

Paper No. _____

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 No. IPR2014-00325
Patent 8,475,832

PETITIONER'S MOTION TO EXCLUDE

I. INTRODUCTION

Exhibit 2043 is a Patent Owner Response from an unrelated IPR proceeding. It is not relevant to the instant proceeding and RB's use of it only serves to confuse the issues and waste time.

Specifically, RB cites two quotes from Exhibit 2043 and characterizes them as an "agreement" from BDSI about the complexity of making pharmaceutical film generally. This is not the case. Instead, the quotes from Ex. 2043 concern the difficulty of successfully manipulating *seven recited limitations* to practice a *specific claim* in an unrelated patent. None of these seven limitations is recited the claims challenged in the instant IPR. Finally, Exhibit 2043 is not only irrelevant under FRE 401, but RB's submission of it only serves to waste time and confuse the issues, and is inadmissible under FRE 403.

II. BACKGROUND

BDSI timely objected to Exhibit 2043 on November 14, 2014 under Federal Rules of Evidence 401-403. Ex. 1054, Nov. 14, 2014 Petitioner's Objections, at 5.

Exhibit 2043 is a Patent Owner Response filed by a BDSI subsidiary in unrelated IPR2014-00376. RB claims it is not involved in IPR2014-00376. RB has not identified either IPR2014-00376, or the patent challenged in that proceeding—US Patent No. 7,579,019 ("019 patent")—as a related matter in the

instant proceeding. Indeed, the '832 patent and the '019 patent are not related in any way by common disclosure, priority, or provenance. *Compare* Exhibit 1001 *with* Exhibit 1055. And, as illustrated by the sole independent claim of the '019 patent (reproduced below), the claims of the '019 and the claims challenged in the instant proceeding share no common claim language, other than the words “film” and “profile”:

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.

Ex. 1055, '019 patent, at 24:47-67.

RB's reference to Ex. 2043 is on page 50 of Patent Owner's Corrected Response. Paper No. 25 ("POCR"), at 50. RB relies on two partial sentences from Ex. 2043 in an attempt to establish an "agreement" that does not exist:

Petitioner agrees, taking the position, in a proceeding in which it is defending its own patent, that *in designing pharmaceutical films for systemic drug delivery*, "tinkering with even one component may have a significant effect on the entire system . . . the combination of ingredients and desired characteristics requires a delicate balance." Ex. 2043, IPR2014-00376, Paper 22 (October 27, 2014) at 2. "[E]ven small changes to the formulation may have drastic effects on the entire device." *Id.* at 35.

POCR at 50 (emphasis added). But the quotes from Ex. 2043 do not evidence an agreement about "designing pharmaceutical films for systemic drug delivery." On the contrary, the quotes specifically refer to seven recited requirements of claims of an unrelated patent challenged in an unrelated IPR. And, contrary to RB's suggestion, Ex. 2043 is not relevant to the alleged complexity of achieving a combination of unspecified and unclaimed "desired characteristics" and "required objectives." See POCR at 49.

III. ARGUMENT

A. Exhibit 2043 is Not Relevant.

RB quotes the two partial sentences from Exhibit 2043 in an attempt to manufacture an “agreement” between RB and BDSI about the field. However, the quoted language does not concern “designing pharmaceutical films for systemic drug delivery,” generally. Instead, the quoted language—and Exhibit 2043—specifically concerns the *claims* of the ‘019 patent. See, e.g., Ex. 2043 at 1-2, 35. RB has made no effort to argue that the claims of the ‘019 patent are in any way relevant to the challenged claims of the ‘832 patent. See POCR at 49-50. And they are not, as even a cursory review of the ‘019 claims demonstrates. See Ex. 1055, ‘019 patent, at 24:47-26:4.

The quotes instead relate to successfully manipulating seven recited requirements of the ‘019 patent claims, none of which is recited in the challenged ‘832 claims:

[W]hat makes this combination so “remarkable” ... is that combining the disparate requirements of [1] thinness, [2] flexibility, [3] residence time, [4] adhesion, [5] bioerosion, [6] fast onset/desired blood level within about 30 minutes, and [7] directional delivery, was, before Tapolsky, no easy feat.

Ex. 2043 at 1 (bracketed numbers added).

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