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2 UNITED STATES PATENT AND TRADEMARK OFFICE
3 -----
4 BEFORE THE PATENT TRIAL AND APPEAL BOARD
5 -----

6 BIODELIVERY SCIENCES INTERNATIONAL, INC.

7 Petitioner,

8 v.

9 RB PHARMACEUTICALS LIMITED,

10 Patent Owner.
11 -----

12 Case IPR2014-00325

13 Patent 8,475,832
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16 DEPOSITION OF THOMAS P. JOHNSTON

17 FRIDAY, JANUARY 23, 2015

18 8:30 a.m.
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25 Reported by: Adrienne M. Mignano, RPR
Job Number: 265794

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A P P E A R A N C E S :

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Johnston
T-H-O-M-A-S P. J-O-H-N-S-T-O-N, called as
a witness, having been duly sworn
by a Notary Public, was examined and
testified as follows:
EXAMINATION BY
MS. FREEMAN:
Q Good morning, Professor
Johnston.
A Good morning.
Q Are you feeling okay today?
A Tired.
Q Me too.
Is there anything that you're
aware of that may interfere with your
ability to testify today?
A Only as Mr. Ladow said I take a
little diuretic so I might have to run to
the men's room now and then, but other
than that, no.
Q Professor Johnston, what does
peroral mean?
A Peroral to me means a dosage
form is swallowed for subsequent
absorption in the gastrointestinal tract.

ESQUIRE

1 Johnston

2 Q What is peroral administration?

3 A Well, in my opinion, that means
4 administering a drug substance that
5 ultimately is absorbed from the
6 gastrointestinal tract.

7 Q And how do you know if the drug
8 is absorbed in the GI tract?

9 A Well, one of those factors would
10 be the rate at which the maximum blood
11 concentration is attained, typically
12 that's 90 minutes after gastrointestinal
13 administration of a drug substance.

14 Q For any drug?

15 A For most drugs.

16 Q So you know something has been
17 absorbed in the GI tract if you get your
18 CMAX within 90 minutes?

19 A No, maybe I should clarify. I'm
20 just saying that most drugs that are taken
21 by peroral administration would reach a
22 maximum blood concentration somewhere 60
23 to 90 minutes after swallowing it.
24 Typically the patient ingests some water
25 with that.

1 Johnston

2 Q I feel like we've gotten off
3 track already.

4 My question was how do you know
5 if something has been absorbed in the GI
6 tract?

7 A Well, as I mentioned, just by
8 the time that that maximum blood
9 concentration is achieved, and also if a
10 drug is administered orally and it is
11 subjected to metabolism, typically you
12 know that a drug has been administered
13 that way if you detect the presence of
14 metabolites of that drug.

15 Q Okay.
16 You just said orally
17 administered. Is that the same as
18 perorally administered?

19 A I should have been more
20 specific. I meant PO, peroral, and when I
21 say that I am referring to swallowing the
22 actual drug substance for subsequent
23 absorption typically in the -- when I
24 refer to peroral drug administration for
25 subsequent absorption primarily in the

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