IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LINDIS BIOTECH, GMBH	)	
	)	
Plaintiff,	)	
v.	)	Case No.
	)	
AMGEN INC.	)	
	)	
Defendant.	)	

COMPLAINT

Lindis Biotech, GmbH ("Lindis"), by and through its undersigned counsel, for its complaint against Amgen Inc. ("Amgen") states as follows:

THE PARTIES

1. Lindis is a corporate entity organized and existing under the laws of Germany. Lindis is a biotechnology company that invents, among other things, immunotherapy regimens for use in treating cancers.

2. Amgen is a corporate entity organized and existing under the laws of the State of Delaware. Amgen's principal place of business is in Thousand Oaks, California. Amgen is a global pharmaceutical company that develops, manufactures and sells drugs used to treat various illnesses, including immunotherapy drugs that are used to treat cancers.

NATURE OF THE ACTION, JURISDICTION AND VENUE

3. This is an action for patent infringement under the laws of the United States.

4. This Court has subject matter jurisdiction over the patent claims asserted in this action under 28 U.S.C. §§ 1331 and 1338(a).

5. Venue is proper under 28 U.S.C. § 1400(b) because defendant is a Delaware corporation and is deemed to reside in this District.

6. This Court has personal jurisdiction over defendant because it is a Delaware corporation, has availed itself of rights and benefits conferred by Delaware law, and has substantial and continuing contacts with Delaware.

FACTUAL BACKGROUND

The Background of the Invention

7. Lindis is the holder of several patents for the immunotherapy regimen which is the subject of this action. Dr. Horst Lindhofer is a principal at Lindis, and is one of the two inventors of the relevant patents. The other inventor is Dr. Marcus M. Heiss. Drs. Lindhofer and Heiss have both worked on the development of immunotherapy regimens for decades.

8. Two fundamental basic challenges exist in the field of immunotherapy. The first challenge lies in directing the body's cell-killing mechanisms (the immune system) to specifically attack only cancer cells and leave healthy cells largely untouched. The second challenge is modulating the body's cell-killing response so that it does not overwhelm the body and kill other healthy cells and/or cause a dangerous inflammatory response. The patents at issue here successfully address both challenges.

9. Immunotherapy is a treatment based on stimulating the body's own immune system to fight disease. In case of cancer, immunotherapy enjoys significant advantages over the use of other cancer treatments, such as chemotherapy or radiation. For one, some cancers do not respond to radiation or chemotherapy, and such therapies are largely ineffective as to those cancers, including B-cell precursor acute lymphoblastic leukemia. Chemotherapy and radiation also have their own unique risks. Both therapies kill healthy cells in addition to cancer cells, and may damage healthy tissues or organs. Another risk of chemotherapy is that the patient may later develop leukemia as a result of the chemotherapy regimen. A common side effect of

chemotherapy is a significantly impaired immune system, which renders the patient highly susceptible to infection, a condition known as neutropenia.

10. The immunotherapy regimen developed by Lindis requires administration of bispecific antibodies to the patient. As implied by its name, bispecific antibodies have a specificity for attraction to two target cells: 1) the body's own cancer killing T-cells and 2) cancer cells expressing a target antigen.

11. Bispecific antibodies bind to the target antigen on the surface of cancer cells, and also bind to T-cells. In this way, these antibodies link the cancer killing T-cells to the specific, targeted cancer cells and bring them next to each other, triggering an immune response. The immune response attacks and destroys the cancer cells through the release of cytokines. Cytokines are regulatory proteins secreted by cells of the body's immune system, and can have both cytotoxic and immunoregulatory properties.

12. Stimulation of an immune response generates the release of cytokines. However, the presence of cytokines in the body can alone trigger the release of additional cytokines. An over-secretion of cytokines is known as a "cytokine storm" and is sometimes referred to as "Cytokine Release Syndrome," which can result in serious adverse effects from the resulting cytotoxicity and inflammation. As indicated above, this condition has been an impediment to immunotherapy.

13. Glucocorticoids have long been known to be effective at treating inflammation. For example, glucocorticoids are used together with other immunosuppressive agents to help prevent the body's rejection of transplanted organs after transplantation. Skin rashes are another common ailment frequently treated by glucocorticoids. However, glucocorticoids were typically given after inflammation had already occurred in a patient, rather than preemptively.

14. The concept of administering glucocorticoids before administering immuno-stimulating antibodies was a novel idea. Traditional medical opinion taught that administration of glucocorticoids would interfere with an immunotherapy regimen, and would keep it from being effective. Before creation of the Lindis immunotherapy regimen and its testing by Drs. Lindhofer and Heiss, accepted medical treatment involved use of a glucocorticoid as a rescue medication after administration of antibodies, not before, in order to treat the ill effects of cytokines.

15. The inventors of the Lindis immunotherapy regimen proved this traditional medical opinion wrong. They discovered that administering glucocorticoids and immunostimulating antibodies surprisingly did not inhibit the effectiveness of the antibodies in eradicating targeted cancer cells. Rather, they learned that pre-administration of glucocorticoids reduced the non-specific release of cytokines and the associated inflammation – the so called "cytokine storm." The specific, targeted release of cytokines against cancer cells was not impaired. This discovery, in turn, allowed the dosage of antibodies to be significantly increased to efficacious levels while retaining a favorable safety profile.

The Invention and the European and U.S. Patents

16. The immunotherapy regimen at issue in this case is for a treatment regimen which consists of administration to the patient of at least one recombinant bi-specific immunostimulatory scFv antibody exhibiting a first specificity against the tumor antigen CD19, and a second specificity against the T-cell marker CD3. That is, the regimen uses a bi-specific antibody with a predisposition to attach itself to both to a particular type of cancer cell and also to a specific type of T-cell.

17. The other key part of the invention is administration of a glucocorticoid as premedication in order to control and limit the non-specific cytokine release. The specific glucocorticoid used is dexamethasone, sometimes in combination with another glucocorticoid. Alternatively, other glucocorticoids, including prednisone, can be used.

18. A patent application, Application No. 05738161.8, for this Lindis immunotherapy regimen was filed in the European Patent Office on September 15, 2004, naming Markus M. Heiss and Horst Lindhofer as inventors. Subsequently, the European patent issued in the name of Markus M. Heiss and Horst Lindhofer, as EP Patent No. 1 874 821 (the "Lindis European Patent").

19. Amgen challenged the Lindis European Patent and sought its revocation through its affiliate entity Amgen Research (Munich) GmbH ("Amgen Research"). An entity named "Strawman Limited" also sought revocation of the Lindis European Patent. Both of these opposition proceedings in Europe were filed on January 17, 2014. Both opposition proceedings were in the nature of an appeal of the issued patent, and sought to revoke the Lindis European Patent. These proceedings have failed to revoke the Lindis European Patent to date.

20. Amgen's opposition proceeding challenged the validity of the Lindis European Patent, which is the European counterpart of the '421 Patent. Amgen was therefore aware of the subject matter and claims of the Lindis European Patent, and the subject matter of the '421 Patent, significantly before January 17, 2014.

21. Lindis filed its first U.S. patent application for this immunotherapy regimen on April 26, 2005. The first US patent in this series, US 8,709,421, issued on April 29, 2014 ("the '421 Patent"). The patent examiner considered 9 US patent documents, 4 foreign patent

documents, and 21 other references (publications), in issuing the '421 Patent with its 15 method claims.

22. Representative claim 1 of the '421 Patent recites:

> A method for reducing the non-specific release of a cytokine in a subject which is associated with a treatment of a cancer or tumor with an antibody comprising
>
> administering to the subject at least one glucocorticoid immediately before or immediately after administering at least one trifunctional, bispecific immunostimulating antibody directed against a tumor antigen and a CD marker,
>
> which glucocorticoid reduces the non-specific release of the cytokine associated with the treatment of the cancer or tumor,
>
> wherein the CD marker is selected from the group consisting of CD2, CD3, CD4, CD5, CD6, CD8, CD28, and CD44.

23. Lindis filed a continuation patent application in this family, and a second US patent issued to Lindis in this series, US 10,071,158 ("the '158 Patent"), on September 11, 2018. The '158 Patent was the result of extensive prosecution at the US Patent and Trademark Office (the "PTO"), including consideration of 94 US patent documents, 60 foreign patent documents, and 126 other references.

24. Representative claim 1 of the '158 Patent recites:

> A method for reducing the non-specific release of at least one cytokine in a subject, which is associated with a treatment of a cancer with at least one bispecific immunostimulating antibody, comprising:
>
> administering an effective amount of at least one glucocorticoid to the subject by way of premedication on the same day and prior in time relative to the administration to the subject of the at least one bispecific immunostimulating antibody directed against a tumor antigen and a CD marker such that said effective amount of said at least one glucocorticoid reduces cytokine release caused by the administration of the least one bispecific immunostimulating antibody,
>
> wherein
>
> the at least one glucocorticoid comprises dexamethasone,

the tumor antigen is CD19, and

the CD marker is CD3.

25. Prior to issue of the '158 Patent, Lindis filed another continuation patent application, and a third US patent issued to Lindis in this series, US 10,576,149 ("the '149 Patent"), on March 3, 2020.

26. Representative claim 1 of the '149 patent recites:

A method of using a bispecific antibody for treating lymphoma in a subject, comprising:

administering dexamethasone to the subject on the same day as and prior in time to beginning administration of the bispecific antibody,

wherein the bispecific antibody is directed against tumor antigen CD19 and T-cell marker CD3.

a. The Infringing Conduct by Amgen

27. Amgen manufactures and sells an immunotherapy drug named blinatumomab, which is marketed and sold under the name Blincyto. Blincyto was approved by the U.S. Food and Drug Administration for use in treating Acute Lymphoblastic Leukemia ("ALL"), a type of cancer affecting the blood and bone marrow. Blincyto was approved in the US to treat ALL on December 3, 2014. In a press release for Blincyto, Amgen claimed that it is the "first and only Bispecific CD 19 Directed CD3 T-Cell Engager (BITE®) Immunotherapy to be Approved by the FDA."

28. Blinatumomab is a bispecific recombinant antibody that links CD19 positive cells—including malignant cells—to CD3 positive T cells. The Amgen immunotherapy regimen uses the bispecific antibody blinatumomab to link the same specific cancer antigen (CD19) to the same type of T-cell (CD3 positive) as does the Lindis regimen.

29. Amgen's prescribing information for Blincyto gives the instruction to "[p]remedicate with prednisone or equivalent dexamethasone." The instruction appears in multiple places, together with warnings for "CYTOKINE RELEASE SYNDROME" risk from the administration of Blincyto. Amgen also places a warning on the boxes and product labels for Blincyto which warn of "Cytokine Release Syndrome (CRS) and Neurological Toxicities."

30. According to its prescribing information, Amgen addresses the risk for over secretion of cytokines from administration of Blincyto through use of a glucocorticoid as a pre-medication to control the cytokine release in the exact same manner as the method which is protected by the Lindis patents. Amgen even uses the same glucocorticoids as Lindis, dexamethasone and prednisone, to control cytokine release.

b. Infringement of the '421 Patent

31. Using Blincyto as instructed by Amgen satisfies all of the elements recited in claim 1 of the '421 Patent. Using Blincyto according to the method instructed by Amgen infringes at least claim 1 of the '421 Patent.

32. The method for using Blincyto as instructed by Amgen includes reducing the non-specific release of at least one cytokine in a subject, which is associated with a treatment of a cancer with at least one bispecific immunostimulating antibody. Amgen's prescribing information for Blincyto states, under "Indications and Usage," that Blincyto "is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of … acute lymphoblastic leukemia (ALL)."

33. The method for using Blincyto as instructed by Amgen includes administering an amount of glucocorticoid that reduces cytokine release caused by administration of a bispecific immunostimulating antibody. Amgen's prescribing information warns about "Cytokine Release

Syndrome," which may be "life-threatening or fatal" in patients receiving BLINCYTO. Amgen's prescribing information further states that "[b]efore you receive BLINCYTO, you will be given a corticosteroid medicine to help reduce infusion reactions," and that "Blinatumomab mediates … production of cytolytic proteins, [and] release of inflammatory cytokines."

34. The method for using Blincyto as instructed by Amgen includes premedication with the glucocorticoid dexamethasone.

35. The method for using Blincyto, as instructed by Amgen, is for the treatment of acute lymphoblastic leukemia, a cancer, through use of an immunostimulating, bispecific antibody with a specificity for the tumor antigen CD19 and the T-cell marker CD3. Amgen's prescribing information states that "BLINCYTO is a bispecific CD19-directed CD3 T-cell engager."

36. Amgen has induced and continues to induce infringement in this District and elsewhere in the United States of the claims of the '421 Patent, including at least claim 1, by actively and successfully encouraging, instructing, enabling, and otherwise causing end users to use Blincyto in a manner that infringes the '421 Patent. As used herein, the term "end users" includes and refers to physicians who prescribe Blincyto for patients, physicians who administer Blincyto to patients, and physicians who supervise the administration of Blincyto to patients by others, such as by oncology nurses.

37. The '421 Patent issued from U.S. Patent Publication No. 2009/0191201 ("the '201 Publication"), published July 30, 2009. The disclosure of the '421 Patent is the same the disclosure of the '201 Publication. The fact that Lindis was pursuing patent protection in the US for the subject matter of the '421 Patent was therefore public knowledge at least as early as July 30, 2009.

38. By April 29, 2014, the issue date of the ‘421 patent, Amgen had knowledge of the ‘421 Patent, and knew that use of Blincyto as instructed would infringe the ‘421 Patent.

39. Amgen had knowledge of the subject matter of the ‘421 Patent from its efforts to oppose and prevent issuance of the European counterpart of the ‘421 Patent. Amgen also had knowledge of the subject matter of the ‘421 Patent as a result of direct communications between Amgen (through affiliate Amgen Research) and Lindis. Amgen Research and Lindis entered into a confidentiality agreement dated November 25, 2013. The parties then exchanged correspondence until early September 2014 about the possibility of a license from Lindis to Amgen for bispecific, trifunctional antibody patent rights. Pursuant to those communications, Amgen obtained information about the subject matter of the ‘421 Patent. The ‘421 Patent issued on April 29, 2014, during the time period when the parties were corresponding about a possible license agreement. The ‘421 Patent had already issued by the time Amgen obtained FDA approval for Blincyto on December 3, 2014.

40. Amgen would have been aware of the filing of the patent application that ultimately issued as the ‘421 Patent because this patent issued in the US a few months after Amgen filed its European opposition. Amgen, by virtue of its detailed analysis of the European claims in its European opposition, was keenly aware of Lindis’ patent prosecution activity, and that Blincyto would infringe the claims of the related ‘421 Patent.

41. Amgen has specifically intended that its end users would use Blincyto in a way that infringes the ‘421 Patent by, at a minimum, providing prescribing information to its end users about how to use Blincyto, and Amgen knew its actions would induce, have induced, and will continue to induce infringement by end users.

42. Amgen has contributed to and continues to contribute to infringement of the '421 Patent, including at least claim 1, by offering to sell and selling Blincyto to end users for use in practicing the patented method covered by the '421 Patent. Amgen's Blincyto constitutes a material part of the invention, and end users have used Blincyto in a manner that infringes one or more claims of the '421 Patent. At least as early as April 29, 2014, Amgen knew that Blincyto was specially made and/or adapted for use(s) that would infringe one or more claims of the '421 Patent and, therefore, is not a staple article or commodity of commerce suitable for any substantial non-infringing uses.

43. Amgen has willfully induced infringement of the '421 Patent and willfully contributed to infringement of one or more claims of the '421 Patent.

c. Infringement of the '158 Patent

44. Using Blincyto as instructed by Amgen satisfies all of the elements recited in claim 1 of the '158 Patent. Using Blincyto according to the method as instructed by Amgen infringes at least claim 1 of the '158 Patent.

45. The method for using Blincyto as instructed by Amgen includes reducing the non-specific release of at least one cytokine in a subject, which is associated with a treatment of a cancer with at least on bispecific immunostimulating antibody. Amgen's prescribing information for Blincyto states, under "Indications and Usage," that Blincyto "is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of … acute lymphoblastic leukemia (ALL)."

46. The method for using Blincyto as instructed by Amgen includes administering an effective amount of at least one glucocorticoid to the subject by way of premedication on the same day and prior in time relative to the administration to the subject of a bispecific

immunostimulating antibody directed against a tumor antigen and a CD marker. Amgen's prescribing information for Blincyto instructs physicians to "[p]remedicate with prednisone or equivalent dexamethasone. (2.1)." In addition, the prescribing information states "[p]remedicate with dexamethasone: For adult patients, premedicate with 20 mg dexamethasone 1 hour prior to the first dose of BLINCYTO."

47. The method for using Blincyto as instructed by Amgen includes administering an amount of glucocorticoid that reduces cytokine release caused by administration of a bispecific immunostimulating antibody. Amgen's prescribing information warns about "Cytokine Release Syndrome," which may be "life-threatening or fatal" in patients receiving BLINCYTO. Amgen's prescribing information further states that "[b]efore you receive BLINCYTO, you will be given a corticosteroid medicine to help reduce infusion reactions," and that "Blinatumomab mediates … production of cytolytic proteins, [and] release of inflammatory cytokines."

48. The method for using Blincyto as instructed by Amgen includes premedication with the glucocorticoid dexamethasone.

49. The method for using Blincyto, as instructed by Amgen, is for the treatment of acute lymphoblastic leukemia, a cancer, through use of an immunostimulating, bispecific antibody with a specificity for the tumor antigen CD19 and the T-cell marker CD3. Amgen's prescribing information states that "BLINCYTO is a bispecific CD19-directed CD3 T-cell engager."

50. Amgen has induced and continues to induce infringement in this district and elsewhere in the United States of the claims of the '158 Patent, including at least claim 1, by actively and successfully encouraging, instructing, enabling, and otherwise causing end users to use Blincyto in a manner that infringes the '158 Patent. At least as early as September 11, 2018,

Amgen had knowledge of the '158 Patent, and knew that use of Blincyto as instructed would infringe the '158 Patent.

51. The '158 Patent is part of the patent family that includes the '421 Patent, which is the earliest issued infringed patent. Both the '158 Patent and the '421 Patent are counterparts of the Lindis European patent. Amgen had knowledge of the subject matter of the related '158 Patent from its efforts to oppose and prevent issuance of the European counterpart of the '158 Patent. Amgen also had knowledge of the subject matter of the '421 Patent as a result of direct communications between Amgen Research and Lindis about the possibility of a license from Lindis for bispecific, trifunctional antibody patent rights, and later during those discussions Amgen had knowledge of the issuance of the '421 Patent on April 29, 2014. Pursuant to these communications Amgen obtained information about the '421 Patent and notice of the '158 Patent.

52. Amgen would have been aware of the filing of the patent application that ultimately issued as the '158 Patent, because this application was filed prior to the issuance of the '421 Patent. Amgen, by virtue of its detailed analysis of the European claims in its European opposition. was keenly aware of Lindis' patent prosecution activity, and that Blincyto would infringe the claims of the related '158 Patent.

53. Amgen has specifically intended that its end users use Blincyto in a way that infringes the '158 Patent by, at a minimum, providing prescribing information to its end users about how to use Blincyto, and Amgen knew its actions would induce, have induced, and will continue to induce infringement by end users.

54. Amgen has contributed to and continues to contribute to infringement of the '158 Patent, including at least claim 1, by offering to sell and selling Blincyto to end users for use in

practicing the patented method covered by the '158 Patent. Amgen's Blincyto constitutes a material part of the invention, and end users have used Blincyto in a manner that infringes one of more claims of the '158 Patent. At least as early as September 11, 2018, Amgen knew that Blincyto was specially made and/or adapted for use(s) that would infringe one or more claims of the '158 Patent and, therefore, is not a staple article or commodity of commerce suitable for any substantial non-infringing uses.

55. Amgen has willfully induced infringement of the '158 Patent and willfully contributed to infringement of one or more claims of the '158 Patent.

d. Infringement of the '149 Patent

56. Using Blincyto as instructed by Amgen satisfies all of the elements recited in claim 1 of the '149 patent. Using Blincyto according to the method instructed by Amgen infringes at least claim 1 of the '149 Patent.

57. The method for using Blincyto as instructed by Amgen includes reducing the non-specific release of at least one cytokine in a subject, which is associated with a treatment of a cancer with at least on bispecific immunostimulating antibody. Amgen's prescribing information for Blincyto states, under "Indications and Usage," that Blincyto "is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of … acute lymphoblastic leukemia (ALL)."

58. The method for using Blincyto as instructed by Amgen includes administering an amount of glucocorticoid that reduces cytokine release caused by administration of a bispecific immunostimulating antibody. Amgen's prescribing information warns about "Cytokine Release Syndrome," which may be "life-threatening or fatal" in patients receiving BLINCYTO. Amgen's prescribing information further states that "[b]efore you receive BLINCYTO, you will

be given a corticosteroid medicine to help reduce infusion reactions," and that "Blinatumomab mediates … production of cytolytic proteins, [and] release of inflammatory cytokines."

59. The method for using Blincyto as instructed by Amgen includes premedication with the glucocorticoid dexamethasone.

60. The method for using Blincyto, as instructed by Amgen, is for the treatment of acute lymphoblastic leukemia, a cancer, through use of an immunostimulating, bispecific antibody with a specificity for the tumor antigen CD19 and the T-cell marker CD3. Amgen's prescribing information states that "BLINCYTO is a bispecific CD19-directed CD3 T-cell engager."

61. Amgen has induced and continues to induce infringement in this district and elsewhere in the United States of the claims of the '149 Patent, including at least claim 1, by actively and successfully encouraging, instructing, enabling, and otherwise causing end users to use Blincyto in a manner that infringes the '149 Patent.

62. The '149 Patent is part of the patent family that includes the '158 Patent and the '421 Patent, the latter of which is the earliest issued infringed patent. The '421 Patent, the '158 Patent, and the '149 Patent are counterparts of the Lindis European Patent. At least as early as April 29, 2014, the issue date of the '421 patent, Amgen had knowledge of the related '421 Patent, and knew that use of Blincyto as instructed would infringe the '421 Patent.

63. Amgen had knowledge of the subject matter of the '149 Patent from its efforts to oppose and prevent issuance of the European counterpart of the '421 Patent. Amgen also had knowledge of the subject matter of the '421 Patent as a result of direct communications between Amgen Research and Lindis about the possibility of a license from Lindis for bispecific, trifunctional antibody patent rights, and later during those discussions Amgen had knowledge of

the issuance of the '421 Patent on April 29, 2014. Pursuant to these communications Amgen obtained information about the '421 Patent, and notice of the '158 Patent and of the '149 Patent.

64. Amgen would have been aware of the filing of the patent application that ultimately issued as the '149 Patent, because this application was filed and pending in the US well after Amgen filed its European opposition. Amgen, by virtue of its detailed analysis of the European claims in its European opposition, was keenly aware of Lindis' patent prosecution activity, and that Blincyto would infringe the claims of the related '149 Patent.

65. Amgen has specifically intended that its end users use Blincyto in a way that infringes the '149 Patent by, at a minimum, providing prescribing information to its end users about how to use Blincyto, and Amgen knew its actions would induce, have induced, and will continue to induce infringement by end users.

66. Amgen has contributed to and continues to contribute to infringement of the '149 Patent, including at least claim 1, by offering to sell and selling Blincyto to end users for use in practicing the patented method covered by the '149 Patent. Amgen's Blincyto constitutes a material part of the invention, and end users have used Blincyto in a manner that infringes one of more claims of the '149 Patent. At least as early as March 3, 2020, Amgen know that Blincyto was specially made and/or adapted for use(s) that would infringe one or more claims of the '149 Patent and, therefore, is not a staple article or commodity of commerce suitable for any substantial non-infringing uses.

67. Amgen has willfully induced infringement of the '149 Patent and willfully contributed to infringement of one or more claims of the '149 Patent.

COUNT I – INFRINGEMENT OF THE '421 PATENT

68. Plaintiff incorporates by reference the allegations of paragraphs 1-67 set forth above as if fully set forth herein.

69. Amgen is currently manufacturing, marketing, distributing and selling the immunotherapy drug Blincyto in the United States, and around the world.

70. Upon information and belief, Amgen also is manufacturing Blincyto in the United States for the purpose of selling Blincyto outside of the United States. Upon information and belief, Amgen ships Blincyto from the US to other countries for distribution, sale and use, together with the prescribing information for Blincyto. This conduct constitutes acts of infringement.

71. Using Blincyto as instructed by Amgen constitutes direct infringement of one or more claims of the '421 Patent.

72. Amgen's actions as set forth above constitute contributory and induced infringement of one or more claims of the '421 Patent.

73. Amgen's acts of infringement have caused and will continue to cause Lindis to suffer significant damages.

COUNT II – INFRINGEMENT OF THE '158 PATENT

74. Plaintiff incorporates by reference the allegations of paragraphs 1-67 set forth above as if fully set forth herein.

75. Amgen is currently manufacturing, marketing, distributing and selling the immunotherapy drug Blincyto in the United States, and around the world.

76. Upon information and belief, Amgen also is manufacturing Blincyto in the United States for the purpose of selling Blincyto outside of the United States. Upon information and

belief, Amgen ships Blincyto from the US to other countries for distribution, sale and use, together with the prescribing information for Blincyto. This conduct constitutes acts of infringement.

77. Using Blincyto as instructed by Amgen constitutes direct infringement of one or more claims of the '158 Patent.

78. Amgen's actions as set forth above constitute contributory and induced infringement of one or more claims of the '158 Patent.

79. Amgen's acts of infringement have caused and will continue to cause Lindis to suffer significant damages.

COUNT III – INFRINGEMENT OF THE '149 PATENT

80. Plaintiff incorporates by reference the allegations of paragraphs 1-67 set forth above as if fully set forth herein.

81. Amgen is currently manufacturing, marketing, distributing and selling the immunotherapy drug Blincyto in the United States, and around the world.

82. Upon information and belief, Amgen also is manufacturing Blincyto in the United States for the purpose of selling Blincyto outside of the United States. Upon information and belief, Amgen ships Blincyto from the US to other countries for distribution, sale and use, together with the prescribing information for Blincyto. This conduct constitutes acts of infringement.

83. Using Blincyto as instructed by Amgen constitutes direct infringement of one or more claims of the '149 Patent.

84. Amgen's actions as set forth above constitute contributory and induced infringement of one or more claims of the '149 Patent.

85. Amgen's acts of infringement have caused and will continue to cause Lindis to suffer significant damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

A. A judgment that Amgen has directly infringed one or more claims of the '421 Patent, the '158 Patent, and/or the '149 Patent;

B. A judgment that Amgen has contributed to infringement committed by another, or has induced infringement by another, of one or more claims of the '421 Patent, the '158 Patent, and/or the '149 Patent;

C. A judgment declaring that Amgen's infringement of the '421 Patent, the '158 Patent, and/or the '149 Patent was willful;

D. An award under 35 U.S.C. § 284 for Lindis' actual damages resulting from Amgen's infringement, together with interest and costs;

E. A declaration that this is an exceptional case under 35 U.S.C. § 285, and an accompanying award of attorneys' fees and costs;

F. Such other and further relief which the Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury for all claims and issues so triable.

SAUL EWING ARNSTEIN & LEHR LLP

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