Paper No._____

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BIODELIVERY SCIENCES INTERNATIONAL, INC.
Petitioner

v.

RB PHARMACEUTICALS LIMITED
Patent Owner

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Case No. IPR2014-00325
Patent 8,475,832

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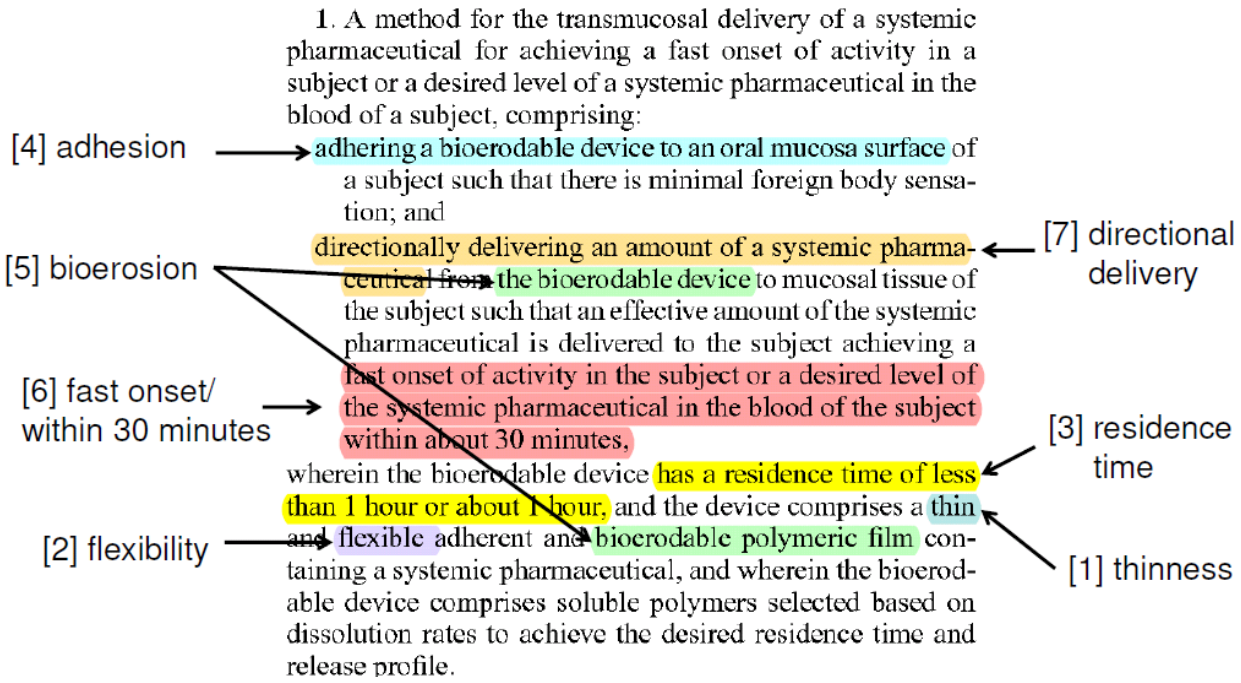
PETITIONER'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE

As explained in the Motion to Exclude, the statements quoted by RB from Exhibit 2043 concern the difficulty in designing a film with *seven* elements *recited* in claims of the unrelated '019 patent, *i.e.*, [1] thinness, [2] flexibility, [3] residence time, [4] adhesion, [5] bioerosion, [6] fast onset/within 30 minutes, and [7] directional delivery. Paper No. 35, at 4. As illustrated below, each of these elements is explicitly recited in claim 1 of the '019 patent:



1. A method for the transmucosal delivery of a systemic pharmaceutical for achieving a fast onset of activity in a subject or a desired level of a systemic pharmaceutical in the blood of a subject, comprising:

adhering a bioerodable device to an oral mucosa surface of a subject such that there is minimal foreign body sensation; and

directionally delivering an amount of a systemic pharmaceutical from the bioerodable device to mucosal tissue of the subject such that an effective amount of the systemic pharmaceutical is delivered to the subject achieving a fast onset of activity in the subject or a desired level of the systemic pharmaceutical in the blood of the subject within about 30 minutes,

wherein the bioerodable device has a residence time of less than 1 hour or about 1 hour, and the device comprises a thin and flexible adherent and bioerodable polymeric film containing a systemic pharmaceutical, and wherein the bioerodable device comprises soluble polymers selected based on dissolution rates to achieve the desired residence time and release profile.

On the other hand, none of these seven elements is recited in the claims challenged in this proceeding, as illustrated by the following comparison of the independent claims:

'019 Patent, Claim 1

1. A method for the transmucosal delivery of a systemic pharmaceutical for achieving a fast onset of activity in a subject or a desired level of a systemic pharmaceutical in the blood of a subject, comprising:

adhering a bioerodable device to an oral mucosa surface of a subject such that there is minimal foreign body sensation; and

directionally delivering an amount of a systemic pharmaceutical from the bioerodable device to mucosal tissue of the subject such that an effective amount of the systemic pharmaceutical is delivered to the subject achieving a fast onset of activity in the subject or a desired level of the systemic pharmaceutical in the blood of the subject within about 30 minutes,

wherein the bioerodable device has a residence time of less than 1 hour or about 1 hour, and the device comprises a thin and flexible adherent and bioerodable polymeric film containing a systemic pharmaceutical, and wherein the bioerodable device comprises soluble polymers selected based on dissolution rates to achieve the desired residence time and release profile.

'832 Patent, Claim 15

15. An orally dissolving film formulation comprising buprenorphine and naloxone, wherein said formulation provides an in vivo plasma profile having a Cmax of between about 0.624 ng/ml and about 5.638 ng/ml for buprenorphine and an in vivo plasma profile having a Cmax of between about 41.04 pg/ml to about 323.75 pg/ml for naloxone.

RB's suggestion in its Opposition—that the claims challenged here somehow claim the same features as those recited in the '019 claims—highlights RB's attempt to rewrite the challenged claims in this proceeding.

For example, in its Motion to Exclude, BDSI correctly pointed out that the claims of the '019 patent share no common claim language with the claims challenged in this proceeding, except for "film" and "profile." Paper No. 35, at 6. Rather than point to any claim language in common or any other relationship between the claims that would make Exhibit 2043 relevant here—neither of which exists—RB simply contends that the '019 patent and '832 patent are both directed to "a film dosage form providing a desired level of a pharmaceutical active to a subject via oral transmucosal absorption…" Paper No. 37, at 6.

This argument is troubling for at least two reasons. First, RB seems to suggest that if the specifications of two patents are directed to the same subject matter—which, in this case, they are not—their claimed subject matter is necessarily the same. There is no support for this contention.

Second, in support of the alleged subject matter in common, RB quotes claim language from claim 1 of the '019 patent, ***but does not quote any language from the claims challenged in this proceeding***. This is because, as illustrated above, the challenged claims in this proceeding do not recite any of the seven recited features at issue in Exhibit 2043.

Obviously aware that the challenged claims do not recite any of these seven features, RB appears to ask this Board to ignore the fundamental principle of claim construction law by ignoring the claim language. Strikingly, RB contends that the fact that the '019 and '832 claims "might use different 'language' does not change [the] fact" that the two patents are allegedly directed to the same thing. Paper No. 37, at 6-7. However:

> The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plan import of its terms.

White v. Dunbar, 119 U.S. 47, 52 (1886). RB seems to be asking the Board to import multiple limitations into the recited claim language in the '832 challenged

claims in order to find some connection between these claims and those of the '019 patent. No such connection exists.

Accordingly, for the reasons explained above and in BDSI's Motion to Exclude (Paper No. 35), RB's Exhibit 2043 should be excluded as inadmissible under Federal Rules of Evidence 401 and 403.

Dated: March 17, 2015

Respectfully submitted,

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