UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN INC., Plaintiff, v. DAIICHI SANKYO CO., LTD., Defendant.	CIVIL ACTION NO. **COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Seagen Inc. ("Seagen") complains and alleges as follows against Defendant Daiichi Sankyo Co., Ltd. ("DSC").

THE NATURE OF THE ACTION

1. Seagen brings this action to protect its proprietary technology enabling the delivery of chemotherapeutic drugs directly to cancer cells. When Seagen began developing this technology, most chemotherapeutic drugs for cancer were not targeted, resulting in the delivery of treatments throughout the patient's body and causing significant adverse side effects. Since then, Seagen's pioneering innovations in the field of antibody-drug conjugates (ADCs), a type of therapy that directly targets chemotherapeutic drugs to cancer cells, have helped establish ADCs as an important pillar of cancer therapy. Seagen's ADC technology is the result of decades of research and development effort by Seagen's scientists and hundreds of millions of dollars of investment. Seagen's transformative innovations have maintained Seagen's leadership status even as other companies have entered the field, and Seagen's innovations are embodied in more approved ADC therapies than those of any other company. DSC is a new entrant in the ADC field, and it infringes Seagen's United States Patent No. 10,808,039 (the "'039 patent"). DSC has already booked

tens of millions of dollars in sales of an infringing product, and appears intent upon expanding its infringing activities.

2. ADCs are specialized cancer treatments that use a "linker" to attach (or "conjugate") chemotherapeutic drugs to an antibody. The antibody in an ADC targets receptors on the surface of a cancer cell. The targeted cell then internalizes the ADC, releasing the ADC's chemotherapeutic drug to kill the cancer cell. This technology is cutting edge. To date, only nine ADCs have been approved by the FDA.

3. After its founding in 1998, Seagen pioneered a class of linkers with a cleavable amino acid unit for use in ADCs. This class is often referred to as "protease cleavable" because specialized enzymes within the cell called "proteases" cleave the bonds of the amino acid unit to release the drug. After more than ten years of fundamental research, Seagen received FDA approval for its first ADC employing this technology, ADCETRIS®, in 2011. Of the nine, now-approved ADCs, more use Seagen's linker technologies than any other.

4. All of the products in DSC's ADC pipeline also use a protease cleavable linker that is covered by the claims of Seagen's '039 patent. The currently accused product is DSC's DS-8201 ADC (now branded ENHERTU®), the first ADC in DSC's pipeline to be FDA approved. On January 6, 2020, DSC announced DS-8201's availability in the United States, noting that DSC would be solely responsible for manufacturing and supply. DSC causes DS-8201 to be imported into, offered for sale, sold, and used in the United States. DSC also ultimately books the United States sales of DS-8201, and these sales have totaled more than $70 million to date.

5. DSC may seek FDA approval for its other pipeline products covered by the claims of the '039 patent, including U3-1402, DS-1062, DS-7300, DS-6157, in the near

future. Seagen intends by this Complaint that these products also be accused products should Seagen learn during the course of discovery that DSC has engaged in infringing activities as to these products.

THE PARTIES

6. Plaintiff Seagen is a biotechnology company formerly known as Seattle Genetics, Inc. Seagen develops and commercializes transformative therapies targeting cancer. Seagen is headquartered in Bothell, Washington, and incorporated under the laws of Delaware.

7. Defendant DSC is a Japanese pharmaceutical corporation having its principal place of business at 3-5-1, Nihonbashi Honchō, Chūo-ku, Tokyo 103-8426, Japan.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. 1331 and under 28 U.S.C. § 1400(b).

9. This Court has personal jurisdiction over DSC, as DSC conducts business and has committed acts of patent infringement, induced acts of patent infringement, and contributed to patent infringement in the United States, the State of Texas, and the Eastern District of Texas.

10. DSC also has sufficient minimum contacts with the forum as a result of business it conducts within Texas and this district. DSC—directly or through subsidiaries or intermediaries including distributors, retailers, and others—offers for sale, and sells (as well distributes, advertises, and markets) products, including DS-8201, that infringe the '039 patent throughout Texas and this district. For example, DSC owns the U.S. registration for the ENHERTU® trademark for DS-8201. DSC acts in concert with others to purposefully and voluntarily place the infringing products in a distribution chain that

foreseeably leads to the infringing products being offered for sale, sold, and used in Texas and this district as part of the ordinary stream of commerce. DSC has done so with the expectation that these infringing products have been, and will continue to be, purchased in Texas and this district and that such purchases be part of the ordinary stream of commerce.

11. In addition, DSC's subsidiaries and contractual business partners have operated as agents of DSC as parts of a business group in which executives of DSC make important operational decisions regarding the manufacture, importation, offer for sale, sale, and intended use of the infringing products, including DS-8201. Through these agents, DSC has conducted business and committed acts of infringement in the United States, Texas, and this district.

12. Alternatively, to the extent that DSC is not subject to jurisdiction in any state court of general jurisdiction, this Court may exercise jurisdiction over DSC pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Seagen's claims arise under federal law; and (b) DSC has sufficient contacts with the United States as a whole, including but not limited to manufacturing the infringing products and importing them into the United States and offering for sale, selling, and causing them to be sold in the United States, such that this Court's exercise of jurisdiction over DSC satisfies due process.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) and 28 U.S.C. § 1391(c). DSC is a foreign corporation and may be sued in this district. Venue is further proper because DSC has committed acts of infringement in this district, and has purposely transacted business involving the infringing products in this district.

PATENT-IN-SUIT – U.S. PATENT NO. 10,808,039

14. Seagen is the sole owner of the '039 patent and holds the sole right to enforce it. The '039 patent claims priority to provisional applications filed on November 6, 2003,

and March 26, August 4, and October 27, 2004. The inventors were all employees of Seagen at the time the priority applications were filed. Although the ’039 patent issued recently, DSC has been aware of one or more parent applications of the ’039 patent since at least 2008, and it has been aware of the specific application that issued as the ’039 patent since at least June of this year. DSC also has notice of the ’039 patent from the filing of this Complaint.

15. The ’039 patent claims technologies associated with ADCs. At the time of the invention, most therapeutics administered to patients to treat cancer—such as chemotherapeutic drugs—were not targeted to cancer cells, resulting in systemic delivery of the therapeutics to cells and tissues of the body, including to healthy cells where they are unnecessary, often undesirable, and can cause considerable adverse side effects. In the late 1990s, custom designed antibodies were developed as targeted agents for the treatment of cancer and certain autoimmune diseases, but they, too, had limitations. Combining these antibodies with chemotherapy drugs to deliver them in a targeted fashion was under investigation as a next-generation technology, and chemotherapeutic drugs that bind tubulin (an important protein for cell division), bind DNA, or inhibit topoisomerases (enzymes involved in DNA replication and transcription) were known to be leading candidates. But linkers that would release drugs only in the target cells proved elusive. The first ADC to reach the market had to be withdrawn due to off-target effects thought to be caused by an unstable linker that disassociated before the ADC reached the intended target.

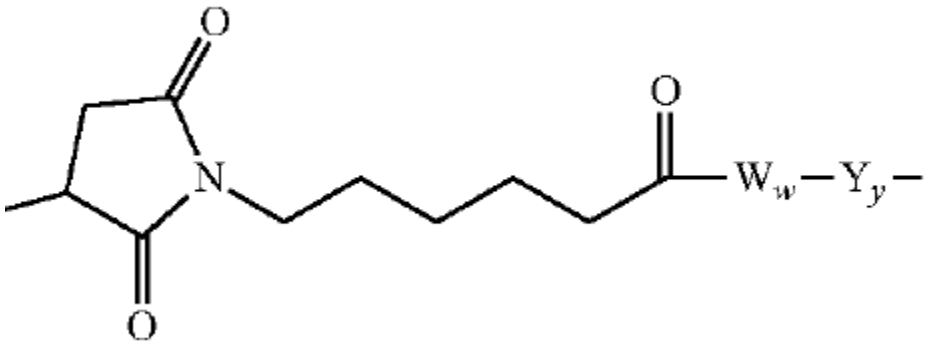
16. Seagen’s path-breaking work led to the development of protease-cleavable ADC linkers that were more stable (and thus more likely to deliver chemotherapeutic drugs to target cancer cells) than other linker types, and included research on a range of amino acid motifs that could be used in such linkers. Seagen also developed more predictable

"cysteine" conjugation technology (technology which differs from the "lysine" conjugation technology favored by other companies), and technology for arriving at a desired drug-to-antibody ratio or "DAR" (a term that refers to the number of drug units linked to each antibody).

DEFENDANT'S INFRINGEMENT

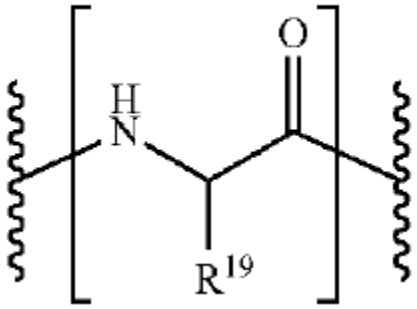
17. The claims of the '039 patent are directed to antibody-drug conjugates comprising a protease cleavable linker of four amino acids in length, wherein each amino acid is either glycine or phenylalanine. The '039 patent is enforceable and valid, and DSC's ADC products fall within the scope of the patent rights provided by the claims of the '039 patent.

18. The claims of the '039 patent cover ADCs with linkers having the formula – A_a—W_w—Y_y–, wherein A_a is a stretcher unit that bonds to a sulfur atom of the amino acid cysteine in the antibody, W_w is an amino acid unit, and Y_y is a spacer unit between the amino acid unit and the drug. Independent claim 1 provides that the stretcher unit A_a is the maleimide maleimidocaproyl, or "mc," as shown in the diagram below.

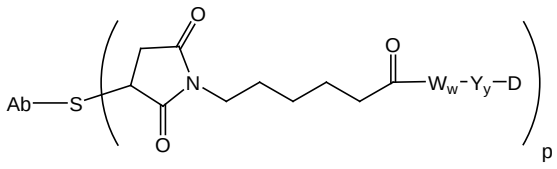
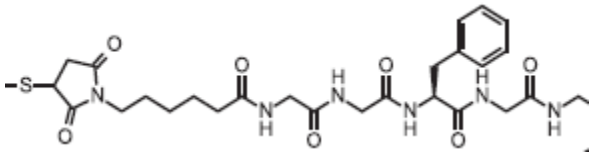
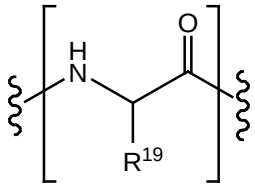


19. Claim 1 further provides that the amino acid unit W_w is a tetrapeptide of four amino acids in length, with each amino acid having the formula shown below in which R^{19} is either hydrogen (i.e., the amino acid glycine, or "G") or benzyl (i.e., the amino acid phenylalanine, or "F"):

20. Claim 4, which includes the limitations of claims 1, 2, and 3, and the claims that depend from claim 4, are exemplary on the issue of infringement. DSC's ADCs with this linker infringe Claim 4 because they comprise a maleimidocaproyl stretcher unit that bonds to a sulfur atom of the amino acid cysteine in the antibody, a tetrapeptide amino acid unit with the amino acid motif GGFG, and a self-immolative spacer unit. The drug-to-antibody ratio for these ADCs is about 3 to about 8. The chart below provides more



detail regarding how DS-8201 infringes claim 4. U3-1402, DS-1062, DS-7300, DS-6157 all use the same linker as DS-8201.

Claim 4	DS-8201
1. An antibody-drug conjugate having the formula:  or a pharmaceutically acceptable salt thereof, wherein:	DS-8201 is an antibody-drug conjugate. In DS-8201, the payload drug is conjugated to the antibody using a linker that has the claimed formula, including a stretcher unit mc, an amino acid unit W_w with the tetrapeptide motif GGFG, and an aminomethylene spacer unit Y_y: 
Ab is an antibody,	In DS-8201, the antibody to which drugs are conjugated is trastuzumab.
S is sulfur,	In DS-8201, the linker's stretcher unit mc bonds to sulfur atoms on cysteine residues of the antibody.
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,	In DS-8201, the linker has an amino acid unit with the tetrapeptide motif GGFG. Glycine, or G, corresponds with the claimed amino acid formula wherein R^{19} is hydrogen. Phenylalanine, or F, corresponds with the claimed amino acid formula wherein R^{19} is benzyl.
Y is a Spacer unit,	In DS-8201, the linker has an aminomethylene spacer unit.

y is 0, 1 or 2,	In DS-8201, there is one spacer, so y is 1.
D is a drug moiety, and	In DS-8201, the drug that is conjugated to the antibody with the linker is the camptothecin derivative DXd, which acts as a topoisomerase inhibitor.
p ranges from 1 to about 20, and	In DS-8201, the value of p, which represents drug loading in terms of the drug-to-antibody ratio or "DAR", is about 7.7.
wherein the S is a sulfur atom on a cysteine residue of the antibody, and	In DS-8201, the linker's stretcher unit mc bonds to sulfur atoms on cysteine residues of the antibody.
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.	DS-8201's linker is cleaved within the cell by proteases to release the camptothecin derivative drug DXd.
2. The antibody-drug conjugate of claim 1, wherein Y is a self-immolative spacer.	In DS-8201, the linker's aminomethylene spacer unit is self-immolative.
3. The antibody-drug conjugate of claim 2, wherein y is 1.	In DS-8201, there is one spacer, so y is 1.
4. The antibody-drug conjugate of claim 3, wherein p is about 3 to about 8.	In DS-8201, the value of p, which represents drug loading in terms of the drug-to-antibody ration or "DAR", is about 7.7.

COUNT I: ENFORCEMENT OF U.S. PATENT NO. 10,808,039 AS TO ACTS OF INFRINGEMENT BY DEFENDANT

21. Seagen hereby restates and re-alleges the allegations set forth in paragraphs 1 through 20 above and incorporates them by reference.

22. DSC has been and is now directly infringing, contributing to infringement, and inducing others to infringe the ’039 patent in this district and elsewhere in violation of 35 U.S.C. § 271 at least by making, using, selling, offering to sell, and importing into the United States ADC products, including DS-8201, that meet the limitations of one or more claims of the ’039 patent.

23. DSC has committed infringing acts without the permission, consent, authorization, or license of Seagen.

24. DSC’s infringement is literal or under the doctrine of equivalents, or both.

25. DSC, in addition to its own direct infringement, is currently actively inducing and encouraging infringement of the ’039 patent, and will continue to actively induce and encourage infringement of the ’039 patent. DSC has known of the ’039 patent at least since the time of Seagen’s transmittal of this Complaint to DSC, and had prior knowledge of the application from which it issued. DSC nevertheless actively encourages others to infringe the ’039 patent such as by promoting and encouraging the use of the infringing products, including DS-8201. DSC knowingly induces infringement by others, including importers, manufacturers, sellers, and users of the infringing products, including DS-8201. These facts give rise to a reasonable inference that DSC knowingly induces others, including importers, manufacturers, sellers, and users, to directly infringe the ’039 patent, and that DSC possesses a specific intent to cause such infringement. Importers, manufacturers, sellers, and users of the infringing products directly infringe the ’039 patent.

26. DSC also contributes to infringement of the ’039 patent by manufacturing, offering to sell, or selling within the United States or importing into the United States components of the infringing products, including linkers such as those found in DS-8201, while having knowledge of the ’039 patent and knowledge that these components are especially made or especially adapted for use in products that infringe the ’039 patent. These components are not staple articles or commodities of commerce suitable for substantial noninfringing uses. Importers, manufacturers, sellers, and users of the infringing products including these components directly infringe the ’039 patent.

27. DSC’s infringement has been willful. DSC had knowledge of the parent applications of the ’039 patent, including the application that issued as the ’039 patent and its published claims, before the filing of this Complaint. DSC has proceeded to make, use, offer for sale, sell, and import the infringing products, including DS-8201, despite knowing that the products would infringe the ’039 patent, and DSC have continued to make, use, offer for sale, sell, and import the infringing products, including DS-8201, since the filing of this Complaint. DSC was also generally aware of Seagen’s linker technology, inquired about it, and directly compared it to the linkers in DSC’s infringing products, including DS-8201, in articles, analyses, and presentations. For these and other reasons, DSC’s infringing acts have been egregious.

28. As a direct and proximate result of DSC’s infringement of the ’039 patent, Seagen has suffered, and will continue to suffer damages, including lost profits.

29. Seagen has also suffered damages from DSC’s infringement of Seagen’s provisional rights in the ’039 patent, as DSC was on notice of the published patent application for the ’039 patent and the issued claims are substantially identical to claims in the published application.

PRAYER FOR RELIEF

WHEREFORE, Seagen respectfully requests the following relief:

a. Judgment in Seagen's favor against DSC that DSC infringed one or more valid and enforceable claims of the '039 patent;

b. A finding that DSC's infringement was willful;

c. An award of damages to Seagen in an amount to be proven at trial, including lost profits but in no event less than a reasonable royalty, as well as pre-judgment and post-judgment interest at the maximum rate permitted by law;

d. An award of attorney fees and enhancement of any damages by virtue of the exceptional nature of this case under 35 U.S.C. § 285;

e. A running royalty; and

f. Such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Seagen hereby demands trial by jury of all claims and issues so triable presented in this Complaint.

Dated: October 19, 2020 CT
(October 20, 2020 ET)

By: /s/ *Melissa R. Smith*

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