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IPR2015-01773, Paper No. 35

IPR2015-01775, Paper No. 36

January 23, 2017

RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,

Petitioner,

v.

POZEN INC.,

Patent Owner.

Case IPR2015-01773 (Patent 8,858,996 B2)

Case IPR2015-01775 (Patent 8,865,190 B2)

Technology Center 1600

Oral Hearing Held: Tuesday, November 29, 2016

Before: TONI R. SCHEINER, LORA M. GREEN, and
JACQUELINE WRIGHT BONILLA, Administrative Patent Judges.

The above-entitled matter came on for hearing on Tuesday,
November 29, 2016, at 9:18 a.m., Hearing Room B, taken at the U.S. Patent
and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

REPORTED BY: RAYMOND G. BRYNTESON, RMR,
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P R O C E E D I N G S

(9:18 a.m.)

JUDGE BONILLA: Good morning. This is a trial hearing for two inter partes review cases, IPR2015-01773 and IPR2015-01775 between Petitioner Lupin Limited and Lupin Pharmaceuticals Inc. and Patent Owner Pozen Inc., the owner of U.S. patents at issue in the two respective cases, that is Patent Number 8,858,996 at issue in the 1773 case and also 8,865,190, which is at issue in the 1775 case.

We will just discuss briefly a few administrative matters before we begin. Just as a reminder to the people presenting, if you are presenting any demonstratives, if you could actually identify the slide by number as you are going through, that makes it easier for people to follow the transcript later.

And as you know, per our order, each side has 60 minutes to present their argument. Because Petitioner has the burden to show unpatentability of the claims, they will go first, followed by Patent Owner who have the full 60 minutes.

Petitioner, you may reserve rebuttal time so you can take some now and some later if you like. But during your rebuttal time you can only respond to arguments that Patent Owner makes in their portion of the oral hearing.

1 At this time I would like counsel to introduce
2 themselves and who you have with you, beginning with
3 Petitioner.

4 MR. PATEL: Good morning, Your Honor. My
5 name is Sailesh Patel. Along with me is my colleague John
6 Hsu and Stephen Smith and Helen Ji from the Schiff Hardin
7 law firm.

8 MR. MONROE: Good morning, Your Honor.
9 James Monroe from Finnegan on behalf of Pozen, and with me
10 today is Danielle Pfifferling.

11 JUDGE BONILLA: And, Petitioner, would you
12 like to reserve any time?

13 MR. PATEL: Yes, Your Honor. We would like to
14 reserve 15 minutes for rebuttal.

15 JUDGE BONILLA: Okay. You may begin.

16 MR. PATEL: Good morning, Your Honors. And
17 as I said, my name is Sailesh Patel and we are delighted to be
18 here today on the IPR petitions for the '996 and '190 patents.

19 Here on slide 2 is a brief outline of what we would
20 like to discuss today. The Panel has granted a petition on
21 some of the claims in both patents and so we have a section on
22 the fact that the prior art discloses each element of the
23 asserted claims, but unless the Panel has any specific
24 questions about where certain elements are located in the prior
25 art I will probably skip over to the crux of the issues here,

1 which is whether the challenged claims would have been
2 obvious.

3 And looking at the prior art that was used, the
4 '225, the WO '185 and Chandramouli, we believe it shows all
5 of the elements in the claim, provides the motivation to
6 replace two ingredients, misoprostol with the esomeprazole,
7 that's in the patent in suit, and replacing naproxen with the
8 NSAIDS that are disclosed in the '225 patent.

9 And we believe that a POSA would have had a
10 reasonable expectation of success in making such a
11 formulation. And to the extent Patent Owner raises any
12 secondary considerations, they were not raised in the response
13 to the petition, but to the extent that any secondary
14 considerations are raised, I will address those in rebuttal.

15 So looking at slide 4, this is the '996 patent
16 entitled "Pharmaceutical Compositions for the Coordinated
17 Delivery of NSAIDS." The priority date here is June 1, 2001,
18 and the claims are directed to the tablet pharmaceutical
19 composition, comprising of naproxen in a certain amount,
20 esomeprazole in a certain amount, and it has a feature wherein
21 at least a portion of said esomeprazole is released regardless
22 of the pH, and release of at least a portion of naproxen is
23 inhibited until the pH of the medium goes to 3.5 or higher.

24 The '190 patent, they are part of the same family,
25 that also has a priority date of June 1, 2001. And this claim is

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