

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMA USA, INC.,
Petitioner,

v.

HORIZON PHARMA USA INC., and
NUVO PHARMACEUTICALS (IRELAND)
DESIGNATED ACTIVITY COMPANY,
Patent Owners.

Case IPR2018-00272
Patent 9,393,208 B2

Held: June 14, 2019

Before MICHELLE N. ANKENBRAND, TONI R. SCHEINER, and
DEBRA L. DENNETT, *Administrative Patent Judges*.

Case IPR2018-00272
Patent 9,393,208 B2

APPEARANCES:

ON BEHALF OF THE PETITIONER:

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ON BEHALF OF THE PATENT OWNER:

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The above-entitled matter came on for hearing on Friday, June 14, 2019, commencing at 9:00 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P R O C E E D I N G S

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2 JUDGE ANKENBRAND: You can be seated. Give us a
3 minute to get situated. Is the court reporter ready?

4 THE REPORTER: I am.

5 JUDGE ANKENBRAND: Okay. Let's go on the record. Good
6 morning everyone. We have today our final hearing in IPR 2018-00272
7 between Petitioner Mylan Pharmaceutical and joined Petitioner Dr. Reddy's,
8 and Patent Owners Horizon Pharma USA Inc., and NUVO Pharmaceuticals
9 (Ireland) Designated Activity Company. I'm Judge Ankenbrand. I'm joined
10 today by Judge Scheiner to my right, and by Judge Dennett who is appearing
11 remotely in Austin.

12 Counsel, can you please introduce yourselves and let us know
13 who will be presenting today. We'll start with Petitioner.

14 MR. WHITE: Good morning, Your Honor. Brandon White, Perkins
15 Coie. I'll be presenting today. Also with me is my colleague, Autumn Nero
16 and Rhea Stumming (phonetic).

17 JUDGE ANKENBRAND: Okay. Thank you. Good morning, and
18 for Patent Owner – oh sorry, I forgot about Dr. Reddy's.

19 MR. POLLAK: Alan Pollak with Windels Marx Lane & Mittendorf
20 on behalf of Petitioner Dr. Reddy's.

21 JUDGE ANKENBRAND: All right. Thank you. And for Patent
22 Owner.

23 MS. KRUMPLITSCH: Good morning, Your Honor. My name is
24 Susan Krumplitsch from Cooley LLC on behalf of Patent Owner Horizon,
25 and with me are my colleagues Tom Blinka and Ellen Scordino.

1 MR. GRITTON: Good morning. I'm Jeff Gritton from Baker Botts
2 on behalf of Patent Owner NUVO Pharmaceuticals.

3 JUDGE ANKENBRAND: All right. Thank you and good
4 morning. It's good to have everyone here and we appreciate everyone
5 making the effort to be here today. We set forth our procedure for today's
6 hearing in the Hearing Order but just to remind everyone about the way the
7 hearing will work, each party will have 45 minutes of total time to present
8 arguments. Since Petitioners have the burden of showing unpatentability
9 they'll go first, so Mr. White you'll proceed first followed by Ms.
10 Krumplitsch and I guess Mr. White, would you like to reserve any time for
11 rebuttal?

12 MR. WHITE: Yes, ten minutes please.

13 JUDGE ANKENBRAND: Ten minutes. Okay. Let me set the time.
14 Objections are only to be made during your own argument time with one
15 exception. I don't think there's anything -- is there anything in the docket
16 that's under seal?

17 MS. KRUMPLITSCH: Your Honor, there are a few exhibits that are
18 under seal but I don't believe that will be discussed.

19 JUDGE ANKENBRAND: Okay. So that would be the only
20 exception, if someone began to discuss something that was filed with a
21 Motion to Seal and provisionally sealed then you can stand up and object,
22 but other than that objections are just made during your own argument time.
23 One more thing before we begin. Keep in mind that Judge Dennett will not
24 be able to view anything that you project onto the screen so when your refer
25 to a demonstrative or an exhibit please state for the record the slide number
26 if it's a demonstrative and if it's an exhibit the exhibit number and page

1 number that you're referring to. Of course it's also important for the clarity
2 of the transcript.

3 Also because our microphones have limitations Judge Dennett won't
4 be able to hear you if you stray too far from the podium so just keep that in
5 mind. I'll try to give everyone a warning when you're reaching the end of
6 argument time. I don't always remember but there is a light bar up here and
7 the clock is behind me so you'll be able to know if you're reaching the end or
8 if you've gone into your rebuttal time, Mr. White, and I think Ms.
9 Krumplitsch, I'll ask you when you get up to speak but there's time for a
10 brief surrebuttal as well. Does anyone have questions? Counsel for
11 Petitioner.

12 MR. WHITE: No, Your Honor.

13 JUDGE ANKENBRAND: For Patent Owner?

14 MR. KRUMPLITSCH: No, Your Honor.

15 JUDGE ANKENBRAND: All right. So the last thing I'd like to
16 remind the parties is that this hearing is open to the public and a full
17 transcript of the hearing will be made part of the record. So with that, I
18 think we're ready to begin. Mr. White, I'll start the clock when you start
19 your argument.

20 MR. WHITE: So good morning, Your Honors. Brandon White of
21 Perkins Coie on behalf of Mylan. Looking at slide 3 in our demonstratives
22 the '208 patent, claim 1 is a long claim and it claims essentially three things;
23 a.m., p.m., twice daily dosing of a combined Naproxen and Esomeprazole
24 formulation, 500 milligrams of Naproxen, 20 milligrams of Esomeprazole,
25 two doses that were known in the art and FDA approved, and then the bulk
26 of the claim -- about two thirds of the claim -- as shown in pink on slide 3

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