make, use, sell, offer for sale, and/or import the Proposed Amgen Nivolumab Biosimilar before the expiration of the '154 Patent. By including the instructions for use in its proposed label for the Proposed Amgen Nivolumab Biosimilar, Amgen knows and/or is willfully blind to the fact that through this intentional conduct,

it will infringe one or more claims of the '154 Patent, either literally or under the doctrine of equivalents.

152. On information and belief, Amgen will actively induce direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Amgen Nivolumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar. Amgen will induce infringement of one or more claims of the '154 Patent under 35 U.S.C. § 271(b), including [redacted].

153. On information and belief, Amgen will offer to sell and sell the Proposed Amgen Nivolumab Biosimilar before the expiration of the '154 Patent. The Proposed Amgen Nivolumab Biosimilar constitutes a material part of the invention of the '154 Patent. Amgen knows and/or is willfully blind to the fact that the Proposed Amgen Nivolumab Biosimilar is especially made or especially adapted for use in an infringement of the '154 Patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Therefore, Amgen will contributorily infringe one or more claims of the '154 Patent under 35 U.S.C. § 271(c), including [redacted].

154. On information and belief, Amgen's infringement of the '154 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '154 Patent.

155. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration

of the '154 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and (D).

156. Plaintiffs have been injured by Amgen's infringement and to the extent Amgen manufactures, uses, offers for sale, or sells within the United States and/or imports into the United States, the Proposed Amgen Nivolumab Biosimilar before the expiration of the '154 Patent, it will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '154 PATENT

157. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

158. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(a), (b) and/or (c). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Amgen's threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar before expiration of the '154 Patent.

159. As set forth in Count VII, incorporated by reference in its entirety herein, Amgen's commercial manufacture, use, offer for sale, sale, and/or import into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '154 Patent will infringe, either literally or under the doctrine of equivalents, one or more claims of the '154 Patent under 35 U.S.C. § 271(b) and/or (c), including [redacted]

160. On information and belief, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to manufacture and sell the Proposed Amgen

Nivolumab Biosimilar, a proposed biosimilar version of Plaintiffs' OPDIVO®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar.

161. On information and belief, Amgen intends to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Amgen Nivolumab Biosimilar upon FDA approval of Amgen's aBLA and prior to the expiration of the '154 Patent.

162. Amgen has knowledge of or is willfully blind to the existence of the '154 Patent, including due to BMS's disclosure of the '154 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), BMS's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

163. An actual controversy has arisen and now exists between the parties concerning whether Amgen's making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar or Amgen's active inducement thereof before the expiration of the '154 Patent will infringe one or more claims of the '154 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

164. Plaintiffs are entitled to a declaratory judgment that Amgen will infringe, directly and/or indirectly, one or more claims of the '154 Patent by making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar before the expiration of the '154 Patent.

165. On information and belief, Amgen's infringement of the '154 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved

product knowing that it only received FDA approval by exploiting the invention covered by the '154 Patent.

166. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '154 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 283.

167. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '154 Patent will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT IX: INFRINGEMENT OF THE '107 PATENT

168. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

169. On information and belief, by submitting its aBLA to the FDA, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

170. Amgen committed an act or acts of infringement with respect to the '107 Patent under 35 U.S.C. § 271(e)(2)(C) at least as of its issuance date of May 12, 2026 by virtue of having submitted its aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

171. On information and belief, Amgen intends to manufacture, use, offer for sale, sell, and/or import its Proposed Amgen Nivolumab Biosimilar before the expiration of the '107 Patent.

172. Amgen has provided information to BMS pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the composition, indications, dosage, and methods of use for the Proposed Amgen Nivolumab Biosimilar. Based on this confidential information, Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others or contribute to the infringement by others of [redacted] of the '107 Patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

173. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), BMS provided Amgen with a detailed statement describing with respect to the '107 Patent, on a claim-by-claim basis, the factual and legal bases of BMS's opinion that the '107 Patent will be infringed by the commercial marketing of the Proposed Amgen Nivolumab Biosimilar that is the subject of Amgen's aBLA. BMS's detailed statement includes, refers to, and relies on confidential information Amgen provided to BMS pursuant to 42 U.S.C. § 262(*l*)(2).

174. According to Amgen's aBLA, [redacted].

175. On information and belief, healthcare providers using the Proposed Amgen Nivolumab Biosimilar in accordance with Amgen's proposed labeling instructions will administer

the Proposed Amgen Nivolumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '107 Patent, including [redacted].

176. Amgen has known about the '107 Patent since at least as early as [redacted]. On information and belief, Amgen will encourage others to make, use, sell, offer for sale, and/or import the Proposed Amgen Nivolumab Biosimilar before the expiration of the '107 Patent. By including the instructions for use in its proposed label for the Proposed Amgen Nivolumab Biosimilar, Amgen knows and/or is willfully blind to the fact that through this intentional conduct, it will infringe one or more claims of the '107 Patent, either literally or under the doctrine of equivalents.

177. On information and belief, Amgen will actively induce direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Amgen Nivolumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar. Amgen will induce infringement of one or more claims of the '107 Patent under 35 U.S.C. § 271(b), including [redacted].

178. On information and belief, Amgen will offer to sell and sell the Proposed Amgen Nivolumab Biosimilar before the expiration of the '107 Patent. The Proposed Amgen Nivolumab Biosimilar constitutes a material part of the invention of the '107 Patent. Amgen knows and/or is willfully blind to the fact that the Proposed Amgen Nivolumab Biosimilar is especially made or especially adapted for use in an infringement of the '107 Patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Therefore, Amgen will contributorily infringe one or more claims of the '107 Patent under 35 U.S.C. § 271(c), including [redacted]

179. On information and belief, Amgen's infringement of the '107 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '107 Patent.

180. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '107 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and (D).

181. Plaintiffs have been injured by Amgen's infringement and to the extent Amgen manufactures, uses, offers for sale, or sells within the United States and/or imports into the United States, the Proposed Amgen Nivolumab Biosimilar before the expiration of the '107 Patent, it will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT X: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '107 PATENT

182. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

183. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(a), (b) and/or (c). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Amgen's threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar before expiration of the '107 Patent.

184. As set forth in Count IX, incorporated by reference in its entirety herein, Amgen's commercial manufacture, use, offer for sale, sale, and/or import into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '107 Patent will infringe, either literally or under the doctrine of equivalents, one or more claims of the '107 Patent under 35 U.S.C. § 271(b) and/or (c), including [redacted].

185. On information and belief, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to manufacture and sell the Proposed Amgen Nivolumab Biosimilar, a proposed biosimilar version of Plaintiffs' OPDIVO®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar.

186. On information and belief, Amgen intends to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Amgen Nivolumab Biosimilar upon FDA approval of Amgen's aBLA and prior to the expiration of the '107 Patent.

187. Amgen has knowledge of or is willfully blind to the existence of the '107 Patent, including due to BMS's disclosure of the '107 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), BMS's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

188. An actual controversy has arisen and now exists between the parties concerning whether Amgen's making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar or Amgen's active inducement thereof before the expiration of the '107 Patent will infringe one or more claims of the '107 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment

action is authorized by the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

189. Plaintiffs are entitled to a declaratory judgment that Amgen will infringe, directly and/or indirectly, one or more claims of the '107 Patent by making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar before the expiration of the '107 Patent.

190. On information and belief, Amgen's infringement of the '107 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '107 Patent.

191. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '107 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 283.

192. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '107 Patent will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT XI: INFRINGEMENT OF THE '153 PATENT

193. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

194. On information and belief, by submitting its aBLA to the FDA, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to engage in

the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

195. Amgen committed an act or acts of infringement with respect to the '153 Patent under 35 U.S.C. § 271(e)(2)(C) at least as of its issuance date of March 31, 2026 by virtue of having submitted its aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

196. On information and belief, Amgen intends to manufacture, use, offer for sale, sell, and/or import its Proposed Amgen Nivolumab Biosimilar before the expiration of the '153 Patent.

197. Amgen has provided information to BMS pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the composition, indications, dosage, and methods of use for the Proposed Amgen Nivolumab Biosimilar. Based on this confidential information, Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others or contribute to the infringement by others of [redacted] of the '153 Patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

198. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), BMS provided Amgen with a detailed statement describing with respect to the '153 Patent, on a claim-by-claim basis, the factual and legal bases of BMS's opinion that the '153 Patent will be infringed by the commercial marketing of the Proposed Amgen Nivolumab Biosimilar that is the subject of Amgen's aBLA. BMS's detailed statement includes, refers to, and relies on confidential information Amgen provided to BMS pursuant to 42 U.S.C. § 262(*l*)(2).

199. According to Amgen's aBLA, [redacted]

200. On information and belief, healthcare providers using the Proposed Amgen Nivolumab Biosimilar in accordance with Amgen's proposed labeling instructions will administer the Proposed Amgen Nivolumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '153 Patent, including [redacted].

201. Amgen has known about the '153 Patent since at least as early as [redacted]. On information and belief, Amgen will encourage others to make, use, sell, offer for sale, and/or import the Proposed Amgen Nivolumab Biosimilar before the expiration of the '153 Patent. By including the instructions for use in its proposed label for the Proposed Amgen Nivolumab Biosimilar, Amgen knows and/or is willfully blind to the fact that through this intentional conduct, it will infringe one or more claims of the '153 Patent, either literally or under the doctrine of equivalents.

202. On information and belief, Amgen will actively induce direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Amgen Nivolumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar. Amgen will induce infringement of one or more claims of the '153 Patent under 35 U.S.C. § 271(b), including [redacted].

203. On information and belief, Amgen will offer to sell and sell the Proposed Amgen Nivolumab Biosimilar before the expiration of the '153 Patent. The Proposed Amgen Nivolumab Biosimilar constitutes a material part of the invention of the '153 Patent. Amgen knows and/or is willfully blind to the fact that the Proposed Amgen Nivolumab Biosimilar is especially made or especially adapted for use in an infringement of the '153 Patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Therefore, Amgen will contributorily infringe one or more claims of the '153 Patent under 35 U.S.C. § 271(c), including [redacted].

204. On information and belief, Amgen's infringement of the '153 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '153 Patent.

205. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '153 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and (D).

206. Plaintiffs have been injured by Amgen's infringement and to the extent Amgen manufactures, uses, offers for sale, or sells within the United States and/or imports into the United States, the Proposed Amgen Nivolumab Biosimilar before the expiration of the '153 Patent, it will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT XII: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '153 PATENT

207. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

208. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(a), (b) and/or (c). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Amgen's threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar before expiration of the '153 Patent.

209. As set forth in Count XI, incorporated by reference in its entirety herein, Amgen's commercial manufacture, use, offer for sale, sale, and/or import into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '153 Patent will infringe, either literally or under the doctrine of equivalents, one or more claims of the '153 Patent under 35 U.S.C. § 271(b) and/or (c), including [redacted].

210. On information and belief, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to manufacture and sell the Proposed Amgen Nivolumab Biosimilar, a proposed biosimilar version of Plaintiffs' OPDIVO®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar.

211. On information and belief, Amgen intends to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Amgen Nivolumab Biosimilar upon FDA approval of Amgen's aBLA and prior to the expiration of the '153 Patent.

212. Amgen has knowledge of or is willfully blind to the existence of the '153 Patent, including due to BMS's disclosure of the '153 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), BMS's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

213. An actual controversy has arisen and now exists between the parties concerning whether Amgen's making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar or Amgen's active inducement thereof before the expiration of the '153 Patent will infringe one or more claims of the '153 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

214. Plaintiffs are entitled to a declaratory judgment that Amgen will infringe, directly and/or indirectly, one or more claims of the '153 Patent by making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar before the expiration of the '153 Patent.

215. On information and belief, Amgen's infringement of the '153 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '153 Patent.

216. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '153 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 283.

217. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '153 Patent will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT XIII: INFRINGEMENT OF THE '917 PATENT

218. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

219. On information and belief, by submitting its aBLA to the FDA, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

220. Amgen committed an act or acts of infringement with respect to the '917 Patent under 35 U.S.C. § 271(e)(2)(C) when it submitted its aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed Amgen Nivolumab Biosimilar.

221. On information and belief, Amgen intends to manufacture, use, offer for sale, sell, and/or import its Proposed Amgen Nivolumab Biosimilar before the expiration of the '917 Patent.

222. Amgen has provided information to BMS pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the composition, indications, dosage, and methods of use for the Proposed Amgen Nivolumab Biosimilar. Based on this confidential information, Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others or contribute to the infringement

by others of [redacted] of the '917 Patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

223. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), BMS provided Amgen with a detailed statement describing with respect to the '917 Patent, on a claim-by-claim basis, the factual and legal bases of BMS's opinion that the '917 Patent will be infringed by the commercial marketing of the Proposed Amgen Nivolumab Biosimilar that is the subject of Amgen's aBLA. BMS's detailed statement includes, refers to, and relies on confidential information Amgen provided to BMS pursuant to 42 U.S.C. § 262(*l*)(2).

224. According to Amgen's aBLA, [redacted]

225. On information and belief, healthcare providers using the Proposed Amgen Nivolumab Biosimilar in accordance with Amgen's proposed labeling instructions will administer the Proposed Amgen Nivolumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '917 Patent, including [redacted].

226. Amgen has known about the '917 Patent since at least as early as [redacted]. On information and belief, Amgen will encourage others to make, use, sell, offer for sale, and/or import the Proposed Amgen Nivolumab Biosimilar before the expiration of the '917 Patent. By including the instructions for use in its proposed label for the Proposed Amgen Nivolumab Biosimilar, Amgen knows and/or is willfully blind to the fact that through this intentional conduct, it will infringe one or more claims of the '917 Patent, either literally or under the doctrine of equivalents.

227. On information and belief, Amgen will actively induce direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Amgen Nivolumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar. Amgen will induce infringement of one or more claims of the '917 Patent under 35 U.S.C. § 271(b), including [redacted].

228. On information and belief, Amgen will offer to sell and sell the Proposed Amgen Nivolumab Biosimilar before the expiration of the '917 Patent. The Proposed Amgen Nivolumab Biosimilar constitutes a material part of the invention of the '917 Patent. Amgen knows and/or is willfully blind to the fact that the Proposed Amgen Nivolumab Biosimilar is especially made or especially adapted for use in an infringement of the '917 Patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Therefore, Amgen will contributorily infringe one or more claims of the '917 Patent under 35 U.S.C. § 271(c), including [redacted].

229. On information and belief, Amgen's infringement of the '917 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved

product knowing that it only received FDA approval by exploiting the invention covered by the '917 Patent.

230. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '917 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and (D).

231. Plaintiffs have been injured by Amgen's infringement and to the extent Amgen manufactures, uses, offers for sale, or sells within the United States and/or imports into the United States, the Proposed Amgen Nivolumab Biosimilar before the expiration of the '917 Patent, it will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

COUNT XIV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '917 PATENT

232. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

233. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(a), (b) and/or (c). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Amgen's threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Amgen Nivolumab Biosimilar before expiration of the '917 Patent.

234. As set forth in Count XIII, incorporated by reference in its entirety herein, Amgen's commercial manufacture, use, offer for sale, sale, and/or import into the United States, of the

Proposed Amgen Nivolumab Biosimilar before the expiration of the '917 Patent will infringe, either literally or under the doctrine of equivalents, one or more claims of the '917 Patent under 35 U.S.C. § 271(b) and/or (c), including [redacted].

235. On information and belief, Amgen seeks FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) to manufacture and sell the Proposed Amgen Nivolumab Biosimilar, a proposed biosimilar version of Plaintiffs' OPDIVO®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Amgen Nivolumab Biosimilar.

236. On information and belief, Amgen intends to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Amgen Nivolumab Biosimilar upon FDA approval of Amgen's aBLA and prior to the expiration of the '917 Patent.

237. Amgen has knowledge of or is willfully blind to the existence of the '917 Patent, including due to BMS's disclosure of the '917 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), BMS's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

238. An actual controversy has arisen and now exists between the parties concerning whether Amgen's making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar or Amgen's active inducement thereof before the expiration of the '917 Patent will infringe one or more claims of the '917 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

239. Plaintiffs are entitled to a declaratory judgment that Amgen will infringe, directly and/or indirectly, one or more claims of the '917 Patent by making, using, offering to sell, or selling within the United States the Proposed Amgen Nivolumab Biosimilar before the expiration of the '917 Patent.

240. On information and belief, Amgen's infringement of the '917 Patent is and will be willful at least because Amgen intends to make, use, offer to sell, sell, or import an FDA-approved product knowing that it only received FDA approval by exploiting the invention covered by the '917 Patent.

241. Plaintiffs will be irreparably harmed if Amgen is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the Proposed Amgen Nivolumab Biosimilar upon FDA approval, before the expiration of the '917 Patent. Plaintiffs have no adequate remedy at law and are entitled to injunctive relief at least under 35 U.S.C. § 283.

242. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Amgen Nivolumab Biosimilar before the expiration of the '917 Patent will cause injury to Plaintiffs, entitling Plaintiffs to damages under at least 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs with respect to the Patents-in-Suit respectfully request that this Court enter judgment in Plaintiffs' favor against Amgen and grant the following relief:

A. a judgment that Amgen has infringed one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(C) by submitting to FDA its aBLA for the Proposed Amgen Nivolumab Biosimilar and any amendment(s) or supplementation(s) thereto;

B. a preliminary and/or permanent injunction that enjoins Amgen and each of its officers, partners, agents, employees, attorneys, affiliates, divisions, subsidiaries, other related business entities, and those persons in active concert or participation with any of them from infringing any of the Patents-in-Suit, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use, offer for sale, sale, distribution, importation, or manufacture of which infringes any of the Patents-in-Suit, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

C. a judgment declaring that Amgen has infringed and/or will infringe directly, or contribute to or induce the infringement of, one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (c) by engaging in the manufacture, use, offer to sell, sale, distribution, or importation of the Proposed Amgen Nivolumab Biosimilar;

D. a judgment that Amgen's infringement was and will continue to be willful and an enhancement of damages;

E. a judgment compelling Amgen to pay to Plaintiffs damages adequate to compensate for Amgen's infringement, in accordance with 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284;

F. a declaration that this is an exceptional case and an award to Plaintiffs of their attorneys' fees pursuant to 35 U.S.C. § 285 and 35 U.S.C. § 271(e)(4);

G. an award of costs, pre- and post-judgment interest, and expenses in this action; and

H. such other relief as this Court may deem just, necessary, or proper.

DEMAND FOR A JURY TRIAL

Plaintiffs hereby demand a jury trial on all issues so triable.

Dated: September 8, 2026

Respectfully submitted,

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