IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| CABARET BIOTECH LTD., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | C.A. No. 19-_____ |
| | ) | |
| KITE PHARMA, INC. and GILEAD SCIENCES, INC., | ) | JURY TRIAL DEMANDED |
| | ) | |
| | ) | |
| Defendant. | ) | |

**PLAINTIFF CABARET BIOTECH LTD.'S COMPLAINT FOR A DECLARATORY JUDGMENT THAT THE '465 PATENT IS NOT INVALID**

Plaintiff Cabaret Biotech Ltd. ("Cabaret"), by its counsel, alleges against Defendants Kite Pharma, Inc. ("Kite") and Gilead Sciences, Inc. ("Gilead") (together, "Defendants") as follows:

## NATURE OF THE ACTION

1. This is an action to end a needless dispute about patent royalties. Kite is the exclusive licensee in oncology applications of Cabaret's U.S. Patent Number 7,741,465 (the "'465 Patent"), and Kite and its parent Gilead have paid royalties to Cabaret under a license agreement to the '465 Patent because of their sale of their cancer treatment YESCARTA® (axicabtagene ciloleucel). Kite and Gilead have publicly trumpeted that the '465 Patent protects YESCARTA® and their other CAR-T therapies in development, and have paid royalties to Cabaret under their license. Now that YESCARTA® sales are increasing, however, Kite and Gilead have balked at the fees they agreed to pay. They have threatened to commence a declaratory judgment action against Cabaret for a declaration that the '465 Patent is invalid. This is Cabaret's attempt to bring that charade to a quick resolution, with a declaration that the '465

Patent is not invalid and, but for the parties' license, would be infringed by making, using, selling, offering for sale, or importing YESCARTA®.

**PARTIES**

2. Plaintiff Cabaret is a company incorporated in Israel with an address at 14 Marva Street, Rehovot 7630950, Israel. Cabaret is a biotechnology company in the field of cancer immunotherapy. The founder of Cabaret, Dr. Zelig Eshhar, pioneered the groundbreaking cell therapy research that led to the use of YESCARTA® for treating non-Hodgkin's lymphoma.

3. Upon information and belief, Defendant Kite is a corporation existing under the laws of the State of Delaware, with its principal place of business at 2400 Broadway, Santa Monica, CA 90404.

4. Upon information and belief, Defendant Gilead is a corporation existing under the laws of the State of Delaware, with its principal place of business at 333 Lakeside Drive, Foster City, CA 94404.

5. Upon information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, import, market, distribute, and sell biopharmaceutical products in this judicial District and throughout the United States.

**JURISDICTION AND VENUE**

6. This action arises under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and the Patent Laws of the United States, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, and 271. This Court has jurisdiction under 28 U.S.C. §§ 1331, 1338, and 2201.

7. There is an actual controversy between Cabaret and Defendants over the validity and infringement of the '465 Patent, because Defendants have protested their royalty payment

obligations since October 2018 and asserted in communications their belief that the ’465 Patent is invalid and therefore cannot be infringed.

8. This Court has personal jurisdiction over Kite because it is a Delaware corporation and, upon information and belief, has conducted business in this District, has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with Delaware.

9. This Court has personal jurisdiction over Gilead because it is a Delaware corporation and, upon information and belief, has conducted business in this District, has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with Delaware.

10. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c).

## BACKGROUND

11. This case is about a seminal patent in cancer immunotherapy. The ’465 Patent teaches how a patient’s immune cells can be programmed to proliferate into a cellular army capable of seeking out and destroying cancer cells within the patient’s body. This patent was thoroughly examined by the United States Patent and Trademark Office (“USPTO”) and then survived two additional third-party-initiated *ex parte* reexaminations.

12. YESCARTA® is a therapy for non-Hodgkin’s lymphoma approved by the Food and Drug Administration (“FDA”) and offered by Defendants to patients since 2017.

13. YESCARTA® embodies the invention disclosed in the ’465 Patent.

14. If the claims of the ’465 Patent are valid, YESCARTA® practices one or more of those claims.

15. This case is also about a precipitous about-face in Defendants' respect for Cabaret's patent rights. Defendants aggressively sought exclusive field-of-use rights to the '465 Patent for oncology applications.

16. Defendants have openly touted the '465 Parent as "protect[ing] the [YESCARTA®] franchise" and as "Kite's Seminal Eshhar CAR-T Patent."

17. In so doing, Defendants informed would-be and actual shareholders that the '465 Patent protects YESCARTA®, an assertion that would be true only if the '465 Patent were valid.

18. Recently, Defendants urged Cabaret to seek a patent term extension for the '465 Patent for the specific purpose of prolonging exclusive protection of YESCARTA®. Kite's Vice President for Intellectual Property Law and Litigation, Scott N. Bernstein, authorized Cabaret to seek a patent term extension of the '465 Patent, and to rely in that application on activities that Kite had taken before FDA to obtain approval of YESCARTA®.

19. Now, however, Defendants have threatened to bring an action for a declaratory judgment that the "[s]eminal" patent that they license and that they touted to shareholders and sought to help extend at the Patent Office is, supposedly, invalid. They do this to avoid paying royalties they are bound by contract to pay.

**A. CAR-T Technology**

20. In the late 1980s, Dr. Zelig Eshhar and his colleagues at the Weizmann Institute of Science in Israel pioneered a groundbreaking cancer treatment. Arie Belldegrun, former Chairman, President, and Chief Executive Officer ("CEO") of Kite, readily acknowledged "the pioneering role of Dr. Zelig Eshhar in developing CAR-T technology."

21. Dr. Eshhar and his team envisioned using the T cells of a patient's own immune system to fight cancer, by equipping those T cells with a hybrid or chimeric antigen receptor T

cell ("CAR-T"). Dr. Eshhar won numerous awards including the Israel Prize and was nominated for the Nobel Prize for this work in 2017.

22. Beginning in 2011, Aya Jakobovits, then President and CEO of Kite, approached Dr. Eshhar to seek his involvement in Kite. Both parties participated in numerous and extensive discussions relating to Dr. Eshhar's patents on CAR-T technology, including the '465 Patent, leading to an exclusive field-of-use-license to the '465 Patent to Kite in 2013.

**B. The License Agreement Between Cabaret and Kite**

23. In December 2013, Dr. Eshhar assigned all of his rights and obligations in the '465 Patent to Cabaret.

24. On December 12, 2013, Cabaret and Dr. Eshhar entered into a License Agreement with Kite to commercialize Dr. Eshhar's cancer therapy in Kite's products. Thereafter, Kite became an exclusive licensee of Dr. Eshhar's patents, including the '465 Patent, in the field of oncology applications.

25. Kite agreed to pay Cabaret an annual licensing fee and royalty payments based on the success of its licensed drugs. At the time, Kite was developing axicabtagene ciloleucel ("KTE-C19" or YESCARTA®) as a potential cancer drug that targets specific leukemia and B-cell lymphomas.

**C. YESCARTA®**

26. The '465 Patent formed the basis for the drug KTE-C19, now known as YESCARTA®.

27. Dr. Eshhar was actively involved in the drug's development.

28. YESCARTA® is engineered to enable a cancer patient's T cells to target specific leukemias and B-cell lymphomas expressing the antigen CD19.

29. In December 2014, Kite submitted to FDA its investigational new drug application ("IND") investigating KTE-C19 in aggressive B-cell lymphomas. Kite submitted to FDA the first module of a Biologics License Application ("BLA") in December 2012, and the final module was submitted March 2017.

30. On October 18, 2017, FDA approved KTE-C19 as a "CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy." Kite markets KTE-C19 under the name YESCARTA®.

31. In 2017, Gilead acquired Kite for $11.9 billion. From December 2013 until October 2018, Kite paid the licensing fees, royalty payments, and milestone payments to Cabaret without protest. Now, that is no longer the case.

**D. YESCARTA® Embodies The '465 Patent**

32. In December 2017, Cabaret applied for a patent term extension for the '465 Patent related to YESCARTA® in accordance with its obligations detailed in the License Agreement. In this application, Cabaret stated that it was "authorized to rely on activities undertaken by IND and BLA applicants before the FDA for obtaining marketing approval for the approved product, YESCARTA®, for purposes of obtaining patent term extension of U.S. Patent No. 7,741,465."

33. Scott Bernstein, Vice President of Intellectual Property Law and Litigation from Kite, signed the authorization letter for Cabaret to rely on activities of Kite Pharma for the purposes of obtaining a patent term extension of the '465 Patent for 1498 more days of exclusivity for YESCARTA®.

34. The patent term extension application also provided a table "to show how at least one of the [] listed claims of the '465 patent claims the approved product."

35. In its February 2019 SEC filings, Gilead reported that the patent protection for YESCARTA® was until 2027 with a pending patent term extension. The ’465 Patent’s expiration date without any extensions is 2027. With the requested patent term extension, if granted, YESCARTA® will be protected until 2031.

36. Defendants know that their YESCARTA® product embodies the ’465 Patent through their representations to the USPTO and SEC as well as their maintenance of the ’465 Patent and defense of the patent in two reexamination proceedings in 2016 and 2017.

**E. Gilead’s Threats of Litigation**

37. Upon information and belief, in July 2018, Gilead underwent a corporate restructuring. Its longtime chairman, chief executive officer, and chief medical officer stepped down in late 2018.

38. In August 2018, the European Medical Agency (“EMA”) approved YESCARTA®, triggering additional royalty payments to Cabaret.

39. In October of 2018, Gilead told Cabaret that it supposedly had serious concerns regarding the License Agreement.

40. On August 20, 2019, Gilead reiterated its allegations and threatened Cabaret with an imminent lawsuit for declaratory judgment of invalidity and noninfringement of the ’465 Patent, even going so far as to provide a draft complaint for such an action in the Eastern District of Virginia. As a result, Cabaret has a reasonable apprehension that Defendants would sue Cabaret to invalidate the ’465 Patent.

## THE PATENT-IN-SUIT

41. Cabaret is the owner of all rights, title, and interest in U.S. Patent No. 7,741,465.

42. Kite is the exclusive licensee of the ’465 Patent in the field of oncology applications.

43. The ’465 Patent is titled “Chimeric Receptor Genes and Cells Transformed Therewith.” The inventors of the ’465 Patent are Zelig Eshhar, Daniel Schindler, Tova Waks, and Gideon Gross.

44. The ’465 Patent was duly and legally issued on June 22, 2010, by the USPTO after the USPTO determined the invention in the ’465 Patent met the patentability requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

45. The ’465 Patent underwent *ex parte* reexamination, and the USPTO issued a reexamination certificate on August 29, 2017. A true and correct copy of the ’465 Patent and its reexamination certificate is attached to this Complaint as Exhibit 1.

46. The ’465 Patent is directed to chimeric DNA molecules engineered to function at one end with antibody specificity and at the other end, as a signaling T cell receptor, to expression vectors comprising said chimeric DNA molecules, and to lymphocytes transformed with said expression vectors. These transformed lymphocytes are useful in therapeutic treatment methods, including cancer therapy.

**COUNT I**
**DECLARATORY JUDGMENT THAT THE ’465 PATENT IS NOT INVALID**

47. Cabaret restates, realleges, and incorporates by reference the allegations made in Paragraphs 1 through 46 of its Complaint and further alleges:

48. An actual controversy exists between Plaintiff Cabaret and Defendants Kite and Gilead regarding the validity of the ’465 Patent and whether it meets the requirements for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112 because Defendants have threatened suit to have the ’465 Patent declared invalid.

49. The ’465 Patent meets the patent-eligibility requirement set forth in 35 U.S.C. § 101.

50. The ’465 Patent meets the novelty requirement set forth in 35 U.S.C. § 102.

51. The ’465 Patent meets the obviousness requirement set forth in 35 U.S.C.§ 103.

52. The ’465 Patent meets the written description and enablement requirements set forth in 35 U.S.C. § 112(a).

53. The ’465 Patent meets the definiteness requirement set forth in 35 U.S.C. § 112(b).

54. Pursuant to the Declaratory Judgment Act, Cabaret requests a declaration that the claims of the ’465 Patent are not invalid under the requirements for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112.

**COUNT II**
**DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’465 PATENT**

55. Cabaret restates, realleges, and incorporates by reference the allegations made in Paragraphs 1 through 54 of its Complaint and further alleges:

56. An actual controversy exists between Plaintiff Cabaret and Defendants regarding whether YESCARTA® infringes the ’465 Patent.

57. In a letter dated August 20, 2019, Defendants through their counsel expressed their intent to file a complaint for declaratory judgment of invalidity and noninfringement of the ’465 Patent if the parties did not reach a resolution.

58. Cabaret is therefore apprehensive that Defendants will terminate the License Agreement or breach the License Agreement in a way that would cause its termination.

59. But for the License Agreement, Defendants infringe the ’465 Patent by their manufacture, use, sale, offer to sale, and importation of YESCARTA®.

60. Cabaret requests a declaration that but for the License Agreement, Defendants infringe the '465 Patent by their manufacture, use, sale, offer to sale, and importation of YESCARTA®.

## JURY DEMAND

61. Cabaret hereby demands a jury trial on any and all issues so triable.

## PRAYER FOR RELIEF

WHEREFORE, Cabaret respectfully requests that this Court:

(a) Enter judgment in favor of Cabaret that U.S. Patent No. 7,741,465 is not invalid;

(b) Enter judgment in favor of Cabaret that but for the License Agreement, YESCARTA® infringes U.S. Patent No 7,741,465;

(c) Find that this action is an "exceptional" case within the meaning of 35 U.S.C. § 285 and award Cabaret its reasonable attorneys' fees and expenses; and

(d) Grant Cabaret any other relief that the Court may deem just and proper.

*/s/ Karen E. Keller*

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
kkeller@shawkeller.com
*Attorneys for Plaintiff*

OF COUNSEL:
Eric A. Stone
Jennifer Gordon
Naz E. Wehrli
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Henry Lebowitz
Michael Schaper
DEBEVOISE & PLIMPTON LLP
919 Third Avenue
New York, NY 10022
(212) 909-6000

Dated: September 16, 2019