

Paper No. _____
Filed March 10, 2015

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

PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION TO
EXCLUDE EXHIBIT 2043

I. Introduction

Patent Owner RB Pharmaceuticals Limited (“Patent Owner”) submits this Opposition to Petitioner’s Motion (Paper 35) to Exclude Exhibit 2043. Patent Owner submits that Ex. 2043 (1) is relevant under F.R.E. 401 and, therefore, admissible under F.R.E. 402 and (2) should not be excluded under F.R.E. 403.

II. Background of Patent Owner’s Reliance on Ex. 2043

In support of Patent Owner’s position that Petitioner failed to meet its burden of establishing that Claims 15-19 of the ‘832 patent were obvious over the combination of Labtec, Birch, and Yang, Patent Owner’s Response asserted that (1) the Petitioner failed to establish that a person skilled in the art would have had a reasonable expectation of successfully combining those references to arrive at the claimed invention, and (2) the proposed combination would have required undue experimentation to arrive at the claimed invention. *See generally* Patent Owner’s Corrected Response, Paper 25, 42-53. Specifically, Patent Owner provided testimony from Dr. Johnston that because “designing pharmaceutical films is a complex art,” “[i]t undoubtedly took extensive research and development . . . [to] design[] the formulation to produce the claimed films.” *Id.* at 49 (citing Ex. 2003 at ¶¶ 110-111, 114-115). Further, Patent Owner submitted that:

As one skilled in the art understands, altering any component of a formulation may have a significant impact on the entire system because the interrelationship of the ingredients and desired

characteristics is complicated.

Id.

To further support its position on the complexity of film design and the sensitivity of desired characteristics, e.g., absorption (or inhibition of absorption) of the active ingredients, to even small changes in the composition of the film formulation, Patent Owner submitted Ex. 2043, which is a patent owner response submitted by Petitioner in IPR2014-00376, to show that Petitioner itself (or at least its admitted subsidiary) previously admitted in another proceeding that, indeed, “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” (Paper 25, 50 (quoting Ex. 2043 at 2)), and “even small changes to the formulation may have drastic effects on the entire device” (*id.* (quoting Ex. 2043 at 35)).

Petitioner, however, chose not to substantively respond to the substance of Patent Owner’s argument in its Reply (Paper 31). Rather, Petitioner now tries to use motion practice to effectively introduce substantive arguments regarding the weight that Ex. 2043 should be afforded – arguments that it did not introduce in its Reply, which is the proper avenue for such arguments.¹

¹ The Board has indicated that a motion to exclude is not an opportunity for a party to supplement the record with arguments regarding the sufficiency of the evidence

Furthermore, Petitioner's argument on relevance is without merit; the Board should be aware that Petitioner is taking a position in an IPR where it is the patent owner that contradicts its position that it takes here as Petitioner. Specifically, Ex. 2043 provides quotes taken straight from Petitioner that Patent Owner uses as evidence of the complexity of designing films to achieve specific characteristics. Petitioner argues that Ex. 2043 is somehow irrelevant to the factual inquiry of whether the limited disclosure of Petitioner's cited references regarding how a person skilled in the art might manipulate certain ingredients to achieve the claimed limitations is insufficient, such that the proposed combination fails to provide a reasonable expectation of success and requires undue experimentation. As discussed below, however, Ex. 2043 is both (1) relevant under F.R.E. 401 and, therefore, admissible under F.R.E. 402, and (2) highly probative as to whether the references provide a reasonable expectation of success or would require undue experimentation with limited, if any, prejudicial effect or danger of confusion or waste of time.

III. Ex. 2043 Is Relevant Under F.R.E. 401

“Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence to prove a particular fact. Office Trial Practice Guide, 77 Fed. Reg. 48765, 48767 (Aug. 14, 2012).

in determining the action.” F.R.E. 401. Here, Ex. 2043 is being used by Patent Owner as evidence of the complexity, sensitivity, and unpredictability of designing a pharmaceutical film with specific characteristics, which is a relevant inquiry in addressing the factual issue of whether the Petitioner has established that a person skilled in the art would have had a reasonable expectation of success in arriving at the claimed invention without undue experimentation.

Ex. 2043 is a Patent Owner Response filed by an admitted subsidiary of Petitioner in another *inter partes* review – IPR2014-00376. There, when defending the validity of its own patent, Petitioner argued that its claimed invention was “remarkable” because of the difficulty of determining the specific combination of ingredients necessary to achieve all of the claimed features. Paper 35, 4 (citing Ex. 2043 at 1). This was because:

Each ingredient and performance characteristic affects the others such that tinkering with even one component may have a significant effect on the entire system. In other words, the combination of ingredients and desired characteristics requires a delicate balance.

Ex. 2043 at 2. Therefore, even though Petitioner was arguing for the patentability of another claim in that proceeding, Petitioner still argued that persons skilled in this art had to strike a “delicate balance” of specific ingredients (none of which were actually recited in the claim at issue) to obtain the claimed film, and that manipulating any one ingredient could significantly affect the claimed

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