

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BRISTOL-MYERS SQUIBB CO. and	)	
E. R. SQUIBB & SONS L.L.C.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 22-346-MFK
	)	
ASTRAZENECA PHARMACEUTICALS LP	)	JURY TRIAL DEMANDED
and ASTRAZENECA UK LTD.,	)	
	)	
Defendants.	)	
_____	)	

JOINT CHARTS OF AGREED UPON AND PROPOSED CONSTRUCTIONS

Pursuant to the Court’s Scheduling Order in the above-captioned case, Plaintiffs Bristol-Myers Squibb Co. and E. R. Squibb & Sons L.L.C. (collectively, “Plaintiffs” or “BMS”) and Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca UK Ltd. (collectively, “Defendants” or “AstraZeneca”) present the following Joint Charts of Agreed Upon and Proposed Constructions for terms for U.S. Patent Nos. 9,580,505 (“the ’505 Patent”); 9,580,507 (“the ’507 Patent”); 10,139,299 (“the ’299 Patent”); 10,266,594 (“the ’594 Patent”); 10,266,595 (“the ’595 Patent”); 10,266,596 (“the ’596 Patent”); 10,308,714 (“the ’714 Patent”); and 10,323,092 (“the ’092 Patent”) (“Asserted Patents”). A separate Joint Appendix of Intrinsic Evidence is filed concurrently herewith.

For ease of reference the terms have been divided by patent family. The ’505 and ’507 Patents comprise the “Korman Patents” and the ’299, ’594, ’595, ’596, ’714, and ’092 Patents comprise the “Cogswell Patents.” The Korman Patents are generally directed to anti-PD-L1 antibodies and share a common specification. The Cogswell Patents are generally directed to

methods of treating cancer by administering anti-PD-L1 antibodies and also share a common specification.

The parties reserve the right to supplement the attached charts with additional evidence and to rely upon additional intrinsic and/or extrinsic evidence in their respective claim construction briefs, including for the purposes of responding to or rebutting evidence and arguments made by the other party.

Dated: January 27, 2023

Respectfully submitted,

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I. Agreed Upon Constructions – Korman Patents

Claim Term	Agreed Upon Construction
“a framework region” (’505 Patent, claims 1, 4, 6, 7; ’507 Patent, claim 1)	Refers to any of FR1, FR2, FR3, or FR4.
“binds to human PD-L1 with a K_D of 5×10^{-9} M or less” (’505 Patent, claims 21, 37; ’507 Patent, claim 15)	K_D means “the dissociation constant, which is obtained from the ratio of K_d to K_a (i.e., K_d/K_a) and is expressed as a molar concentration (M).”
“wherein the framework region of the heavy chain variable region and/or light chain variable comprises no more than 10 amino acid differences from the corresponding framework region...” (’505 Patent, claims 4, 7) “framework region of the light chain variable region exhibits at least 95% sequence identity to the corresponding framework region...” (’505 Patent, claim 6)	“Framework region” refers to any of FR1, FR2, FR3, or FR4.

Claim Term	Agreed Upon Construction
“exhibiting at least 90% sequence identity to a framework region of the heavy chain and/or light chain variable region of the reference antibody” (’507 Patent, claim 1)	“Framework region” refers to any of FR1, FR2, FR3, or FR4. “The reference antibody” refers to the reference antibody with which the anti-PD-L1 antibody or antigen-binding portion thereof competes.
“the VL exhibits at least 90% sequence identity to” a light chain variable region comprising the amino acid sequences in SEQ ID Nos. 11-20 (’507 Patent, claim 3)	The parties agree that comparison is between the anti-PD-L1 antibody or antigen-binding portion thereof and any of the enumerated sequences.
“the [VL/VH] comprises a” (’507 Patent, claims 4, 5, 6, 7, 11)	The parties agree that comparison is between the anti-PD-L1 antibody or antigen-binding portion thereof and any of the enumerated sequences.
“pharmaceutically acceptable carrier” (’507 Patent, claim 28)	“Any and all solvents, dispersion media, coatings, antibacterial and antifungal agents, isotonic and absorption delaying agents, and the like that are physiologically compatible.”

II. Proposed Constructions – Korman Patents¹

Claim Term	Plaintiffs' Position	Defendants' Position
“cross-competes for binding to human PD-L1 with a reference antibody” (’505 Patent, claims 1, 29; ’507 Patent, claim 1)	“Inhibits the binding of a reference antibody to human PD-L1 by, for example, Biacore analysis, ELISA analysis, or flow cytometry.” Intrinsic Record Cites: ’505 Patent at 27:25-28:6, 68:43-70:4, Claim 1, Figures 32-34. U.S. Patent No. 9,102,725 File History, including: • January 22, 2013 Application and claims • July 23, 2014 Restriction Requirement • September 23, 2014 Response • November 14, 2014 Non-Final Rejection	“binds to the same epitope on PD-L1” Intrinsic Record Cites: ’505 patent at 15:56–60; 16:9–18; 22:21–23:19; 27:25–28:6; 43:53–44:27. Prosecution file history of Application No. 11/917,727 including December 14, 2009 Office Action; March 15, 2010 Preliminary Amendment and Response to Restriction Requirement; June 8, 2010 Office Action; September 8, 2010 Amendment and Response to Non-Final Office Action; October 22, 2010 Office Action; and December 21, 2010 Amendment and Response to Final Office Action. Prosecution file history of Application No. 13/091,936 including January 31, 2012 Office Action; and April 9, 2012, Amendment and Response to Non-Final Office Action. Prosecution file history of Application No. 13/746,773 including July 23, 2014,

¹ For brevity, citations are provided to only the specification of the ’505 patent, but equivalent citations can be found in the ’507 patent, which has the same specification.

Claim Term	Plaintiffs' Position	Defendants' Position
		Office Action; September 23, 2014, Response to Restriction Requirement; November 14, 2014 Office Action; and March 16, 2015 Amendments and Response to Non-Final Office Action. Prosecution file history of Application No. 14/807,522 including July 23, 2015 Preliminary Amendment and December 7, 2015 Second Preliminary Amendment. Prosecution file history of Application No. 15/188,860 including June 21, 2016 Preliminary Amendment and August 29, 2016 Second Preliminary Amendment. Prosecution file history of Application No. 15/413,244 including February 27, 2017, Preliminary Amendment and February 21, 2019 Office Action. Prosecution file history of Application No. 16/448,721 including November 16, 2021 Office Action; February 16, 2022 Amendment and Reply to Restriction Requirement; and March 16, 2022 Office Action.
“reference antibody” (’505 Patent, claims 1, 29; ’507 Patent, claim 1)	“An antibody used as a reference in a cross-competition experiment” Intrinsic Record Cites:	“Antibody” is defined to include whole antibodies and any antigen binding fragment or single chain thereof. If a

Claim Term	Plaintiffs' Position	Defendants' Position
	'505 Patent at 14:57-17:25, 27:25-28:6, 37:45-38:67, 62:42-64:5, 68:43-71:17, 73:18-74:11, Claim 1. U.S. Patent No. 9,102,725 at Claim 1. U.S. Patent No. 9,102,725 File History, including: • January 22, 2013 Application and claims • July 23, 2014 Restriction Requirement • September 23, 2014 Response • November 14, 2014 Non-Final Rejection	constant region is present, it can be any constant region, e.g., IgG, IgM, etc. “Antigen binding fragment” also is defined and includes, inter alia, an Fab fragment and an scFv.” Intrinsic Record Cites: '505 patent at 8:45–49; 14:57–38:67; 42:1–39; 44:28–39; 48:49–56; Claim 41. '507 patent at Claims 12–13, and 22. U.S. Patent No. 9,102,725 at Claims 8–10 and 26–31. U.S. Patent No. 9,273,135 at Claims 17, 18, and 20. Prosecution file history of Application No. 13/746,773 including July 23, 2014, Office Action; September 23, 2014, Response to Restriction Requirement; November 14, 2014 Office Action; and March 16, 2015 Amendments and Response to Non-Final Office Action.

III. Agreed Upon Constructions – Cogswell Patents

Claim Term	Agreed Upon Construction
“A method of treating a tumor in a human subject in need thereof, comprising administering . . . an anti-PD-L1 antibody” (’299 Patent, claim 1; ’594 Patent, claims 1, 28; ’595 Patent, claims 1, 28; ’596 Patent, claims 1, 28; ’714 Patent, claim 1) “A method of treating a late stage non-small cell lung cancer (NSCLC) tumor in a human subject, comprising administering ... an anti –PD-L1 antibody” (’092 Patent, claim 1)	“A method of treating” should be given its plain and ordinary meaning, which does not require that the treatment be successful in every patient.
“the tumor is derived from a [bladder cancer/cancer of the renal pelvis/cancer of the ureter/cancer of the urethra]” (’299 Patent, claim 1; ’594 Patent, claims 1, 28; ’595 Patent, claims 1, 28; ’596 Patent, claims 1, 28; ’714 Patent, claim 1)	“A primary or secondary tumor from cancer of the [bladder, renal pelvis, ureter, urethra].”

Claim Term	Agreed Upon Construction
“a therapeutically effective amount” (’594 Patent, claim 1; ’595 Patent, claim 1; ’596 Patent, claim 1; ’714 Patent, claim 1)	“any amount of the drug that, when used alone or in combination with another therapeutic agent, protects a subject against the onset of a disease or promotes disease regression evidenced by a decrease in severity of disease symptoms, an increase in frequency and duration of disease symptom-free periods, or a prevention of impairment or disability due to the disease affliction.”
“the tumor is locally advanced” (’299 Patent, claim 3; ’594 Patent, claim 3; ’595 Patent, claim 3; ’596 Patent, claim 3; ’714 Patent, claim 3) “the tumor is <u>locally advanced</u> or metastatic” (’594 Patent, claim 29; ’595 Patent, claim 29; ’596 Patent, claim 29)	Locally advanced means “the tumor that has grown into adjacent structures and is difficult to operate on.”

IV. Proposed Constructions – Cogswell Patents²

Claim Term	Plaintiffs’ Position	Defendants’ Position
“administered intravenously over 60 minutes infusion” (’299 Patent, claim 1; ’594 Patent, claims 1, 28; ’595 Patent, claims	No construction is needed. Intrinsic Record Cites: ’092 Patent at 7:4-37; Examples 4, 6, 11, 12; Claim 1.	The claimed method requires that each intravenous infusion last 60 minutes. Intrinsic Record Cites:

² For brevity, citations are provided only to the specification of one of the Cogswell patents, but equivalent citations can be found in each of the other Cogswell patents, which have the same specification.

Claim Term	Plaintiffs' Position	Defendants' Position
1, 28; '596 Patent, claims 1, 28; '714 Patent, claim 1; '092 Patent, claim 1)		'299 Patent at 67:45–63. Prosecution file history of Application No. 16/006,493 including August 10, 2018 Office Action.
“the tumor is metastatic” ('299 Patent, claim 4; '594 Patent, claim 4; '595 Patent, claim 4; '596 Patent, claim 4; '714 Patent, claim 4; '092 Patent, claim 4) “the tumor is locally advanced or <u>metastatic</u>” ('594 Patent, claim 29; '595 Patent, claim 29; '596 Patent, claim 29)	Metastatic means “cancer cells have left the primary tumor and spread from where the tumor first formed.” Intrinsic Record Cites: '092 Patent at 2:61-64, 5:15-61, 9:42-48, 30:10-17, 32:14-33, 34:10-33, 35:1-2, 35:41-36:5, 39:14-67, 54:9-62; Examples 7, 11, 14; Figures 5-8; Claims 1-4. '299 Patent at Claims 1-4; '594 Patent at Claims 1-4, 29; '595 Patent at Claims 1-4, 29; '596 Patent at Claims 1-4, 29; '714 Patent at Claims 1-4, 25.	Metastatic means “the tumor has formed a secondary tumor in a distant part of the body” Intrinsic Record Cites: '299 Patent at 2:61–62; 5:40–59; 9:40–46; 28:1–36:40; 39:14–41:34; 53:35–55:60; 57:5–63:35; 67:45–71:55; Fig. 7.
“about 10 mg/kg of an anti-PD-L1 antibody once every 2 weeks” ('299 Patent, claim 1; '594 Patent, claim 28; '595 Patent, claim 28; '596 Patent, claim 28; '092 Patent, claim 1)	No construction is needed. Intrinsic Record Cites: '092 Patent at 25:47–50, 25:60–26:11; Examples 4, 11, 13; Figures 4, 10A, 10B, 10D; Claim 1, 6.	“about 10 mg/kg of an anti-PD-L1 antibody every fourteen days.” The claimed method is not practiced until a second dose has been administered, and ceases to be practiced if a subject is not treated 2 weeks after the preceding dose. Intrinsic Record Cites:

Claim Term	Plaintiffs' Position	Defendants' Position
		'299 Patent at 12:32-48; 25:35-26:8; 57:5-63:35; 67:45-71:55. U.S. Patent No. 10,316,091, claim 2
“late stage non-small cell lung cancer (NSCLC) tumor” (’092 Patent, claim 1)	“Stage III or stage IV non-small cell lung cancer (NSCLC) tumor.” Intrinsic Record Cites: ’092 Patent at 2:22-44, 53:12-55:45; Example 11; Claims 1-4. ’092 Patent File History, including: • August 10, 2018 Non-Final Rejection • November 9, 2018 Response to Non-Final Rejection	“Stage IV/metastatic non-small cell lung cancer (NSCLC) tumor” Intrinsic Record Cites: ’092 Patent at 2:20-42; 4:15-44; 5:36-41; 5:66-6:10; 6:23-25; 30:10-32:33; 39:14-67; 53:12-55:40; 57:28-59; 59:30-61:40; 66:61-68:15; 69:29-71:30; Figs. 7, 10A-10D and 13; Claims 1-5. Prosecution file history of Application No. 16/006,473 including June 14, 2018, Preliminary Amendment; June 14, 2018, Second Preliminary Amendment; August 7, 2018, Office Action; and September 19, 2018, Amendment and Reply. Prosecution file history of Application No. 16/024,340 including June 29, 2018, Preliminary Amendment; July 2, 2018, Second Preliminary Amendment; August 15, 2018, Office Action; and September 20, 2018, Amendment and Reply. Prosecution file history of Application No. 16/006,493 including June 12, 2018, Preliminary Amendment; June 14, 2018,

Claim Term	Plaintiffs' Position	Defendants' Position
		Second Preliminary Amendment; August 10, 2018, Office Action; November 9, 2018, Amendment and Reply; and January 17, 2019, Notice of Allowance.
“wherein the subject is pretreated for a chemotherapy and a radiotherapy” (’092 Patent, claim 1)	“The subject previously received a chemotherapy and a radiotherapy treatment.” Intrinsic Record Cites: ’092 Patent at 10:10-16, 30:10-32:33, 43:7-40, 66:64-67:8, 67:61-63; Examples 4, 8, 11; Figures 6, 8A, 8B; Claims 1, 12, 24. ’714 Patent at Claim 26.	“pretreated” means “wherein the subject has failed on a chemotherapy and a radiotherapy” Intrinsic Record Cites: ’092 Patent at 2:20–42; 4:15–44; 5:36–41; 5:66–6:10; 6:23–25; 30:10–32:33; 39:14–67; 53:12–55:40; 57:28–59; 59:30–61:40; 66:61–68:15; 69:29–71:30; Figs. 7, 10A-10D and 13; Claims 1–5. Prosecution file history of Application No. 16/006,473 including June 14, 2018, Preliminary Amendment; June 14, 2018, Second Preliminary Amendment; August 7, 2018, Office Action; and September 19, 2018, Amendment and Reply. Prosecution file history of Application No. 16/024,340 including June 29, 2018, Preliminary Amendment; July 2, 2018, Second Preliminary Amendment; August 15, 2018, Office Action; and September 20, 2018, Amendment and Reply. Prosecution file history of Application No. 16/006,493 including June 12, 2018, Preliminary Amendment; June 14, 2018,

Claim Term	Plaintiffs' Position	Defendants' Position
		Second Preliminary Amendment; August 10, 2018, Office Action; November 9, 2018, Amendment and Reply; and January 17, 2019, Notice of Allowance.
“the tumor is advanced or recurrent” (’092 Patent, claim 3)	“Advanced” should be construed according to its plain and ordinary meaning, which is: “cannot be surgically removed in its entirety.” No construction is needed for the remainder of the term. Intrinsic Record Cites: ’092 Patent at 1:61-67, 2:63-67, 5:22-37, 5:42-61, 30:51-31:27, 31:28-41, 32:14-33, 39:16-37, 54:9-55:40; Examples 4, 11; Figures 8A, 8B; Claims 2, 3, 4. ’092 Patent File History, including: • August 10, 2018 Non-Final Rejection • November 9, 2018 Response to Non-Final Rejection ’594 Patent at Claims 1-4, 29; ’595 Patent at Claims 1-4, 29; ’596 Patent at Claims 1-4, 29; ’714 Patent at Claims 1-4, 25.	“advanced” has the same meaning as “late stage” (“stage IV/metastatic”) Intrinsic Record Cites: ’092 Patent at 2:20-42; 4:15-44; 5:36-41; 5:66-6:10; 6:23-25; 30:10-32:33; 39:14-67; 53:12-55:40; 57:28-59; 59:30-61:40; 66:61-68:15; 69:29-71:30; Figs. 7, 10A-10D and 13; Claims 1-5. Prosecution file history of Application No. 16/006,473 including June 14, 2018, Preliminary Amendment; June 14, 2018, Second Preliminary Amendment; August 7, 2018, Office Action; and September 19, 2018, Amendment and Reply. Prosecution file history of Application No. 16/024,340 including June 29, 2018, Preliminary Amendment; July 2, 2018, Second Preliminary Amendment; August 15, 2018, Office Action; and September 20, 2018, Amendment and Reply.

Claim Term	Plaintiffs' Position	Defendants' Position
		Prosecution file history of Application No. 16/006,493 including June 12, 2018, Preliminary Amendment; June 14, 2018, Second Preliminary Amendment; August 10, 2018, Office Action; November 9, 2018, Amendment and Reply; and January 17, 2019, Notice of Allowance.