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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, 2022[3]

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

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[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.

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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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PROCEEDINGS

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2:00 p.m.

JUDGE NEW: Good afternoon. Welcome to the Board. My name is Judge New. I am joined today by Judge Mitchell and remotely by Judge Franklin.

We are convened to hear oral arguments in the matter of IPR2021-00880 and 00881. This hearing relates to claims 1 to 12 of US Patent 9,669,069 B2 in the 00880 IPR; and claims 1, 3 to 11, 13, 14, 16 to 24, and 26 of US Patent 9,254,338 B2 in the 00881 IPR.

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

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

We're in receipt of the parties' objections to various evidence and Petitioner's motion to exclude. However, we will reserve ruling upon the objections and motions at this time.

Lastly, I'd like to remind you all that there are a number of documents and exhibits under seal in these proceedings, and that this hearing and trial transcript will be available to the public. I therefore caution

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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

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known as aflibercept, was used to treat patients, both A and B, using a series of monthly loading doses followed by PRN dosing.

Similar disclosures are found in the Heier 2009 reference, which serves as our Ground 1 reference. That's Exhibit 1020.

On slide 3 is set forth our Ground 3 reference, the April 2009 press release from Regeneron, which disclosed the VEGF Trap-Eye Phase III CRVO trial using PRN dosing after a series of six monthly loading doses. In other words, an initial dose followed by one or more secondary doses.

Slide 4, Petitioner's asserted art references cover each and every limitation of the claims. It's undisputed in these proceedings that the references disclosed the dosing regimen steps and the molecule VEGF Trap-Eye, also known as aflibercept. The dosing steps are indicated here on this slide in the green highlighting.

The sole dispute at issue in these proceedings centers around the sequence. However, as we'll show, Patent Owner's arguments in this regard should be given no weight.

At this point, I would like to jump ahead real quick to slide 10 just to show you the sequence that we're talking about. This is actually an alignment that we put into the record as Exhibit 1122. This shows an alignment of the '069 and '338 claimed sequences. This is the sequence from that last wherein of claim 1 of each of the patents.

The top line in this alignment is that of the '069 and '338 claimed sequence. The next line down is the sequence of the prior art, 2006 WHO Drug Information aflibercept sequence. And then the lines below that are the prior art '758 and '959 patent sequences, showing that these sequences

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