UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyme Inc.,
Patent Owner.

_____

Case No. PGR2025-00017
U.S. Patent No. 12,110,520

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Declaration of Jeffrey P. Kushan

I, Jeffrey P. Kushan, make the following Declaration pursuant to 28 U.S.C. § 1746:

1.   I am a partner at the law firm of Sidley Austin LLP.

2.   I provide this declaration in connection with the above-identified post grant review proceeding before the United States Patent and Trademark Office and initiated by Merck Sharp & Dohme LLC ("Merck") against Halozyme Inc. under 35 U.S.C. § 321. Unless otherwise stated, the facts stated in this Declaration are based on my personal knowledge.

3.   For each of the exhibits addressed below, an exhibit label and page numbers have been added, but no other alterations have been made. Where the exhibit is a PDF generated from a webpage displayed in a web browser, the PDF may contain information in the header and footer (*e.g.*, the URL, the title of the page being displayed, or similar items), which was generated automatically by the web browser displaying the page.

4.   EX1015 is a document mapping citations in Merck's Petition to U.S. Patent No. 12,110,520 ("the '520 Patent") to corresponding text in U.S. Patent Application No. 13/694,731 ("the '731 Application"). This mapping was prepared by staff at my law firm working under my supervision, and is true and accurate to the best of my knowledge.

5.   Exhibit 1016 is a true and correct copy of a publication by Boris

Steipe titled "Consensus-Based Engineering of Protein Stability: From Intrabodies

to Thermostable Enzymes" ("Steipe"). This paper was published as a chapter in

"Methods in Enzymology," Vol. 388, on pages 176-186. As the Steipe paper itself

does not include the year in which it was published, I have appended the

publication information at the end of Exhibit 1016, as pages 187-192. Pages 187-

192 of Exhibit 1016 are a true and correct copy of the web page available from the

following URL:

https://www.sciencedirect.com/science/article/abs/pii/S0076687904880169

6.   Exhibit 1045 is a true and correct copy of a redline that I had created

for U.S. Patent Application No. 13/694,731 and U.S. Patent No. 12,110,520 using

Litera Compare in Microsoft Word. To create this redline, the text of U.S. Patent

Application No. 13/694,731 (as published in U.S. Patent Application Publication

2013-0302275) was copied and compared to the text of U.S. Patent No.

12,110,520, both obtained from the USPTO's Patent Center website. The text of

both documents was pasted into separate Word documents. Any text that appeared

before the "Background/Summary" heading and the claim language was deleted.

The Word document with the text from U.S. Patent Application No. 13/694,731

was designated as the original file and the Word document with the text from U.S.

Patent No. 12,110,520 was designated as the modified file. I saved the redline as a

PDF and included it here as Exhibit 1045. The redline shows certain differences as a result of formatting changes (principally in the presentation of tables). In my review of the redline (with one exception[1]), I have not identified any substantive differences between U.S. Patent Application No. 13/694,731 and U.S. Patent No. 12,110,520, and I believe them to be substantively identical.

    a.   The text file that I copied for the '731 Application is available from the following URL: https://image-ppubs.uspto.gov/dirsearch-public/patents/html/20130302275?source=US-PGPUB&requestToken=eyJzdWIiOiI2ODY2MWZjNy1mODMzLTQ0YTItYmJkNy00MmZkN2M2ZjdlYTMiLCJ2ZXIiOiIyYjBhM2VjNS04MTRjLTRhMTUtYTI2Ni0wODExZmRlZWUwY2QiLCJleHAiOjB9

    b.   The text file that I copied for the '520 Patent is available from the following URL: https://image-ppubs.uspto.gov/dirsearch-public/patents/html/12110520?source=USPAT&requestToken=eyJzd

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[1] The '520 Patent alters the list of mutations that should be avoided in enzymatically active PH20 proteins by removing positions 282, 298, and 431 from the list in the '731 Application. *See* EX1045, 78; *also* EX1001, 80:15-27; EX1026, 91:30-92:1.

WIiOiIzNTM4NGNkNC1jZDQ1LTQxYTItYmVhMy02YTFhZTAz

OTU3NjMiLCJ2ZXIiOiI0ZDI2YzdmOS01NTllLTRlMjAtOTEyNC0

4OTAwMjMwOTBlZjYiLCJleHAiOjB9

7.   Exhibit 1064 is a true and correct copy of a set of web pages available

from the Internet Archive at the URLs listed below:

a.   Pages 1-2 of Exhibit 1064 ("Basic Local Alignment Search Tool") are

a true and correct copy of the web page available from the following

URL:

https://web.archive.org/web/20110721055636/http://blast.ncbi.nlm.ni

h.gov/Blast.cgi?CMD=Web&PAGE_TYPE=BlastHome

b.   Page 3 of Exhibit 1064 ("Help") is a true and correct copy of the web

page available from the following URL:

https://web.archive.org/web/20110721055521/http://blast.ncbi.nlm.ni

h.gov/Blast.cgi?CMD=Web&PAGE_TYPE=BlastDocs

c.   Pages 4-22 of Exhibit 1064 ("Blast Program Selection Guide") are a

true and correct copy of the web page available from the following

URL:

https://web.archive.org/web/20110721055500/http://blast.ncbi.nlm.ni

h.gov/Blast.cgi?CMD=Web&PAGE_TYPE=BlastDocs&DOC_TYPE

=ProgSelectionGuide

d.   Pages 23-28 of Exhibit 1064 ("BLASTP Suite") are a true and correct

copy of the web page available from the following URL:

https://web.archive.org/web/20110728070830/http://blast.ncbi.nlm.ni

h.gov/Blast.cgi?PROGRAM=blastp&BLAST_PROGRAMS=blastp&

PAGE_TYPE=BlastSearch&SHOW_DEFAULTS=on&LINK_LOC=

blasthome

8.   Exhibit 1065 is a true and correct copy of a set of web pages available

from the Internet Archive at the URLs listed below:

a.   Pages 1-3 of Exhibit 1065 ("Clustal Omega") are a true and correct

copy of the web page available from the following URL:

https://web.archive.org/web/20111022151531/http://www.clustal.org/

omega/

b.   Pages 4-13 of Exhibit 1065 ("Introduction") are a true and correct

copy of the web page available from the following URL:

https://web.archive.org/web/20120110130931/http://www.clustal.org/

omega/README

9.   Exhibit 1066 is a true and correct copy of a set of web pages available

from the Internet Archive at the URLs listed below:

a.   Pages 1-2 of Exhibit 1066 ("SWISS-MODEL") are a true and correct

copy of the web page available from the following URL:

https://web.archive.org/web/20110519141121/http://swissmodel.expa

sy.org/?pid=smh01&uid=&token=

b.   Pages 3-4 of Exhibit 1066 ("Introduction to SWISS-MODEL

Workspace") are a true and correct copy of the web page available

from the following URL:

https://web.archive.org/web/20110519140410/http://swissmodel.expa

sy.org/?pid=smd11&uid=&token=

c.   Pages 5-12 of Exhibit 1066 ("Help – Introduction to SWISS-MODEL

Workspace") are a true and correct copy of the web page available

from the following URL:

https://web.archive.org/web/20110519144707/http://swissmodel.expa

sy.org/?pid=smd02&uid=&token=

d.   Pages 13-24 of Exhibit 1066 ("Tutorial – Introduction") are a true and

correct copy of the web page available from the following URL:

https://web.archive.org/web/20110519144916/http://swissmodel.expa

sy.org/?pid=smd03&uid=&token=

e.   Pages 25-26 of Exhibit 1066 ("SwissModel Automatic Modelling

Mode") are a true and correct copy of the web page available from the

following URL:

https://web.archive.org/web/20110519141354/http://swissmodel.expa sy.org/workspace/index.php?func=modelling_simple1

f.   Pages 27-28 of Exhibit 1066 ("Protein Structure & Model Assessment

Tools") are a true and correct copy of the web page available from the

following URL:

https://web.archive.org/web/20110519144444/http://swissmodel.expa sy.org/workspace/index.php?func=tools_structureassessment1&userid =USERID&token=TOKEN

g.   Pages 29-38 of Exhibit 1066 ("Template Library – Introduction to

SWISS-MODEL Workspace") are a true and correct copy of the web

page available from the following URL:

https://web.archive.org/web/20110925072951/http://swissmodel.expa sy.org/workspace/index.php?func=special_help&=#QMEAN6

h.   Pages 39-42 of Exhibit 1066 ("QMEAN Server – Quick Help") are a

true and correct copy of the web page available from the following

URL:

https://web.archive.org/web/20110924165101/http://swissmodel.expa sy.org/qmean/cgi/index.cgi?page=help

i.   Pages 43-44 of Exhibit 1066 ("Visualisation") are a true and correct

copy of the web page available from the following URL:

https://web.archive.org/web/20110519144341/http://swissmodel.expa
sy.org/repository/?pid=smd08

10.   Exhibit 1067 is a true and correct copy of a set of web pages available
from the Internet Archive at the URLs listed below:

a.   Page 1 of Exhibit 1067 ("PyMol") is a true and correct copy of the
web page available from the following URL:
https://web.archive.org/web/20110701072314/http://pymol.org/

b.   Pages 2-3 of Exhibit 1067 ("Support") are a true and correct copy of
the web page available from the following URL:
https://web.archive.org/web/20110709092136/http://www.pymol.org/
support

c.   Pages 4-5 of Exhibit 1067 ("PyMOL Wiki") are a true and correct
copy of the web page available from the following URL:
https://web.archive.org/web/20110716184103/http://www.pymolwiki.
org/index.php/Main_Page

d.   Pages 6-7 of Exhibit 1067 ("Commands") are a true and correct copy
of the web page available from the following URL:
https://web.archive.org/web/20110714225113/http://www.pymolwiki.
org/index.php/Category:Commands

e.   Page 8 of Exhibit 1067 ("Center") is a true and correct copy of the

web page available from the following URL:

https://web.archive.org/web/20110529094111/http://www.pymolwiki.

org/index.php/Center

f.   Pages 9-12 of Exhibit 1067 ("Color") are a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20110529095125/http://www.pymolwiki.

org/index.php/Color

g.   Pages 13-14 of Exhibit 1067 ("Create") are a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20110404080403/http://www.pymolwiki.

org/index.php/Create

h.   Page 15 of Exhibit 1067 ("Disable") is a true and correct copy of the

web page available from the following URL:

https://web.archive.org/web/20110809113427/http://www.pymolwiki.

org/index.php/Disable

i.   Page 16 of Exhibit 1067 ("Enable") is a true and correct copy of the

web page available from the following URL:

https://web.archive.org/web/20110809113452/http://www.pymolwiki.

org/index.php/Enable

j. Pages 17-18 of Exhibit 1067 ("Extend") are a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20111013065541/http://www.pymolwiki.

org/index.php/Extend

k. Pages 19-21 of Exhibit 1067 ("Get Area") are a true and correct copy

of the web page available from the following URL:

https://web.archive.org/web/20110515092633/http://www.pymolwiki.

org/index.php/Get_Area

l. Pages 22-23 of Exhibit 1067 ("Get Model") are a true and correct

copy of the web page available from the following URL:

https://web.archive.org/web/20071024002140/http://www.pymolwiki.

org/index.php/Get_Model

m. Pages 24-25 of Exhibit 1067 ("Hide") are a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20110523082224/http://www.pymolwiki.

org/index.php/Hide

n. Pages 26-27 of Exhibit 1067 ("Select") are a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20110714221710/http://www.pymolwiki.

org/index.php/Select

o.   Pages 28-29 of Exhibit 1067 ("Set") are a true and correct copy of the

web page available from the following URL:

https://web.archive.org/web/20101006204019/http://www.pymolwiki.

org/index.php/Set

p.   Page 30 of Exhibit 1067 ("Set Name") is a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20110426091639/http://www.pymolwiki.

org/index.php/Set_Name

q.   Pages 31-32 of Exhibit 1067 ("Show") are a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20110714224117/http://www.pymolwiki.

org/index.php/Show

r.   Pages 33-39 of Exhibit 1067 ("Cartoon") are a true and correct copy

of the web page available from the following URL:

https://web.archive.org/web/20110728104502/http://www.pymolwiki.

org/index.php/Cartoon

s.   Pages 40-41 of Exhibit 1067 ("Lines") are a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20110522111856/http://www.pymolwiki.

org/index.php/Lines

t.   Pages 42-44 of Exhibit 1067 ("Spheres") are a true and correct copy

of the web page available from the following URL:

https://web.archive.org/web/20110809121448/http://www.pymolwiki.

org/index.php/Spheres

u.   Pages 45-46 of Exhibit 1067 ("Sticks") are a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20110522120033/http://www.pymolwiki.

org/index.php/Sticks

v.   Pages 47-51 of Exhibit 1067 ("Surface") are a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20110607231738/http://www.pymolwiki.

org/index.php/Surface

w.   Page 52 of Exhibit 1067 ("Plugins") is a true and correct copy of the

web page available from the following URL:

https://web.archive.org/web/20110728104325/http://www.pymolwiki.

org/index.php/Category:Plugins

x.   Pages 53-57 of Exhibit 1067 ("APBS") are a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20110728103647/http://www.pymolwiki.

org/index.php/APBS

y.   Page 58 of Exhibit 1067 ("TOPTOC") is a true and correct copy of

the web page available from the following URL:

https://web.archive.org/web/20110606042538/http://www.pymolwiki.

org/index.php/TOPTOC

z.   Page 59 of Exhibit 1067 ("Biochemical Properties") is a true and

correct copy of the web page available from the following URL:

https://web.archive.org/web/20110610033151/http://www.pymolwiki.

org/index.php/Category:Biochemical_Properties

aa.   Page 60 of Exhibit 1067 ("Nonstandard Amino Acids") is a true and

correct copy of the web page available from the following URL:

https://web.archive.org/web/20101129073634/http://www.pymolwiki.

org/index.php/Nonstandard_Amino_Acids

bb.   Pages 61-62 of Exhibit 1067 ("Mutagenesis") are a true and correct

copy of the web page available from the following URL:

https://web.archive.org/web/20101121002000/http://www.pymolwiki.

org/index.php/Mutagenesis

I, Jeffrey P. Kushan, do hereby declare and state, that all statements made

herein of my own knowledge are true and that all statements made on information

and belief are believed to be true; and further that these statements were made

with the knowledge that willful false statements and the like so made are

punishable by fine or imprisonment, under Section 1001 of Title 18 of the United

States Code.

Dated: January 17, 2025   Respectfully Submitted,

                                                  /Jeffrey P. Kushan

                                                  Jeffrey P. Kushan

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                                                  Washington D.C. 20005