Paper No. ___
Filed: March 30, 2020

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 MOTION TO STRIKE

I. INTRODUCTION

This Motion to Strike is filed pursuant to the Board's authorization of March 12, 2020. *See also* stipulated extension of time, Paper 27, filed March 18, 2020.

Reply arguments are deemed improperly new where they seek to take the case in a new direction or where they are used to belatedly present evidence to fill in gaps in the *prima facie* case presented in the petition. Consol. Prac. Guide., 73-74. Petitioner's Reply does both. Petitioner based its petition on overlapping ranges caselaw, overlooking that this legal theory is based on a routine optimization rationale. This was made clear by Petitioner's embrace of the complexity and unpredictability of the technology in its Petition. Indeed, Dr. Janoff expressly disavowed Petitioner's routine optimization theory.

The petition lacks critical evidence necessary to support a *prima facie* case of obviousness in view of the overlapping range caselaw. *E.g.*, POR, 14-19. In an attempt to backfill these holes, the Reply advances new evidence and argument. This is improper. A such, the Reply should be struck in its entirety. Alternatively, and at a minimum, the portions of the Reply identified below should be struck or ignored by the Board.

II. Petitioner's New Phospholipid Theory

The Reply (5) argues that disclosure of "non-cationic/neutral lipid range of 5-90mol%" suffices as an overlapping range for the claimed phospholipid range.

This is improperly new. The Petition (39, 57-58) presented a different theory that overlapping ranges of 0-19% or 0-19.5% phospholipid could be derived from the prior art by assuming levels for cationic lipid, cholesterol, and conjugated lipid. *See also* D.I., 23, 36. This new argument is untimely, improper, and waived. The Board should strike it from the Reply.

III. Assertions of Routine Optimization are Untimely

The Reply's main arguments are premised on a routine optimization theory. Specifically, the Reply (7-22) assumes that a POSA would begin with four components (*i.e.*, cationic lipid, phospholipid, cholesterol, and conjugated lipid) then seek to optimize the level of each to obtain the claimed nucleic acid-lipid particles. The Reply provides no evidence that might support such a rationale and the introduction of this new theory is improper. *See also* D.I. 26, fn 11. Contrary to these new arguments, Petitioner and Dr. Janoff conceded that optimization of the prior art ranges would not be routine. Dr. Janoff admitted the broad lipid ranges in the cited art would require "undue experimentation, not simple optimization" and emphasized the unpredictability of the technology. *E.g.*, EX2033, 42:7-10, 60:5-16, 19:25-20:15. Petitioner cannot now decide to replace its old insufficiently plead arguments with new arguments advanced by its new expert. The Board should strike each paragraph related to Petitioner's new routine optimization theory.

IV. Motivation to Include Optional Lipids Is Untimely

The challenged claims recite specific concentration ranges for each component which comprise nucleic acid-lipid particles. Under the overlapping ranges legal framework, a presumption of obviousness only exists where there is motivation to include the recited components in nucleic acid-lipid particles along with disclosure of overlapping ranges for each lipid component. To the extent the Petition (7-8) has any discussion of the cholesterol, phospholipid, and conjugated lipid components, it is limited to general allegations the level of each can affect properties of lipid particles. The Petition is devoid of any motivation to include all three of these components in lipid particles. This omission is glaring because the prior art, including the grounds references, identify these components as optional.

The Reply attempts to backfill this missing motivation. For example, the Reply (20) now argues that a "POSITA would be motivated to include cholesterol to provide increased rigidity to the particle." This is improper. To the extent the Petition (7-8) discussed cholesterol, it was to assert that it was optionally included in lipid particles, offering only conclusory legal arguments and providing no clear evidence for motivation to include cholesterol. Similarly, the Reply (21) newly argues that a POSITA would want to include "phospholipid as a bilayer stabilizing component," an argument not advanced in the Petition, and thus, improper.

V. Belated Argument Regarding Objective Indicia Is Improper

Petitioner was aware of the very evidence of objective indicia that PO relies on here when it filed its petition, but failed to analyze such evidence, much less rebut it. *Praxair Distribution, Inc. v. Mallinckrodt Hospital Products*, IPR2016-00777, Paper 10, 9 (concluding that petitioner should have addressed available evidence of objective indicia in the petition). Any attempt to address objective indicia in the Reply is therefore untimely and should be ignored.

PO submitted its Response in IPR2018-00739, which included evidence of objective indicia, on December 21, 2018. Petitioner filed the petition in this case on January 9, 2019. Because the objective indicia evidence was already in Petitioner's possession at the time the petition was filed, it should have addressed long-felt need, failure of others, skepticism, and commercial success.

That Petitioner waited until the Reply is particularly prejudicial here because it now attempts to walk away from positions that were previously conceded. For example, Dr. Janoff admitted that patisiran "contains 50% cationic lipid, 38.5% cholesterol, 10%DSPC, and 1.5% PEG." IPR2018-00739, EX1021, ¶33. In the Reply (28), Petitioner relies on a new witness to promote a new, unexplained, and contradictory theory that patisiran "does not use the claimed lipid ranges." This is improper and the Board should strike each related paragraph.

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