

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD
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5
6 MYLAN PHARMACEUTICALS, INC.,
MSN LABORATORIES PRIVATE LTD.,
and MSN PHARMACEUTICALS, INC.,

7 Petitioners,

8 v.

9 BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

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12 Case No. IPR 2022-00722

Patent 7,041,786

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15 Telephone Conference held on:

16 August 17, 2023

3:02 p.m.

17
18 Before:

19 Judge Michael Valek

Judge Tina Hulse

20 Judge Cynthia Hardman

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23 MYLAN EXHIBIT - 1076

24 Mylan Pharmaceuticals, Inc. v. Bausch Health Ireland, Ltd.

25 IPR2022-00722

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APPEARANCES:

FOR THE PETITIONER: JAD A. MILLS, Esquire
Wilson, Sonsini, Goodrich & Rosatio

FOR THE PATENT OWNER: JUSTIN HASFORD, Esquire
Finnegan, Henderson, Farabow,
Garrett & Dunner

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

2 JUDGE VALEK: I'd like to have parties introduce
3 themselves beginning with the petitioner.

4 MR. MILLS: This is Jad Mills from Wilson Sonsini on
5 behalf of Petitioner Mylan. On the call we have Rick Torczon
6 and Tasha Thomas.

7 JUDGE VALEK: Okay. Who is on the line for patent
8 owner.

9 MR. HASFORD: Your Honor, for patent owner, this is
10 Justin Hasford of Finnegan here and I'm also joined by my
11 partner, Joshua Goldberg.

12 JUDGE VALEK: Okay. Well, we're here today regarding
13 patent owner's request to submit supplemental information.

14 Mr. Hasford, before you get into the substance of your
15 argument, can you just briefly identify what it is you're
16 seeking to submit as supplemental information in this
17 proceeding.

18 MR. HASFORD: Certainly, Your Honor. We're seeking to
19 submit the expert report of Dr. Sunny Zhou that we contend sets
20 forth position. Looks like the report was served by Mylan in
21 parallel district court with the issue involving the same
22 parties and the same active pharmaceutical ingredient that's at
23 issue here. And it's our position that this expert report of
24 Dr. Zhou sets forth positions that contradict Mylan's arguments
25 in this IPR proceeding.

1 JUDGE VALEK: When was Dr. Zhou's report served on
2 patent owner?

3 MR. HASFORD: It was served July 14th, Your Honor.

4 JUDGE VALEK: And Dr. Zhou is not currently a witness
5 in this IPR proceeding, is that correct?

6 MR. HASFORD: That is correct, Your Honor.

7 JUDGE VALEK: So, it kind of goes without saying, but
8 patent owner's request for supplemental information comes very
9 late in this proceeding. But, Mr. Hasford, you can have a few
10 minutes to explain why patent owner believes it is in the
11 interest of justice to allow this information into the record at
12 this point.

13 MR. HASFORD: Certainly, Your Honor. Specifically, in
14 this IPR proceeding, Mylan is arguing obviousness of the 786
15 patent claims. And Mylan and it's IPR expert, Dr. Blake
16 Peterson have argued that topoisomerism was not a problem that
17 would have persuaded a person of ordinary skill in the art from
18 selecting human uroganylin, a unique compound, and modifying it
19 to make the claimed Plecanatide compound with a reasonable
20 expectation of success.

21 And point out, Your Honors, that Dr. Peterson presents
22 his opinion throughout Section 3(b) of his second declaration.
23 More specifically, in paragraph 31 of his second declaration,
24 Dr. Peterson opines that with respect to topoisomerism
25 associated with human uroganylin, quote, a person of ordinary

1 skill in the art would not expect this to have a materially
2 adverse impact of its efficacy, end quote.

3 And Mylan repeatedly cites this opinion from Dr.
4 Peterson in its reply brief, Your Honor, and in the final oral
5 hearing, Mr. Mills on behalf of Mylan stated, quote,
6 topoisomeric interconversion is not a credible concern, end
7 quote.

8 Now, however, Your Honor, in the parallel district
9 court case, Mylan and Dr. Zhou just argued that topoisomerism in
10 fact was a long known property with human uroguanylin, because
11 one topoisomer of human uroguanylin was, quote, practically
12 inactive, end quote.

13 This is exactly the opposite of Mylan's and Dr.
14 Peterson's argument in this IPR proceedings, Your Honors. And
15 it's consistent with patent owner's and Dr. Davies' position
16 that human uroguanylin would not have been a suitable choice and
17 a lead compound for drug development. Dr. Zhou presents this
18 opinion, at least, six times in his expert report in the
19 district court case, Your Honors, and Dr. Zhou relies on some of
20 the same prior art, including the Chino reference that Mylan and
21 Dr. Peterson address at this IPR proceeding.

22 Mylan served the expert report of Dr. Zhou a full
23 month after final oral hearing in this IPR proceeding. Patent
24 owner could not obtain this new concession from Mylan earlier,
25 Your Honors, and respectfully submits the Board's consideration

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