Exhibit 1

<u>Trials@uspto.gov</u> 571-272-7822

Paper No. 93 Entered: October 26, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., CELLTRION, INC., and APOTEX, INC., Petitioners,

v.

REGENERON PHARMACEUTICALS INC., Patent Owner.

IPR2021-00880 (Patent 9,669,069 B2)¹ IPR2021-00881 (Patent 9,254,338 B2)²

Record of Oral Hearing Held: August 10, 2022³

Before ERICA A. FRANKLIN, JOHN G. NEW, and SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

³ The consolidated hearing for these cases does not indicate that IPR2021-00880 and IPR2021-00881 have been joined.



¹ IPR2022-00257 and IPR2022-00301 have been joined with this proceeding.

² IPR2022-00258 and IPR2022-00298 have been joined with this proceeding.

Case 1:22-cv-00061-TSK-JPM Document 505-2 Filed 05/26/23 Page 3 of 75 PageID #:

IPR2021-00880 (Patent 9,669,069 B2) IPR2021-00881 (Patent 9,254,338 B2)

APPEARANCES:

ON BEHALF OF THE PETITIONER:

NEIL B. MCGLAUGHLIN, PH.D. RMMS Legal 6 West Hubbard Street Chicago, Illinois 60654 (703)-943-6084 nmcglaughlin@rmmslegal.com

ON BEHALF OF THE PATENT OWNER:

DEBORAH FISHMAN, ESQ. Arnold & Porter Kaye Scholer LLP 601 Massachusetts Avenue NW Washington, DC 20001 202-942-6828 deborah.fishman@arnoldporter.com

The above-entitled matter came on for hearing on Wednesday, August 10, 2022, commencing at 2:00 p.m. EST, in Hearing Room D.



Case 1:22-cv-00061-TSK-JPM Document 505-2 Filed 05/26/23 Page 4 of 75 PageID #: 40063

IPR2021-00880 (Patent 9,669,069 B2) IPR2021-00881 (Patent 9,254,338 B2)

1	PROCEEDINGS
2	
3	2:00 p.m.
4	JUDGE NEW: Good afternoon. Welcome to the Board. My name
5	is Judge New. I am joined today by Judge Mitchell and remotely by Judge
6	Franklin.
7	We are convened to hear oral arguments in the matter of IPR2021-
8	00880 and 00881. This hearing relates to claims 1 to 12 of US Patent
9	9,669,069 B2 in the 00880 IPR; and claims 1, 3 to 11, 13, 14, 16 to 24, and
0	26 of US Patent 9,254,338 B2 in the 00881 IPR.
1	Consistent with the hearing order, each party has a total of 60
2	minutes for its presentation. Petitioner may reserve a portion of their time to
.3	respond to arguments presented by Patent Owner. Patent Owner has also
4	been authorized to reserve a portion of time for rebuttal.
.5	Please be mindful that a court reporter is transcribing this hearing
.6	and there is no shared display for demonstrative exhibits for Judge Franklin,
7	who is with us remotely. So please, when referring to a particular
.8	demonstrative exhibit, identify it clearly by number so that she can follow
9	along with all of us here.
20	We're in receipt of the parties' objections to various evidence and
21	Petitioner's motion to exclude. However, we will reserve ruling upon the
22	objections and motions at this time.
23	Lastly, I'd like to remind you all that there are a number of
24	documents and exhibits under seal in these proceedings, and that this hearing
25	and trial transcript will be available to the public. I therefore caution



Case 1:22-cv-00061-TSK-JPM Document 505-2 Filed 05/26/23 Page 5 of 75 PageID #: IPR2021-00880 (Patent 9,669,069 B2) IPR2021-00881 (Patent 9,254,338 B2) counsel against discussing or raising any matter that may be under seal and considered confidential. And with that, Counsel for Petitioner, you may proceed after introducing yourself and indicating any time you would like to reserve for rebuttal. MR. McGLAUGHLIN: Thank you, Your Honors. Neil McGlaughlin on behalf of Petitioners, Mylan Pharmaceuticals and the joint parties. We would like to reserve 15 minutes of our time for rebuttal. We also want to bring the Board's attention to, in case you didn't receive it, the corrected exhibits that Petitioner filed. Do you have copies of those? JUDGE NEW: We do, yes. Thank you very much. MR. McGLAUGHLIN: The '069 patent claims are directed to a prior art PRN dosing regimen that was in use by ophthalmologists when administering anti-VEGF agents long before the filing date of the '069 patent. The '069 claims set forth the same regimen using a prior art molecule, aflibercept, also known as VEGF Trap-Eye, a molecule of known structure and sequence. Petitioner has set forth in this proceeding clear, straightforward grounds of anticipation based on disclosures of use of VEGF

Trap-Eye in PRN dosing clinical trials, one example of which is shown here on slide 2.

This is from Exhibit 1006, the Dixon reference, from page 1576, the disclosure of the CLEAR-IT-2 Phase II trial in which VEGF Trap-Eye, also



1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

