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

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