IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

KITE PHARMA, INC. and GILEAD SCIENCES, INC., Plaintiffs, v. CABARET BIOTECH LTD., Defendant.	)	Civil Action No. 19-1193

COMPLAINT FOR DECLARATORY JUDGMENT OF INVALIDITY AND NONINFRINGEMENT OF U.S. PATENT NO. 7,741,465

Plaintiffs Kite Pharma, Inc. ("Kite") and Gilead Sciences, Inc. ("Gilead") (collectively, "Plaintiffs"), by their undersigned counsel, bring this action against Defendant Cabaret Biotech Ltd. ("Cabaret") and allege as follows:

NATURE OF THE ACTION

1. This is a civil action seeking a declaratory judgment of invalidity and noninfringement under 28 U.S.C. §§ 2201 and 2202.

PARTIES

2. Plaintiff Kite is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 2400 Broadway, Santa Monica, California 90404.

3. Plaintiff Gilead is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 333 Lakeside Drive, Foster City, California 94404. Kite is a wholly owned subsidiary of Gilead.

4. Plaintiffs have a license to practice U.S. Patent No. 7,741,465 (the "'465 patent") in the field of oncology applications.

5. On information and belief, defendant Cabaret is a company incorporated in Israel with an address at 14 Marva Street, Rehovot 7630950, Israel. According to the Patent and Trademark Office's public assignment records, Cabaret purports to be the owner of the '465 patent, entitled "Chimeric receptor genes and cells transformed therewith." After issuance, the '465 patent underwent *ex parte* reexamination. A reexamination certificate, which included amended claims, issued on August 29, 2017. The '465 patent, with its reexamination certificate, is attached hereto as **Exhibit A**.

JURISDICTION AND VENUE

6. This action arises under the Patent Laws of the United States, Title 35 of the United States Code, §§ 101 *et seq.*, and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy exists between Kite and Cabaret. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

7. Pursuant to 35 U.S.C. § 293: "Every patentee not residing in the United States may file in the Patent and Trademark Office a written designation stating the name and address of a person residing within the United States on whom may be served process or notice of proceedings affecting the patent or rights thereunder . . . . [I]f no person has been designated, the United States District Court for the Eastern District of Virginia shall have jurisdiction . . . to take any action respecting the patent or rights thereunder that it would have if the patentee were personally within the jurisdiction of the court."

8. As the purported owner and assignee of the '465 patent and an Israeli company, Cabaret is a "patentee not residing in the United States" under 35 U.S.C. § 293. On information and belief, Cabaret has not filed with the Patent and Trademark Office a "written designation stating the name and address of a person residing within the United States on whom may be served process or notice of proceedings affecting the patent or rights thereunder." 35 U.S.C. § 293. Thus, this Court has jurisdiction to take action with respect to the '465 patent.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1391(c)(3).

FACTUAL ALLEGATIONS

10. Kite is a biopharmaceutical company that was founded in 2009. In association with its strategic collaborators, including the National Cancer Institute ("NCI"), Kite has advanced an industry-leading pipeline of life-saving therapies for the treatment of hematological and solid cancers. Using a team of key innovators in the cutting-edge field of T-cell therapy, Kite and the NCI developed a chimeric antigen receptor ("CAR") for the treatment of cancer. CARs are engineered proteins that are produced by introducing DNA into a patient's cells. CARs allow the cells to recognize a specific protein (antigen) on tumor cells to target and kill those cancer cells.

11. Kite manufactures and sells axicabtagene ciloleucel ("KTE-C19" or "YESCARTA®"), a revolutionary drug therapy for the treatment of various forms of cancer. YESCARTA® is known as a "CAR-T" therapy because it involves engineering a cancer patient's own T-cells to target CD19, an antigen found on the surface of leukemias and B-cell lymphomas. CAR-T therapies effectively repurpose the body's immune system to treat the specific form of cancer in each patient. Unlike conventional cancer therapies, the field of CAR-T treatments represents a truly individualized form of treatment.

12. On October 18, 2017, Kite's YESCARTA® CAR-T therapy received FDA approval for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy. This includes diffuse large B-cell lymphoma ("DLBCL") not otherwise specified, primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. DLBCL is the most common aggressive non-Hodgkin lymphoma, accounting for three out of every five cases.

13. Beginning in or around 2011, Kite and Dr. Zelig Eshhar, one of the named inventors of the '465 patent, participated in numerous discussions relating to a potential exclusive license to Kite of certain intellectual property purported to be held in part by Dr. Eshhar at the time, including the '465 patent.

14. On information and belief, in 2013, Dr. Eshhar formed Cabaret for the purpose of holding the consolidated ownership interest in certain intellectual property rights, and thereafter assigned to Cabaret all of his rights, title and interest in the '465 patent.

15. On or around December 12, 2013, Kite, Cabaret, and Dr. Eshhar executed a license agreement pursuant to which Kite obtained a license to the '465 patent and other Licensed IP Rights in a defined field of use (which included oncology applications), in exchange for Kite's agreement to pay royalties on Licensed Products. Cabaret warranted that it had obtained from all persons or entities all right, title and interest in and to (or the exclusive control of) the '465 patent and other Licensed IP Rights.

16. Since the date of Kite's first sales of YESCARTA® in late 2017, Kite has made quarterly royalty payments to Cabaret in connection to such sales.

17. Cabaret has alleged that, without a license from Cabaret, Kite's YESCARTA® product would infringe the '465 patent.

18. Kite denies that any claim of the ’465 patent is valid and enforceable. In addition, Kite denies that any of its products or services, including YESCARTA®, infringes any valid claim of the ’465 patent. Accordingly, Kite has informed Cabaret that it is making its payment of royalties under protest and with reservation of all rights.

19. Kite is permitted to terminate the license agreement for convenience. However, Kite has a reasonable apprehension that Cabaret would sue Kite for infringement of the ’465 patent if it were to exercise its ability to terminate the agreement.

20. For example, Cabaret itself has threatened to terminate the license agreement if Kite were to stop making payments under the agreement. Kite reasonably considers Cabaret’s threats to terminate the license agreement a clear indication that it intends to enforce the ’465 patent in the absence of a license agreement.

COUNT I
(Declaratory Judgment of Invalidity of the ’465 Patent)

21. Plaintiffs repeat and reallege Paragraphs 1-20 of this Complaint.

22. An actual, justiciable, and continuing case or controversy exists between Plaintiffs and Cabaret regarding the validity of the ’465 patent. Cabaret has alleged that Kite’s YESCARTA® product infringes the ’465 patent and has indicated that it will terminate the license agreement and bring an action against Kite if Kite were to stop paying royalties. Kite denies that it is infringing the ’465 patent because the claims of the ’465 patent are invalid, and Kite cannot infringe an invalid patent.

23. The claims of the ’465 patent are invalid under one or more provisions of Title 35, United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112.

24. For example, the ’465 patent claims are invalid under 35 U.S.C. § 112 because the patent specification fails to provide a written description that conveys with reasonable clarity to a

person of ordinary skill in the art that, as of the filing date, the purported inventors of the '465 patent were in possession of the subject matter claimed therein. The '465 patent claims also are invalid under 35 U.S.C. § 112 because the specification fails to provide an enabling disclosure that teaches a person of ordinary skill in the art how to make and use the full scope of the claimed subject matter without undue experimentation. The '465 patent claims are also indefinite for failing to particularly point out and distinctly claim the subject matter of the alleged invention.

25. The '465 patent claims recite a "chimeric DNA comprising: a first DNA segment encoding a single-chain Fv domain (scFv)" and "a second DNA segment ***encoding partially or entirely*** the transmembrane and cytoplasmic, ***and optionally*** the extracellular, domains of an endogenous protein," where, upon transfection with the chimeric DNA, "transfected lymphocytes are triggered to activate and/or proliferate and have MHC non-restricted antibody-type specificity when said expressed scFv domain binds to its antigen." In addition, independent claims 21 and 30 recite "wherein said endogenous protein is ***CD28***" and "wherein said endogenous protein is ***CD8***," respectively. Furthermore, by reciting the transitional phrase "comprising," the claims are open-ended and allow for inclusion of any additional DNA segments, including but not limited to DNA encoding domains of additional proteins.

26. The claimed genus of DNA "***encoding partially or entirely . . . and optionally***" the recited domains of CD28 or CD8 encompasses a vast number of potential combinations, and the specification does not provide sufficient written description support for which of these combinations are capable of achieving the claimed function of triggering to activate and/or proliferate the cell when the scFv binds to its antigen. In addition, at the filing date of the '465 patent it would have required undue experimentation for a person of ordinary skill in the art to

determine which of the possible combinations of partial, entire, and/or optional domains of CD28 or CD8 could achieve the claimed function.

27. Moreover, the specification does not disclose, let alone sufficiently describe or enable, the claimed genus of chimeric DNA containing further DNA segments (*e.g.*, domains of additional proteins) beyond those recited in the claims.

28. Thus, the specification fails to demonstrate that the applicant possessed or enabled species sufficient to support the claims to the functionally-defined genus, or that the claims had practical utility as of the filing date of the '465 patent.

29. The '465 patent claims also recite "which chimeric DNA, upon transfection to lymphocytes, expresses ***both said scFv domain and said domains*** of said endogenous protein in one single, continuous chain ***on the surface*** of the transfected lymphocytes." These claims, which purport literally to require that all of the domains be expressed on the surface of the cell, lack utility for inoperability, lack written description support, are not enabled, and are indefinite.

30. To the extent the patent owner argues that the claims are supported by the specification, the claims would have been obvious under 35 U.S.C. § 103 because the specification does not provide sufficiently detailed teachings about the broad, functionally claimed chimeric DNA beyond what would have been obvious over the prior art. *See, e.g.*, '465 patent prosecution history, Declaration of Ronald Levy (Jan. 20, 2012) (arguing unpredictability of the claimed DNA construct to distinguish over the prior art).

31. Plaintiffs are therefore entitled to a judicial declaration that the claims of the '465 patent are invalid.

COUNT II

(Declaratory Judgment of Noninfringement of the '465 Patent)

32. Plaintiffs repeat and reallege Paragraphs 1- 31 of this Complaint.

33. An actual, justiciable, and continuing case or controversy exists between Plaintiffs and Cabaret regarding the infringement of the '465 patent. Cabaret has alleged that Kite's YESCARTA® product infringes the '465 patent and has indicated that it will terminate the license agreement and bring an action against Kite if Kite were to stop paying royalties. Kite denies that it is infringing the '465 patent because the claims of the '465 patent are invalid, and Kite cannot infringe an invalid patent.

34. The manufacture, use, sale, offer for sale, or importation of Kite's YESCARTA® product has not infringed, and does not infringe, either directly or indirectly, any valid claim of the '465 patent, either literally or under the doctrine of equivalents.

35. For example, as set forth above, the claims of the '465 patent are invalid under one or more provisions of Title 35, United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112.

36. Plaintiffs are therefore entitled to a judicial declaration that the YESCARTA® product does not infringe any valid claim of the '465 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment:

A. Declaring that the claims of the '465 patent are invalid for failure to satisfy one or more of the conditions for patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112;

B. Declaring that the manufacture, use, sale, offer for sale, or importation of the YESCARTA® product has not infringed, and does not infringe, either directly or indirectly, any valid claim of the '465 patent, either literally or under the doctrine of equivalents; and

C. Awarding any other remedy or relief to which Plaintiffs may be entitled and which is deemed appropriate by the Court.

Dated: September 16, 2019

Respectfully Submitted,

/s/ Charles Molster

Charles B. Molster, III (VSB 23613)
THE LAW OFFICES OF CHARLES B. MOLSTER, III PLLC
2141 Wisconsin Avenue, N.W., Suite M
Washington, D.C. 20007
T: (703) 346-1505
Email: cmolster@molsterlaw.com

David B. Bassett (*pro hoc vice* forthcoming)
Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
T: (212) 937-7518
F: (212) 230-8888
David.Bassett@wilmerhale.com

Vinita Ferrera (*pro hoc vice* forthcoming)
Emily R. Whelan (*pro hoc vice* forthcoming)
Shirley X. Li Cantin (*pro hoc vice* forthcoming)
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
T: (617) 526-6000
F: (617) 526-5000
Vinita.Ferrera@wilmerhale.com
Emily.Whelan@wilmerhale.com
Shirley.Cantin@wilmerhale.com

Counsel for Plaintiffs KITE PHARMA, INC. and GILEAD SCIENCES, INC.