IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DAIICHI SANKYO, INC., DAIICHI SANKYO COMPANY, LIMITED, and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. SEAGEN INC., Defendant.	)	C. A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR DECLARATORY JUDGMENT OF NON-INFRINGEMENT

Plaintiffs Daiichi Sankyo, Inc., Daiichi Sankyo Company, Limited, and AstraZeneca Pharmaceuticals LP (collectively, "Plaintiffs") by their attorneys, for their Complaint against Defendant Seagen Inc., f/k/a Seattle Genetics, Inc., allege as follows:

I. THE PARTIES

1. Daiichi Sankyo, Inc. ("DSI") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Basking Ridge, New Jersey. DSI is in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to treat serious diseases, including cancer.

2. Daiichi Sankyo Company, Limited ("DSC") is a corporation organized and existing under the laws of Japan, having a principal place of business in Tokyo, Japan. DSC is in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to treat serious diseases, including cancer.

3. AstraZeneca Pharmaceuticals LP ("AstraZeneca") is a limited partnership organized and existing under the laws of the State of Delaware, with its corporate headquarters in

Wilmington, Delaware. AstraZeneca is in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to treat serious diseases, including cancer.

4. On information and belief, Seagen Inc. ("SGI") is a corporation organized and existing under the laws of Delaware, with its principal place of business in Bothell, Washington.

II. NATURE OF THE ACTION

5. This is a civil action for declaratory relief pursuant to Federal Rule of Civil Procedure 57, the patent laws of the United States, including Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201. DSI, DSC, and AstraZeneca seek a declaration that the importation into the United States, manufacture, use, offer for sale, or sale of ENHERTU®, an FDA-approved pharmaceutical for the treatment of adult patients suffering from certain breast cancers, does not infringe United States Patent No. 10,808,039 ("the '039 patent") and that Plaintiffs do not induce infringement of, or contribute to the infringement of, the '039 patent.

6. This action arises out of SGI's allegations that ENHERTU® infringes the '039 patent.

7. A related action between SGI and Plaintiff DSC concerning intellectual property rights relating to ENHERTU® was previously filed by DSC and is pending in this Court.[1] In addition, SGI's claim to intellectual property rights relating to ENHERTU® is subject to an arbitration initiated by SGI against DSC.[2]

[1] C.A. No. 19-2087-LPS (filed Nov. 4, 2019).
[2] AAA Case Number 01-19-0004-0115.

III. JURISDICTION AND VENUE

A. Subject-Matter Jurisdiction

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

9. As described in more detail below, an immediate, real, and justiciable controversy exists between Plaintiffs and SGI as to whether Plaintiffs are infringing or have infringed the '039 patent.

B. Personal Jurisdiction

10. This Court has general personal jurisdiction over SGI because SGI is a Delaware corporation and thus resides at and is at home in the District of Delaware. Further, on information and belief, SGI has availed itself of the rights and benefits of Delaware law, and has engaged in systematic and continuous contacts with the State of Delaware.

C. Venue

11. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c).

IV. BACKGROUND

A. ENHERTU®

12. ENHERTU® is a type of biologic product known in the pharmaceutical industry as an antibody-drug conjugate ("ADC"). ENHERTU® is commonly referred to by other names, including DS-8201, fam-trastuzumab deruxtecan, and fam-trastuzumab deruxtecan-nxki.

13. ENHERTU® was approved by the United States Food and Drug Administration ("FDA") on an accelerated basis on December 20, 2019 for the treatment of unresectable or metastatic HER2-positive breast cancer in patients who have received two or more prior anti-HER2-based regimens in the metastatic setting. DSI submitted a Biologics License

Application pursuant to which the FDA granted ENHERTU®'s accelerated approval, thus becoming the only company licensed by the FDA to introduce or deliver for introduction into interstate commerce ENHERTU®. Consistent with this regulatory approval, of the Plaintiffs, ENHERTU® is offered for sale and sold in the United States only by DSI.

14. Plaintiff DSC manufactures ENHERTU®. ENHERTU® is not manufactured in the United States.

15. DSI purchases bulk vials of ENHERTU® from DSC and sells packaged ENHERTU® only to a select network of specialty distributors and pharmacies, who in turn sell ENHERTU® to customers in the United States.

16. ENHERTU® is marketed in the United States collaboratively by Plaintiffs DSI and AstraZeneca. Both DSI and AstraZeneca employ sales representatives who build awareness of ENHERTU® in the medical community. Both DSI and AstraZeneca publish resources to inform patients about taking ENHERTU®, for example, the ENHERTU 4U website.[3] Both DSI and AstraZeneca employ medical science liaisons who educate the medical community about ENHERTU®.

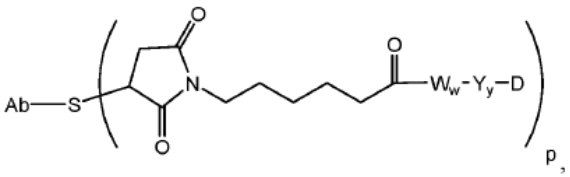
B. The '039 Patent

17. On information and belief, on October 20, 2020, the '039 patent entitled "Monomethylvaline Compounds Capable of Conjugation to Ligands" issued to Svetlana O. Doronina, Peter D. Senter, Brian E. Toki, and Toni Beth Kline. Based upon allegations made by Defendant SGI in a complaint filed in the United States District Court for the Eastern District of

[3] https://www.enhertu4u.com/patient.html

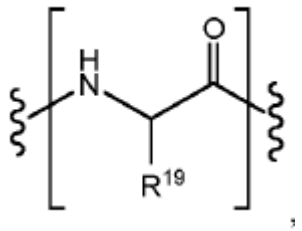
Texas, SGI is the sole owner of the '039 patent and holds the sole right to seek enforcement of that patent.[4] A true and correct copy of the '039 patent is attached to this Complaint as Exhibit A.

18. The '039 patent claims, among other things, certain ADCs, having the formula:



or a pharmaceutically acceptable salt thereof, wherein:

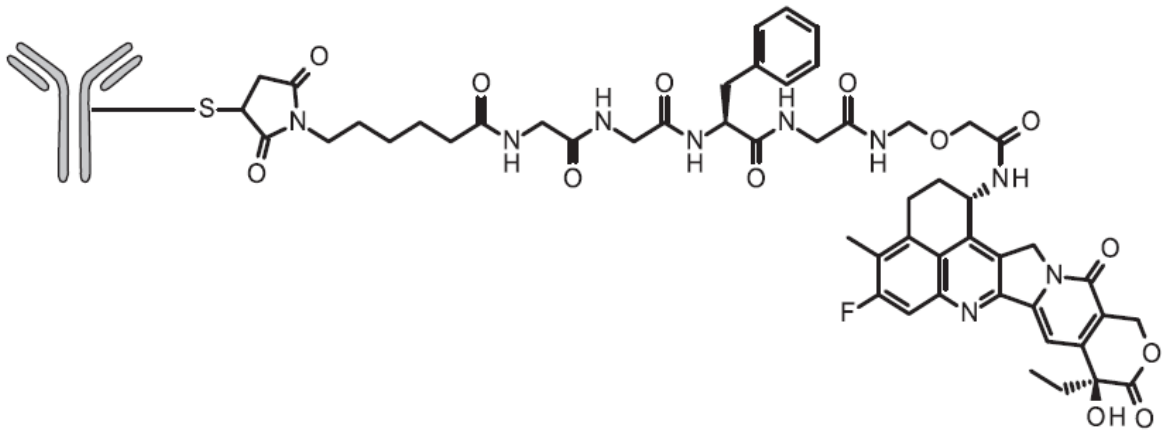
Ab is an antibody, S is sulfur, each -W_w- unit is a tetrapeptide; wherein each -W- unit is independently an Amino Acid unit having the formula denoted below in the square bracket:



wherein R^{19} is hydrogen or benzyl, Y is a Spacer unit, y is 0, 1, or 2, D is a drug moiety, and p ranges from 1 to about 20, wherein the S is a sulfur atom on a cysteine residue of the antibody, and wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate.

[4] Case 2:20-cv-00337 (E.D. Tex.), D.I. 1 ¶ 14 ("Texas Complaint").

19. ENHERTU®, on the other hand, is depicted in the figure below.



This figure is one way to illustrate the chemical structure of ENHERTU®. For simplicity, the figure does not show the chemical structure of the antibody in ENHERTU®, which is trastuzumab, and does not show that approximately eight molecules of drug are attached to each antibody molecule. S in the figure is a sulfur atom at a cysteine residue of the antibody.

20. ENHERTU® is a HER2-directed ADC. ENHERTU® is composed of trastuzumab (an anti-HER2 antibody) attached to a topoisomerase I inhibitor compound through a cleavable linker. Following binding to HER2 on tumor cells, ENHERTU® undergoes internalization and intracellular linker cleavage by lysosomal enzymes, releasing a membrane-permeable topoisomerase I inhibitor compound known today as DXd, which causes DNA damage and apoptotic cell death. Approximately, eight molecules of drug are attached to each antibody molecule.

C. SGI's Allegation that ENHERTU® Infringes the '039 Patent

21. SGI has asserted the '039 patent in the United States District Court for the Eastern District of Texas against Plaintiff DSC. In that action, SGI does not name either of Plaintiff DSI or Plaintiff AstraZeneca as a party.

22. SGI's Texas Complaint alleges, among other things, that DSC's "subsidiaries and contractual business partners have operated as agents of DSC . . . Through these agents, DSC has conducted business and committed acts of infringement in the United States, Texas, and this district." Texas Complaint ¶ 11. The conduct accused of infringement in SGI's Texas Complaint is described at paragraphs 17–20 and the product charted by SGI for purposes of alleging infringement is DS-8201, i.e., ENHERTU®.

23. SGI's infringement allegations extend beyond ENHERTU®. SGI alleges that various ADCs in clinical development, U3-1402, DS-1062, DS-7300, and DS-6157, "all use the same linker as DS-8201." Texas Complaint ¶ 20. SGI's count alleging infringement refers to infringement based on "making, using, selling, offering to sell, and importing into the United States ADC Products, *including* DS-8201[.]" Texas Complaint ¶ 22 (emphasis added).

24. No entity has been licensed by FDA to sell any of U3-1402, DS-1062, DS-7300, or DS-6157.

25. Based on the foregoing allegations made by SGI in the Texas Complaint, there is a substantial controversy of sufficient immediacy and reality between the Parties as to whether Plaintiffs are infringing or have infringed the '039 patent.

COUNT 1: DECLARATORY JUDGMENT OF NON-INFRINGEMENT

26. Paragraphs 1–25 are incorporated by reference as if fully set forth herein.

27. As set forth above, SGI has asserted the '039 patent against the making, using, selling, offering to sell, and importing into the United States of ENHERTU®, the product sold by Plaintiff DSI and co-marketed by Plaintiff AstraZeneca. Plaintiffs, however, have not infringed and do not infringe any claim of the '039 patent, either directly or indirectly, literally or under the

doctrine of equivalents. Among other reasons, ENHERTU® (depicted and described above) does not fall within the scope of any claim of the '039 patent.

28. As set forth above, SGI also has asserted the '039 patent against various ADCs that have not been approved for marketing by the FDA. Plaintiffs have not infringed and do not infringe any claim of the '039 patent, either directly or indirectly, literally or under the doctrine of equivalents, with respect to these ADCs. Among other reasons, Plaintiffs do not infringe the '039 patent with respect to these ADCs because any conduct involving these ADCs is protected from infringement by statute, 35 U.S.C. § 271(e)(1).

29. SGI's litigious history, the infringement allegations by SGI against DSC, and Plaintiffs' denial of infringement have created a substantial, immediate, and real controversy between the Parties as to the non-infringement of the '039 patent. A valid and justiciable controversy has arisen and exists between SGI and Plaintiffs within the meaning of 28 U.S.C. § 2201.

30. Plaintiffs seek a declaration that they have not and do not infringe any claim of the '039 patent and that they are not otherwise liable for infringement, and SGI is entitled to no relief.

31. On information and belief, absent a declaration of non-infringement of the '039 patent, SGI will assert the '039 patent against Plaintiffs and will in this way cause damage to Plaintiffs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor against SGI and grant the following relief:

A. Judgment that Plaintiffs have not and do not infringe any claim of the '039 patent;

B. Judgment entered in favor of Plaintiffs and against SGI on Plaintiffs' claim;

C. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

D. An award of Plaintiffs' costs and expenses in this action; and

E. Such further relief as this court may deem just and proper.

JURY DEMAND

Plaintiffs, by and through their undersigned counsel, hereby demand, pursuant to Fed. R. Civ. P. 38, a trial by jury on all claims so triable in this action.

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