

Exhibit 1

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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*.

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

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

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

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

APPEARANCES:

ON BEHALF OF THE PETITIONER:

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

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1 P R O C E E D I N G S

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
10 26 of US Patent 9,254,338 B2 in the 00881 IPR.

11 Consistent with the hearing order, each party has a total of 60
12 minutes for its presentation. Petitioner may reserve a portion of their time to
13 respond to arguments presented by Patent Owner. Patent Owner has also
14 been authorized to reserve a portion of time for rebuttal.

15 Please be mindful that a court reporter is transcribing this hearing
16 and there is no shared display for demonstrative exhibits for Judge Franklin,
17 who is with us remotely. So please, when referring to a particular
18 demonstrative exhibit, identify it clearly by number so that she can follow
19 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

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1 counsel against discussing or raising any matter that may be under seal and
2 considered confidential.

3 And with that, Counsel for Petitioner, you may proceed after
4 introducing yourself and indicating any time you would like to reserve for
5 rebuttal.

6 MR. McGLAUGHLIN: Thank you, Your Honors. Neil
7 McGlaughlin on behalf of Petitioners, Mylan Pharmaceuticals and the joint
8 parties.

9 We would like to reserve 15 minutes of our time for rebuttal.

10 We also want to bring the Board's attention to, in case you didn't
11 receive it, the corrected exhibits that Petitioner filed. Do you have copies of
12 those?

13 JUDGE NEW: We do, yes. Thank you very much.

14 MR. McGLAUGHLIN: The '069 patent claims are directed to a
15 prior art PRN dosing regimen that was in use by ophthalmologists when
16 administering anti-VEGF agents long before the filing date of the '069
17 patent.

18 The '069 claims set forth the same regimen using a prior art
19 molecule, aflibercept, also known as VEGF Trap-Eye, a molecule of known
20 structure and sequence. Petitioner has set forth in this proceeding clear,
21 straightforward grounds of anticipation based on disclosures of use of VEGF
22 Trap-Eye in PRN dosing clinical trials, one example of which is shown here
23 on slide 2.

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

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