

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MODERNA THERAPEUTICS, INC.,
Petitioner,

v.

ARBUTUS BIOPHARMA CORPORATION
Patent Owner.

Case IPR2019-00554
Patent No. 8,058,069

**PATENT OWNER'S NOTICE OF OBJECTION TO
DEMONSTRATIVE EXHIBITS**

I. INTRODUCTION

Pursuant to the Board's trial hearing order (Paper 32, 4), Arbutus Biopharma Corporation ("Patent Owner") submits the following objections to Moderna Therapeutics, Inc. ("Petitioner")'s demonstrative slides, and any reference to or reliance on the foregoing by Petitioner. The demonstrative slides are objected to under FRE106, 401, 403, and 705. Further non-limiting discussion is provided below and is meant to illustrate the objectionable content.

II. OBJECTIONS

1. Slides 5 and 29

Slides 5 and 29 are improper as irrelevant to the obviousness inquiry – the '910 publication is not a grounds reference. FRE106, 401, 403. Additionally, the documents are incomplete and more prejudicial than probative. The slide 5 depiction of an Examiner's Office Action rejection in view of the '910 publication reflects an incomplete record. FRE106. Slide 29 presents only a portion of Fig. 23. Petitioner fails to mention that the Office Action challenges were overcome during prosecution or that the '910 publication specifically identifies the 30mol% cationic lipid concentration as the best concentration and that all subsequent *in vivo* testing was limited to formulations having 30% or less cationic lipid. EX1015 ¶¶335, 337-354; *see also* Surreply, 15-16; EX2043, 12:18-20, 16:6-11, 17:24-19:24.

2. Slides 6, 7, 53, 55

These slides are more prejudicial than probative as they falsely represent the 1:57 as one single formulation. FRE403. EX1001, 3:45-56 (defining the “1:57 formulation” as those including “a cationic lipid comprising from about 52 mol % to about 62 mol % of the total lipid present in the particle”); *see also* POR, 33-37 (detailing the ’069 patent’s testing of multiple 1:57 formulations); EX2008.

3. Slides 10 and 11

It was Petitioner’s witness, Dr. Janoff – not Patent Owner – that testified for limiting the claimed invention to SNALPs. EX2001, 118:19-119:4, 119:9-17, 120:5-6, 121:14-25. In the ’739 IPR, the Board confused Dr. Janoff’s interpretation with the more tempered construction advanced by Patent Owner. Slides 10 and 11 are thus irrelevant and more prejudicial than probative. FRE401, 403

4. Slide 14

Slide 14 is an incomplete representation of the cited evidence, and is more prejudicial than probative. FRE401, 403. Dr. Janoff’s initially proffered definition in his ’739 IPR declaration (referenced in Slide 14) was rejected at institution in the ’739 IPR and abandoned by Petitioner. During cross-examination, Dr. Janoff repeatedly testified that the claimed particle of the ’739 IPR should be defined as a SNALP. EX2001, 118:19-119:4, 119:9-17, 120:5-6, 121:14-25; *see also* POR, 10.

5. Slide 21

To the extent Petitioner relies on slide 21 as supporting a phospholipid range of 5 mol % to about 90 mol %, it is irrelevant to the challenge advanced in the petition materials. FRE401. Petitioner never presented such an invalidity theory in the petition. Rather, the petition alleged that one might arrive at phospholipid ranges of 0-19.5% and 0-19% after making a series of assumptions. Pet. 39, 54. Indeed, paragraph [0152] of the '189 publication as shown on slide 21 was never relied upon in the petition.

6. Slides 22, 24, 26

These slides are irrelevant to the instituted grounds and are more prejudicial than probative. FRE401, FRE 403. The petition *never* argued that the 2:40 formulation was a starting point for optimization. Tellingly, slides 22, 24, and 26 do not offer any citations to the petition and instead only point to the reply, where such arguments were first introduced.

7. Slide 27

The content of this slide is irrelevant to establishing *prima facie* obviousness – the '069 patent is not prior art against itself. FRE401. Thus, to the extent that any relevance is attributed to slide 27, it supports the criticality of the claimed range and the validity of the '069 patent.

8. Slide 28

Slide 28 is irrelevant to the obvious inquiry in the manner submitted.

FRE401. WO2010088537 is not a reference for any of the instituted grounds.

Indeed, it is not prior art to the '069 patent at all. To the extent that the reference is relied upon, it demonstrates post-filing data reflecting criticality of the claimed range. *See also* POR, 37-43; Surreply, 3.

9. Slide 30

Slide 30 is a yet another new, attorney-generated graphical representation of unsubstantiated argument of a fabricated “trend.” Petitioner’s own witness, Dr. Anchordoquy, conceded that there were “hundreds, if not thousands” publications existing before the time of invention – none of which are identified on slide 30. EX2043, 29:25-30:4, 30:25-31:7; Surreply, 15. Further, Petitioner plots for the time on slide 30 an additional datapoint for the year 2008, presumably based on the '069 patent itself. Slide 30 is thus an incomplete and prejudicial depiction of the state of the art and, as a further extension of new arguments asserted in reply, has no relevance to the invalidity theories presented in the petition. FRE106, 401, 403.

10. Slide 31

The new assertion of a “trend” to “keep PEG low” was never presented in the petition or in any of Petitioner’s briefings. Slide 31 is thus irrelevant to the obviousness theories advanced in the petition materials. FRE401. Slide 31 mischaracterizes the very evidence it cites, rendering slide 31 more prejudicial than

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