IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DAIICHI SANKYO COMPANY, LIMITED,	)	
	)	
	)	
Plaintiff,	)	
	)	C.A. No. _____
v.	)	
	)	
SEATTLE GENETICS, INC.,	)	
	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Daiichi Sankyo Company, Limited ("Daiichi Sankyo" or "Plaintiff"), by its undersigned attorneys, respectfully submits this Complaint for a Declaratory Judgment against Seattle Genetics, Inc. ("SGI" or "Defendant") and hereby alleges as follows:

INTRODUCTION

1. This action concerns SGI's wrongful attempt to usurp Daiichi Sankyo's rights to a number of patents and patent applications relating to antibody drug conjugates ("ADC")—technology, which SGI neither conceived nor reduced to practice.

2. ADCs include a class of medicines designed to deliver targeted cytotoxic chemotherapy to cancer cells. ADCs typically consist at least of an antibody, a linker, and a cytotoxic payload. ADCs can be comprised of, among other things, a wide variety of antibodies, linkers, and cytotoxic payloads.

3. In the 1990s and early 2000s, Daiichi Sankyo devoted significant resources to developing cytotoxic payloads and conjugating materials for cytotoxic drug delivery. By

November 2006, Daiichi Sankyo had developed technologies relating to conjugating antibodies for cytotoxic payloads.

4. On November 30, 2006, in addition to conducting its own research and developing technologies relating to ADCs, Daiichi Sankyo entered into a collaboration agreement with SGI to produce and evaluate ADCs with two of Daiichi Sankyo's anti-DR5 antibodies and two of SGI's Auristatin-based cytotoxins for the purpose of exploring a possible further research collaboration.

5. On July 2, 2008, Daiichi Sankyo entered into that further research collaboration with SGI ("Collaboration Agreement"), which was limited to the development of particular ADCs. Specifically, the Collaboration Agreement was limited to the development of ADCs utilizing a Daiichi Sankyo-developed antibody that binds to the human DR5 antigen and SGI-developed Auristatin-based cytotoxins known as monomethyl Auristatin E ("MMAE") and monomethyl Auristatin F ("MMAF") (collectively, "SGI's Auristatin-based cytotoxins").

6. Under the terms of the Collaboration Agreement, patents and patent applications covering Improvements (as defined in the Collaboration Agreement) of Drug Conjugation Technology (as defined in the Collaboration Agreement) from this research program would be assigned to SGI.

7. Daiichi Sankyo conducted research utilizing SGI's Auristatin-based cytotoxins, but the research did not result in the discovery of any clinical drug candidate. As a result, Daiichi Sankyo provided SGI with a notice of termination on April 1, 2015, and the Collaboration Agreement terminated on June 30, 2015.

8. Before, during, and after the collaboration, Daiichi Sankyo conducted research relating to different types of ADCs utilizing, among other things, different cytotoxins and linkers. This research resulted in at least three novel ADCs, which are the subject of numerous Daiichi Sankyo patents and patent applications. These ADCs do not relate to the anti-DR5 antibody, SGI's Auristatin-based cytotoxins, or SGI's linker technology, and were not the subject matter of the Collaboration Agreement.

9. Upon information and belief, before, during, and after the term of the Collaboration Agreement, SGI was monitoring Daiichi Sankyo's research with respect to ADC technology development.

10. Following the termination of the Collaboration Agreement, information regarding the technology of Daiichi Sankyo's novel ADCs was presented to the public and was also the focus of SGI-initiated discussions with Daiichi Sankyo regarding a new potential research collaboration. Daiichi Sankyo declined SGI's offer.

11. On August 19, 2019, four years after the termination of the Collaboration Agreement, and many years after Daiichi Sankyo began filing patent applications covering ADC technology that it conceived and reduced to practice, SGI demanded assignments of Daiichi Sankyo patents and patent applications covering Daiichi Sankyo's ADC technology.

12. On September 23, 2019, Daiichi Sankyo met with SGI to discuss its assertions. SGI attempted to rationalize its overreach by asserting in conclusory fashion that Daiichi Sankyo's obligation to assign Improvements under the Collaboration Agreement was not limited to ADC technology for SGI's Auristatin-based cytotoxins, but instead applied to ADC technology ***for any drug***. In contrast to the terms of the Collaboration Agreement, Daiichi Sankyo's Patents and Patent Applications at Issue (defined below), however, fall outside the

scope of SGI's patent rights under the Collaboration Agreement because they are not Improvements of Drug Conjugation Technology as defined in the Collaboration Agreement.

13. Given SGI's attempted misappropriation, an actual, present, and justiciable controversy exists between the parties regarding Daiichi Sankyo's rights to the Patents and Patent Applications at Issue. A declaration by this Court of Daiichi Sankyo's ownership rights to the Patents and Patent Applications at Issue will resolve SGI's threat and claimed patent rights under the Collaboration Agreement.

NATURE OF THE ACTION

14. This is a civil action for a declaration pursuant to 28 U.S.C. § 2201, the Declaratory Judgment Act. Daiichi Sankyo seeks a judgment declaring its ownership rights to the Patents and Patent Applications at Issue and affirming that SGI does not have any ownership rights because the Patents and Patent Applications at Issue are not Improvements of Drug Conjugation Technology as defined in the now-expired Collaboration Agreement Daiichi Sankyo had with SGI.

THE PARTIES

15. Plaintiff Daiichi Sankyo is a corporation organized and existing under the laws of Japan, having a principal place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, 103-8426 Japan.

16. Upon information and belief, Defendant SGI is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 21823 30th Drive S.E., Bothell, Washington 98021.

JURISDICTION AND VENUE

17. This Court has diversity jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332. Daiichi Sankyo is incorporated in Japan and is therefore a citizen of a foreign state pursuant to 28 U.S.C. § 1332(c). SGI is incorporated in the State of Delaware and is therefore a citizen of the State of Delaware pursuant to 28 U.S.C. § 1332(c). SGI also has its principal place of business in Bothell, Washington, and is therefore a citizen of the State of Washington pursuant to 28 U.S.C. § 1332(c). Moreover, the amount in controversy exceeds $75,000 as is facially apparent based on the facts described herein.

18. This Court has personal jurisdiction over SGI because SGI is incorporated in the State of Delaware, has availed itself of the rights and benefits of Delaware law, and has engaged in systematic and continuous contacts with the State of Delaware.

19. Venue is proper in this district pursuant to 28 U.S.C. § 1391 because it is a judicial district in which SGI resides.

20. This Court is authorized to issue declaratory judgments pursuant to 28 U.S.C. § 2201.

BACKGROUND FACTS

Daiichi Sankyo

21. Daiichi Sankyo is a global pharmaceutical company that, along with its related companies, employs 15,000 people worldwide and provides innovative products and services. Daiichi Sankyo's mission is to contribute to the quality of life of patients around the world through the creation of innovative pharmaceuticals, and through the provision of pharmaceuticals addressing diverse medical needs.

22. Daiichi Sankyo remains committed to leveraging its world-class, innovative science and pushing beyond traditional thinking in order to create meaningful treatments for patients with cancer. Daiichi Sankyo is dedicated to transforming science into value for patients, and this sense of obligation informs everything Daiichi Sankyo does.

23. Daiichi Sankyo's investigational ADC program involves designing proprietary ADC technology to target and deliver chemotherapy to cancer cells and reduce systemic exposure to cytotoxic payloads (or chemotherapy) in comparison to traditional chemotherapy. Daiichi Sankyo has developed multiple ADCs and its investigational ADC program currently consists of seven novel proprietary ADCs, including trastuzumab deruxtecan ("DS-8201"), patritumab deruxtecan ("U3-1402"), and an investigational TROP2 targeting ADC ("DS-1062") (together, "Daiichi Sankyo's ADCs").

24. ADC technologies developed by Daiichi Sankyo are reflected in at least the following patents and patent applications owned by Daiichi Sankyo: U.S. Patent Nos. 9,808,537, 9,850,312, 9,872,924, 10,155,821, and 10,195,288; U.S. Patent Application Nos. 15/285,156, 15/302,803, 15/579,512, 15/821,662, 15/821,697, 16/130,615, 16/142,354, 16/256,715, 16/264,395, and 16/330,085; and International Patent Application Nos. PCT/JP2017/036215, PCT/JP2018/007152, and PCT/JP2018/018572, as well as all corresponding patents and patent applications filed in other countries and territories (together, the "Patents and Patent Applications at Issue").

SGI

25. Upon information and belief, SGI is a biotechnology company that develops and commercializes very specific, targeted cancer therapies. SGI's targeted cancer therapies include a specific ADC technology. (*See* SGI's Annual Report (Form 10-K) (Feb. 7, 2019) at 3.) Specifically, SGI's ADCs use its "proprietary [A]uristatin-based ADC technology." (*Id.*)

26. Upon information and belief, and according to SGI's website, SGI's ADC technology drug pipeline has been limited to ADCs utilizing cytotoxin MMAE. SGI's only FDA-approved product is ADCETRIS® (brentuximab vedotin), which is an ADC composed of an anti-CD30 monoclonal antibody attached to MMAE via a valine-citrulline dipeptide para-aminobenzylcarbamate ("Val-Cit-PABC") linker. (*Id*. at 3, 5.) Other than ADCETRIS®, SGI advertises three ADCs in its pipeline: enfortumab vedotin, tisotumab vedotin, and ladiratuzumab vedotin. All three of these ADCs conjugate a different antibody (targeting Nectin-4, Tissue factor, and LIV-1, respectively) to MMAE via a Val-Cit-PABC linker.

27. Upon information and belief, in addition to Daiichi Sankyo, SGI has entered into collaboration agreements with other companies that are limited to SGI's Auristatin-based cytotoxins. For example, SGI's collaborations with AbbVie Biotechnology Ltd., Bayer Pharma AG, Celldex Therapeutics, Inc., Genentech, Inc., GlaxoSmithKline LLC, Genmab A/S, and Progenics Pharmaceuticals, Inc. are limited to the use of its Auristatin-based ADC technology. (*Id.* at 3-4.)

The Collaboration Agreement Between Daiichi Sankyo and SGI

28. On November 30, 2006, in addition to conducting its own research and developing technologies relating to ADCs, Daiichi Sankyo entered into a research collaboration agreement with SGI to produce and evaluate ADCs with two of Daiichi Sankyo's anti-DR5

antibodies and two of SGI's Auristatin-based cytotoxins for the purpose of exploring a business relationship.

29. On July 2, 2008, Daiichi Sankyo and SGI entered into the Collaboration Agreement granting Daiichi Sankyo an exclusive worldwide license under SGI patent rights and know-how related to SGI's Auristatin-based ADC technology for use with Daiichi Sankyo's antibody, which targets the DR5 antigen.

30. The Collaboration Agreement is limited to an "Antibody" that binds to a "Designated Antigen"—defined as "the ***human DR5 antigen***, encoded by the gene designated Gene ID: 8795 (NCBI Entrez Gene Symbol TNFRSF10B), naturally occurring variants of the human DR5 antigen, and naturally occurring post-translational modifications thereof." (Collaboration Agreement at 3, § 1.1.15 (emphasis added).) Daiichi Sankyo owns the intellectual property rights relating to the anti-DR5 antibody, which binds to the ***human DR5 antigen***.

31. Although Daiichi Sankyo provided unhindered access to the anti-DR5 antibody, SGI provided "Drug Conjugation Materials" to make a narrow and defined class of ADCs using SGI's "Drug Conjugation Technology."

32. The Collaboration Agreement narrowly defines "Drug Conjugation Materials" as "(a) the compounds ***monomethyl Auristatin E*** and ***monomethyl Auristatin F*** and variants, derivatives, analogues and salts thereof, (b) compounds that are useful in attaching ***such compounds to antibodies*** and (c) any related raw materials and reagents SGI provides to Licensee pursuant to the Research Program, in each case to the extent included in or covered by the SGI Technology." (*Id.* at 3, § 1.1.16 (emphases added).)

33. Similarly, the Collaboration Agreement narrowly defines "Drug Conjugation Technology" to mean "(a) cytotoxins or cytostatic compounds such as ***monomethyl Auristatin E*** and ***monomethyl Auristatin F*** and certain variants, derivatives, analogues and salts thereof, and methods of making and using such cytotoxic or cytostatic compounds (b) compositions and methods useful for attaching ***the foregoing cytotoxic or cytostatic compounds to antibodies*** and (c) any related assays and methods SGI provides to Licensee pursuant to the Research Program." (*Id.* at 3, § 1.1.17 (emphases added).)

34. The Collaboration Agreement is also limited to the cytotoxins MMAE and MMAF. Both MMAE and MMAF were embodied by some of the "SGI Patents" set forth in Schedule B of the Collaboration Agreement, which details the specific patents licensed to Daiichi Sankyo pursuant to the Collaboration Agreement.

35. The Collaboration Agreement provided that "[i]n the event that, during the Term, [Daiichi Sankyo] conceives, develops or reduces to practice an Improvement ***that relates to the Drug Conjugation Technology***, [Daiichi Sankyo] shall promptly notify SGI of the discovery of such Improvement." (*Id.* at 11, § 3.3.1 (emphasis added).) Moreover, "SGI shall own all such Improvements that relate to the Drug Conjugation Technology and, to the extent that such Improvements shall have been conceived, developed or reduced to practice by [Daiichi Sankyo], [Daiichi Sankyo] hereby assigns all of its right, title and interest therein to SGI." (*Id.*)

36. Section 1.1.32 of the Collaboration Agreement defined "Improvements" to mean "all patentable or non-patentable inventions, discoveries or other know-how developed and Controlled by either Party after the Effective Date that utilize, incorporate, derive directly from, directly relate to, are made using or are based directly on the SGI Technology." (*Id.* at 4, § 1.1.32.)

37. Pursuant to the Collaboration Agreement, Daiichi Sankyo conducted research in hopes of discovering a clinical drug candidate composed of a conjugation of an anti-DR5 antibody to MMAE or MMAF via a cleavable Val-Cit-PABC dipeptide-based linker and to MMAF via a non-cleavable linker. The research did not result in the discovery of any clinical drug candidate. As a result, on April 1, 2015, Daiichi Sankyo provided SGI with a notice of termination of the Collaboration Agreement, and the termination took effect on June 30, 2015.

SGI Alleges that the Patents and Patent Applications at Issue Fall Within the Scope of the Collaboration Agreement and Are Therefore Owned by SGI

38. SGI alleges that unrelated ADC technology developed by Daiichi Sankyo—*e.g.*, technology that does not use or relate to the Drug Conjugation Technology as defined by the Collaboration Agreement—is an Improvement under the Collaboration Agreement.

39. Specifically, on August 19, 2019—four years after the termination of the Collaboration Agreement and many years after Daiichi Sankyo began filing patent applications covering ADC technology that it conceived and reduced to practice—SGI sent a letter to Daiichi Sankyo alleging that it had "recently come to SGI's attention that the drug conjugation technology used in [Daiichi Sankyo's] DS-8201 drug candidate, including associated patent and know-how rights, constitutes Improvements under the [Collaboration] Agreement." SGI continued that "[t]hese Improvements include rights to inventions, discoveries, and know-how disclosed in" a subset of the Patents and Patent Applications at Issue. Without further explanation, SGI claimed to own that subset of the Patents and Patent Applications at Issue, and demanded Daiichi Sankyo provide "confirmatory assignments."

40. Daiichi Sankyo responded to SGI on August 27, 2019. In that letter, Daiichi Sankyo disputed the claims made in SGI's letter dated August 19, 2019, and noted that it did not understand how that subset of the Patents and Patent Applications at Issue constitutes an

Improvement of Drug Conjugation Technology as defined in the Collaboration Agreement. Daiichi Sankyo further requested a basis for SGI's assertion.

41. Representatives from Daiichi Sankyo and SGI met in Chicago, Illinois, on September 23, 2019. From a written statement provided by SGI at that meeting, Daiichi Sankyo first learned that SGI claims to own each of the Patents and Patent Applications at Issue, which are related to Daiichi Sankyo's ADC technology. Despite its attempts, Daiichi Sankyo was unable to resolve its dispute with SGI regarding the scope of patent rights for the Patents and Patent Applications at Issue.

Daiichi Sankyo's Patents and Patent Applications at Issue Are Not Improvements of Drug Conjugation Technology Under the Collaboration Agreement

42. Daiichi Sankyo protects its innovative research and development through intellectual property, including patents and patent applications. Those innovative research and development efforts, including, among other things, the Patents and Patent Applications at Issue, are distinct and independent from the technology covered by the Collaboration Agreement, and, as such, are not Improvements of Drug Conjugation Technology.

43. The Collaboration Agreement is limited to the anti-DR5 antibody. Conversely, Daiichi Sankyo's ADCs and ADC technology at issue here is entirely different. For example, DS-8201 contains an anti-HER2 antibody, U3-1402 contains an anti-HER3 antibody, and DS-1062 contains an anti-TROP2 antibody, which are specific for HER2, HER3, and TROP2 transmembrane proteins, respectively. These antibodies do not target the Designated Antigen, DR5. HER2 and HER3 are tyrosine kinase receptor growth-promoting proteins and TROP2 is a calcium signal transducer transmembrane glycoprotein. DR5, on the other hand, is a TRAIL receptor that includes a Death Domain that activates cellular apoptosis. Moreover, HER2, HER3, and TROP2 share no structural or functional similarity with DR5.

44. The Collaboration Agreement is also limited to specific linker technologies: a cleavable Val-Cit-PABC dipeptide-based linker conjugated to MMAE or MMAF and a non-cleavable linker conjugated to MMAF. Daiichi Sankyo's linker technology at issue is different. Daiichi Sankyo's linker technology is a glycine-glycine-phenylalanine-glycine tetrapeptide-based linker conjugated to Daiichi Sankyo's cytotoxin.

45. The Collaboration Agreement is further limited to the cytotoxins MMAE and MMAF. Daiichi Sankyo's ADCs and ADC technology, however, are designed to deliver, through a unique metabolic pathway, the cytotoxin DXd—a derivative of Daiichi Sankyo's DX cytotoxin, which was independently developed by Daiichi Sankyo. Daiichi Sankyo's cytotoxin DXd is not a variant, derivative, analogue or salt of MMAE or MMAF. Moreover, Daiichi Sankyo's DXd is functionally different from SGI's MMAE and MMAF. For example, DXd inhibits Topoisomerase I resulting in DNA damage and cellular apoptosis, whereas MMAE and MMAF inhibit tubulin polymerization resulting in an arrested cell cycle.

46. The Collaboration Agreement makes clear that technology wholly unrelated to Drug Conjugation Technology is not an Improvement. Improvements must relate to the Drug Conjugation Technology. Given that Daiichi Sankyo's Patents and Patent Applications at Issue involve entirely independent and unrelated technology, Daiichi Sankyo's Patents and Patent Applications at Issue are not Improvements of Drug Conjugation Technology as defined in the Collaboration Agreement. Accordingly, the Patents and Patent Applications at Issue fall outside the scope of SGI's patent rights under the Collaboration Agreement.

47. In addition, SGI has unreasonably delayed in making its assertion that it owns rights to the Patents and Patent Applications at Issue. Daiichi Sankyo's ADC technology

reflected in the Patents and Patent Applications at Issue had been conceived and reduced to practice several years before SGI sent its August 19, 2019 letter to Daiichi Sankyo.

48. Upon information and belief, SGI had knowledge of the ADC technology reflected in the Patents and Patent Applications at Issue years before SGI sent its August 19, 2019 letter to Daiichi Sankyo, including by at least one of its employees attending a conference in 2015. In addition, in 2016 Daiichi Sankyo's ADC technology had been part of SGI discussions with Daiichi Sankyo for potential new research collaboration following the termination of the Collaboration Agreement.

49. As a result of SGI's unreasonable delay in raising its meritless ownership assertion, Daiichi Sankyo has been unjustly prejudiced. Over the years that SGI remained inactive in bringing its assertion, Daiichi Sankyo invested considerable time, resources, and monies into the research and development of novel ADCs, which is now threatened by SGI's wrongful attempt to usurp Daiichi Sankyo's rights to the Patents and Patent Applications at Issue. SGI's ownership claims are both meritless and untimely.

50. Based on the foregoing facts, there is actual, present, and justiciable controversy relating to the scope of patent rights. Accordingly, Daiichi Sankyo has filed this action pursuant to Section 19.3.6 of the Collaboration Agreement, which states that "any disputes relating to inventorship or the . . . scope of any patent or trademark rights shall be submitted for resolution by a court of competent jurisdiction."

COUNT: DECLARATORY JUDGMENT THAT DAIICHI SANKYO, NOT SGI, HAS OWNERSHIP RIGHTS TO THE PATENTS AND PATENT APPLICATIONS AT ISSUE

51. Daiichi Sankyo incorporates by reference each of the preceding paragraphs as if fully set forth herein.

52. An actual, present, and justiciable controversy has arisen and now exists between the parties with respect to Daiichi Sankyo's ownership of the Patents and Patent Applications at Issue and SGI's claimed patent rights under the Collaboration Agreement.

53. Daiichi Sankyo, not SGI, has ownership rights, title, and interest in the Patents and Patent Applications at Issue under the patent laws of the United States.

54. Daiichi Sankyo's Patents and Patent Applications at Issue are not Improvements of the Drug Conjugation Technology as defined in the Collaboration Agreement.

55. SGI's asserted patent rights under the Collaboration Agreement are separately barred by the statute of limitations or the doctrines of laches, estoppel, waiver and/or acquiescence.

56. Daiichi Sankyo is entitled to a declaratory judgment, pursuant to 28 U.S.C. § 2201, declaring that Daiichi Sankyo has ownership rights to the Patents and Patent Applications at Issue, and SGI has no ownership interest in the Patents and Patent Applications at Issue as they do not constitute Improvements of Drug Conjugation Technology as defined in the Collaboration Agreement.

PRAYER FOR RELIEF

WHEREFORE, Daiichi Sankyo respectfully requests the following relief:

A. The entry of judgment on this Complaint in favor of Daiichi Sankyo, and against SGI;

B. The entry of a declaratory judgment pursuant to 28 U.S.C. § 2201, declaring that Daiichi Sankyo has ownership rights of the Patents and Patent Applications at Issue and SGI has no ownership interest in the Patents and Patent Applications at Issue as they do not constitute Improvements of Drug Conjugation Technology as defined in the Collaboration Agreement;

C. The entry of a declaratory judgment pursuant to 28 U.S.C. § 2201, declaring that SGI's asserted patent rights under the Collaboration Agreement are barred by the statute of limitations, doctrines of laches, estoppel, waiver and/or acquiescence;

D. An award to Daiichi Sankyo of its costs and expenses in this action; and

E. Such other and further relief as the Court may deem just and proper.

ASHBY & GEDDES

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