

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC.,
Petitioner,

v.

RB PHARMACEUTICALS LIMITED,
Patent Owner.

Case IPR2014-00325
Patent 8,475,832 B2

Held: March 20, 2015

BEFORE: ZHENYU YANG, JACQUELINE WRIGHT BONILLA,
and TONI R. SCHEINER, *Administrative Patent Judges*.

The above-entitled matter came on for hearing on Friday,
March 20, 2015, commencing at 1:01 p.m., at the U.S. Patent and
Trademark Office, 600 Dulany Street, Alexandria, Virginia.

Case IPR2014-00325
Patent 8,475,832 B2

APPEARANCES:

ON BEHALF OF THE PETITIONER:

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ON BEHALF OF PATENT OWNER:

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P R O C E E D I N G S

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JUDGE YANG: Good afternoon and welcome everyone. This is the oral hearing in the case of Case Number IPR2014-00325 between Petitioner BioDelivery Sciences International, Inc. and the owner of U.S. Patent Number 8,475,832, RB Pharmaceuticals Limited.

Would counsel please introduce yourselves, please, starting with Petitioner.

MS. HERRITT: My name is Danielle Herritt. I'm representing BioDelivery Sciences.

MS. FREEMAN: My name is Kia Freeman, also representing BioDelivery Sciences.

JUDGE YANG: Thank you. Welcome.

MR. LADOW: Good afternoon, Your Honors. With me at the table here is Magnus Sessunger from my firm, Chris Haley who is helping with the slides and my lead counsel, James Bollinger.

MR. BOLLINGER: Good afternoon, Your Honor.

JUDGE YANG: Thank you. Welcome.

So we have just a couple of administrative matters before we begin. Per our trial hearing order that went out on March 3rd, each party has 45 minutes to present its argument.

In this case, Patent Owner, you didn't file any motion to amend, so we're here just to decide the patentability of the challenged

1 claims. On that issue, Petitioner bears the burden to show
2 unpatentability, so Petitioner will proceed first and followed then by
3 the Patent Owner.

4 Petitioner, you have the option to reserve time for rebuttal,
5 but during your reserved time you can only rebut what the Patent
6 Owner argued.

7 Both parties also submitted demonstratives, so when you
8 discuss the demonstratives, please identify each slide you're referring
9 to by the slide number so that later when we read the transcript it is
10 clear what you were talking about. Okay?

11 Any questions?

12 MR. LADOW: No, Your Honor.

13 JUDGE YANG: Okay. Then, Petitioner, would you like to
14 reserve any time for rebuttal?

15 MS. HERRITT: I think I'll take about 20 minutes on my
16 prima facie case and I'll reserve 25, if needed, for the rebuttal.

17 JUDGE YANG: Okay. Very well. You may begin.

18 Please proceed.

19 MS. HERRITT: Would you like to give them copies of the
20 demonstrative?

21 MS. PROCTOR: May we provide demonstrative to the
22 Board?

23 JUDGE YANG: Whenever you're ready.

1 MS. HERRITT: Thank you. Good afternoon. May it
2 please the Board, my name is Danielle Herritt representing
3 BioDelivery Sciences.

4 Interesting thing about this case, in this case each and every
5 recited limitation of the claims is disclosed in the applied reference,
6 Labtec. RB doesn't refute that. You're going to hear a lot from RB
7 today that the claimed film requires oral transmucosal absorption,
8 perhaps mucoadhesion, perhaps bioequivalence or substantial
9 bioequivalence.

10 But here is the claim, and this is what it says -- there's three
11 parts. There's a preamble, an orally dissolving film formulation, there
12 is the components of the film formulation, buprenorphine and
13 naloxone, and there's a wherein clause which provides some
14 pharmacokinetic ranges, which are to be met.

15 JUDGE YANG: Counsel, in the petition the Petitioner
16 argued that the wherein clause shouldn't be given any patentable
17 weight and the Patent Owner, of course, just disagreed. I don't recall
18 seeing any response in the reply. Does it mean you agree or if not,
19 what are you --

20 MS. HERRITT: I decided to reply to their arguments in the
21 response to be responsive to their arguments. It doesn't matter for the
22 purposes of this, because Labtec has all of these elements. So I
23 decided to spend my time responding to their arguments, but I do not
24 agree.

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