

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC., MSN LABORATORIES
PRIVATE LTD. and MSN PHARMACEUTICALS INC.,
Petitioners,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

IPR2022-00722¹
Patent 7,041,786 B2

Held: June 14, 2023

Before TINA E. HULSE, CYNTHIA M. HARDMAN, and
MICHAEL A. VALEK, *Administrative Patent Judges*.

¹ IPR2023-00016 has been joined with this proceeding.

IPR2022-00722
Patent 7,041,786 B2

APPEARANCES:

ON BEHALF OF THE PETITIONER:

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Tasha Thomas
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Andrew Larsen
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ON BEHALF OF THE PATENT OWNER:

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The above-entitled matter came on for hearing on Wednesday
June 14, 2023, commencing at 2:00 p.m. ET, via video teleconference.

P R O C E E D I N G S

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JUDGE VALEK: I'm Judge Valek, and with me on the panel are Judges Hulse and Hardman. This is the oral hearing for IPR2022-00722, and IPR2023-00016, which has been joined with this proceeding. The Petitioners are Mylan Pharmaceuticals, MSN Laboratories, and MSN Pharmaceuticals. The Patent Owner is Bausch Health Ireland. This hearing is open to the public, and a transcript will be made of record. Counsel for Petitioner, would you please identify who is present for the Petitioner and who will be speaking on its behalf?

MR. MILLS: Yes, this is Jad Mills present for the Petitioner. I'm lead counsel. I will be speaking on behalf of the Petitioner, Mylan, and with me in the conference room I have Rick Torczon, and Tasha Thomas.

JUDGE VALEK: Thank you. Counsel for Patent Owner, would you please identify who is present for Patent Owner and who will be speaking on its behalf?

MR. HASFORD: Yes, Your Honor. It's Justin Hasford here of Finnegan, on behalf of Patent Owner. I'm also joined by my partner, Kassandra Officer of Finnegan for the Patent Owner. We plan to divide our argument. At the present time we plan to have 50 minutes have been reserved, 10 minutes for rebuttal, and I plan to speak for roughly the first 40 minutes, and she plans to speak for the next 10 on objective indicia.

JUDGE VALEK: Okay. Now I know that they're in an understudy role, but do we have any counsel for MSN on the line?

MR. LARSEN: Yes, this is Andrew Larsen. I'm lead counsel for Joint Petitioner, MSN. We're the joined Petitioners. I believe with me

1 listening in is our back up counsel, Melissa Hayworth, as well.

2 JUDGE VALEK: Okay. Thank you, Mr. Larsen. As indicated
3 in our trial order, each side will have the 60 minutes to present its case.
4 Petitioner will present its case first, followed by the Patent Owner. Counsel
5 for Petitioner, would you please -- would you like to reserve any time for
6 rebuttal?

7 MR. MILLS: Yes. We would like to reserve 25 minutes for
8 rebuttal.

9 JUDGE VALEK: Counsel for Patent Owner, would you like to
10 reserve any of your time to follow Petitioner's rebuttal?

11 MR. HASFORD: Yes, Your Honor, we plan to reserve 10
12 minutes.

13 JUDGE VALEK: Okay. Before we begin the parties'
14 presentations, I'd like to go over a few things. First, this is an all-video
15 remote hearing. Our primary concern is your right to be heard. If at any
16 time during the hearing you encounter technical or other difficulties that you
17 feel undermine your ability to represent your client, please let us know
18 immediately. To help with the transcript, we ask that you identify yourself
19 when you speak, and mute your microphone when not speaking. Also, let's
20 all do our best to remember to pause and try to avoid talking over each other.
21 The panel has access to the entire record, as well as the demonstratives. If
22 you wish, you can share your screen so that you can control the particular
23 demonstratives on display.

24 But please make sure that you orally announce the demonstrative
25 number or the particular page of the paper or exhibit you're referring to so

1 that the record is actually on the transcript. In addition to the issues that are
2 presented by the Petition, each side has filed a motion to exclude certain
3 exhibits and testimony from this trial. Those motions are Papers 54 and 55.
4 We expect to rule on those motions in our final written decision. There are
5 no other motions pending, so you're free to allocate your time today as you
6 choose, but it is the panel's expectation that the arguments will focus
7 primarily on the grounds in the Petition. Does either side have any questions
8 before we begin?

9 MR. MILLS: No, Your Honor.

10 MR. HASFORD: None from us, Your Honor.

11 JUDGE VALEK: Okay. Mr. Mills, you may begin Petitioner's
12 argument.

13 MR. MILLS: Thank you, Your Honors. This is a
14 straightforward case of obviousness. There was good reason to look to the
15 body's natural laxative peptide, which is uroguanylin, and which was
16 designed through millions of years of evolution to add fluid to the intestines
17 naturally and gently. And to make one conservative substitution, it was
18 specifically suggested by the uroguanylin consensus sequence disclosed in
19 the prior art. Having established good reason to make the claimed peptide,
20 there is no dispute that there was a reasonable expectation of success for
21 making the claimed peptide.

22 Looking now at slide 2. In the face of the straightforward case,
23 Bausch peppers the record with misdirected arguments, but each of them is
24 riddled with errors. As just a couple of examples, I want to talk with you a
25 little bit later today about the mischaracterization of the Hamra and Li

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