

EXHIBIT E

**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.

ASTRAZENECA PHARMACEUTICALS LP
and ASTRAZENECA UK LTD.,

Defendants.

C.A. No. 22-346-MFK

JURY TRIAL DEMANDED

**PLAINTIFFS' DISCLOSURE OF
PROPOSED CONSTRUCTIONS FOR CLAIM TERMS**

Pursuant to the Court’s Scheduling Order dated May 10, 2022 entering the parties’ proposed case schedule, and the Joint Stipulation and Order to Extend Time to exchange proposed claim constructions (D.I. 56), Plaintiffs Bristol-Myers Squibb Co. and E. R. Squibb & Sons L.L.C. hereby provide their positions for the proposed claim terms in the asserted claims of U.S. Patent Nos. 10,138,299 (“the ’299 Patent”); 10,308,714 (“the ’714 Patent”); 10,266,594 (“the ’594 Patent”); 10,266,595 (“the ’595 Patent”); 10,266,596 (“the ’596 Patent”); 10,323,092 (“the ’092 Patent”); 9,580,505 (“the ’505 Patent”); and 9,580,507 (“the ’507 Patent”) that have been identified by Plaintiffs and the Defendants in the above captioned litigation¹.

¹ Plaintiffs reserve the right to supplement or revise these constructions in response to Defendants' proposed construction and/or further discussions between the parties.

A. Proposed Terms for the Korman Patents:

Claim Term	Plaintiffs' Position
“cross-competes for binding to PD-L1 with a reference antibody” ('505 Patent, claims 1, 4, 6, 7, 21, 28, 30, 32, 36, 37, 41; '507 Patent, claims 1, 3, 4, 5, 6, 7, 11, 15, 22, 27, 28)	“Inhibits the binding of a reference antibody to human PD-L1 by, for example, Biacore analysis, ELISA analysis, or flow cytometry.”
“reference antibody” ('505 Patent, claims 1, 4, 6, 7, 21, 28, 30, 32, 36, 37, 41; '507 Patent, claims 1, 3, 4, 5, 6, 7, 11, 15, 22, 27, 28)	No construction is needed.
“a framework region” ('505 Patent, claims 1, 4, 6, 7, 21, 28, 30, 32, 36, 37, 41; '507 Patent, claims 1, 3, 4, 5, 6, 7, 11, 15, 22, 27, 28)	Refers to any of FR1, FR2, FR3, or FR4.
“a framework region . . . derived from” ('505 Patent, claims 1, 4, 6, 7, 21, 28)	Has a structure based on the amino acid sequence of a heavy chain variable germline sequence.
“binds to human PD-L1 with a K_D of 5×10^{-9} M or less”	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).”

Claim Term	Plaintiffs' Position
('505 Patent, claims 21, 37; '507 Patent, claim 15)	The remainder of the term does not require construction.
“exhibiting at least 90% sequence identity to” a framework region of the heavy chain and/or light chain variable region <u>of the reference antibody</u>” ('507 Patent, claims 1, 3, 4, 5, 6, 7, 11, 15, 22, 27, 28)	No construction is needed. The parties agree that “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)	No construction is needed. 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)	No construction is needed. 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)	No construction needed. To the extent a construction is needed, the terms should be construed to mean:

Claim Term	Plaintiffs' Position
	“Any and all solvents, dispersion media, coatings, antibacterial and antifungal agents, isotonic and absorption delaying agents, and the like that are physiologically compatible.”

B. Proposed Terms for the Cogswell Patents:

Claim Term	Plaintiffs' Position
“a method of treating a tumor in a human subject in need thereof, comprising administering . . . an anti-PD-L1 antibody” (’299 Patent, claims 1, 3, 4, 10; ’594 Patent, claims 1, 3, 4; ’595 Patent, claims 1, 3, 4; ’596 Patent, claims 1, 3, 4, 28, 29, 30; ’714 Patent, claims 1, 3, 4; ’092 Patent, claims 1, 3, 4)	“A method of treating a tumor” should be given its plain and ordinary meaning, which does not require that the treatment be successful in every patient.
“administered intravenously over 60 minutes infusion” (’299 Patent, claims 1, 3, 4, 10; ’594 Patent, claims 1, 3, 4, 28, 29, 30; ’595 Patent, claims 1, 3, 4, 28, 29, 30; ’596 Patent, claims 1, 3, 4, 28, 29, 30; ’714 Patent, claims 1, 3, 4; ’092 Patent, claims 1, 3, 4)	No construction is needed.
“the tumor is derived from a [bladder cancer/cancer of the renal pelvis/cancer of the ureter/cancer of the urethra]” (’299 Patent, claims 1, 3, 4, 10; ’594 Patent, claims 1, 3, 4, 28, 29, 30; ’595 Patent, claims 1, 3, 4, 28, 29,	“A primary or secondary tumor from cancer of the [bladder, renal pelvis, ureter, urethra].”

Claim Term	Plaintiffs' Position
30; '596 Patent, claims 1, 3, 4, 28, 29, 30; '714 Patent, claims 1, 3, 4)	
"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 that has grown into adjacent structures and is difficult to operate on."
"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)	"Cancer cells have left the primary tumor and spread from where the tumor first formed."
"wherein at least 1% of the tumor cells exhibit membrane PD-L1 expression" ('299 Patent, claim 10; '594 Patent, claim 30; '595 Patent, claim 30; '596 Patent, claim 30; '092 Patent, claims 1, 3, 4)	No construction is needed. This is not a method step.
"a therapeutically effective amount" ('594 Patent, claims 1, 3, 4; '595 Patent, claims 1, 3, 4; '596 Patent, claims 1, 3, 4; '714 Patent, claims 1, 3, 4)	"An amount sufficient to achieve the claimed effect."
"about 10 mg/kg of an anti-PD-L1 antibody once every 2 weeks"	No construction is needed.

Claim Term	Plaintiffs' Position
('594 Patent, claims 28, 29, 30; '595 Patent, claims 28, 29, 30; '596 Patent, claims 28, 29, 30; '092 Patent, claims 1, 3, 4)	
“the tumor is refractory to a platinum based chemotherapy” ('596 Patent, claims 28, 29, 30)	No construction is needed.
“late stage non-small cell lung cancer (NSCLC) tumor” ('092 Patent, claims 1, 3, 4)	“Stage III or stage IV non-small cell lung cancer tumor.”
“wherein the subject is pretreated for a chemotherapy and a radiotherapy” ('092 Patent, claims 1, 3, 4)	“The subject previously received a chemotherapy and a radiotherapy treatment.”
“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.

Dated: December 9, 2022

Respectfully submitted,

FARNAN LLP

By: /s/ Brian E. Farnan

Brian E. Farnan (Bar No. 4089)

Michael J. Farnan (Bar No. 5165)

919 N. Market St., 12th Floor

Wilmington, DE 19801

Tel: (302) 777-0300

Fax: (302) 777-0301

bfarnan@farnanlaw.com

mfarnan@farnanlaw.com

Of Counsel:

Steven D. Maslowski

Matthew A. Pearson

Jason Weil

Karina J. Moy

Anthony D. Sierra

Vincent P. Jones

**AKIN GUMP STRAUSS HAUER &
FELD LLP**

1735 Market Street, 12th Floor

Philadelphia, PA 19103

Tel.: (215) 965-1200

Fax: (215) 965-1210

smaslowski@akingump.com

mpearson@akingump.com

jweil@akingump.com

kmoy@akingump.com

asierra@akingump.com

jonesv@akingump.com

Rachel J. Elsby

**AKIN GUMP STRAUSS HAUER &
FELD LLP**

Robert S. Strauss Tower

2001 K Street, N.W.

*Counsel for Plaintiffs Bristol-Myers Squibb Co. and
E. R. Squibb & Sons L.L.C.*

Washington, DC 20006
Tel: (202) 887-4000
Fax: (202) 887-4288
relsby@akingump.com

CERTIFICATE OF SERVICE

I, Brian E. Farnan, hereby certify that on December 9, 2022, a copy of Plaintiffs’

Disclosure of Proposed Constructions for Claim Terms was served on the following as indicated:

Via E-Mail

Daniel M. Silver
Alexandra M. Joyce
MCCARTER & ENGLISH, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Defendants

Via E-Mail

David I. Berl
Thomas S. Fletcher
Kevin Hoagland-Hansen
Matthew Heins
WILLIAMS & CONNOLLY LLP
ImfinziWC@wc.com

Attorneys for Defendants

/s/ Brian E. Farnan

Brian E. Farnan (Bar No. 4089)