Paper No. ___
Filed: April 15, 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 REPLY IN SUPPORT OF MOTION TO EXCLUDE EVIDENCE

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Petitioner fails to show the admissibility of the objected to evidence.

I. Exhibit 1020

Petitioner (Opp., 1-3) argues the Motion to Exclude ("MTE") is improper where it seeks exclusion of Dr. Anchordorquy's declaration on the basis that it presents new and belated argument. The Consolidated Trial Practice Guide ("CTPG") (79-80) recommends motions to strike directed to briefing ("If a party believes that a ***brief*** filed by the opposing party raises new issues….") and motions to exclude directed towards evidence ("Objections may be preserved only by a motion to exclude the evidence."). Patent Owner did file a motion to strike the reply brief and the corresponding motion to exclude, as appropriate. As explained in the MTE, this new and belated evidence is more prejudicial than probative as there was insufficient time and opportunity to fully respond, and rebuttal evidence was prohibited. *See* Paper 25. It is thus a proper target of a motion to exclude.

Petitioner (Opp., 3) points to the Institution Decision ("DI") as somehow excusing its untimely arguments as to routine optimization. *See also*, Opp. 9-10. The petition materials, however, misapprehended the relevant caselaw and lacked any meaningful argument or evidence to support a routine optimization case. These are not deficiencies that can be cured in Reply. Indeed, the ***single conclusory sentence*** about only one lipid component (cationic lipid) identified by the Board (*e.g.*, DI, 26) as "unrebutted" at institution was explored during discovery and

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thoroughly rebutted in the POR. That single sentence didn't mention "routine optimization" and lacked a shred of supporting evidence (*compare* EX1008, ¶109 *with* 37 C.F.R §42.65(a)). When questioned during cross-examination, Dr. Janoff disavowed "routine optimization" in a manner consistent with his direct testimony emphasizing high unpredictability in the field. The testimony of the witnesses (further including Dr. Thompson) and the scientific literature all indicate that routine optimization does not apply here. Petitioner's attempted 180^0 turn in reply not only ignores the overwhelming evidence and admissions of its own witness, but is untimely, highly prejudicial, and lacks underlying evidentiary basis.

Petitioner (Opp., 3) attempts to side-step its obligation to provide particularity and corresponding supporting evidence in the petition, asserting that only new ***theories*** are prohibited—whereas new evidence is welcome. Petitioner cites *Genzyme,* but that case is inapposite at least because it did not address the facts presented here, which include 1) petition materials lacking meaningful evidence to support routine optimization even if asserted *sub silentio*; and 2) the theory was effectively disavowed and described as "undue experimentation" in the direct and deposition testimony of Petitioner's expert. Under the circumstances presented here, allowing new evidence at this late stage of the proceeding, where Patent Owner cannot adequately respond or provide evidence of its own, is highly prejudicial and conflicts with Board's rules and Federal Circuit guidance. CTPG,

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73; *Intelligent BioSys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016).

Petitioner's (Opp. 4) belated "damage control" efforts to cabin Dr. Janoff's conflicting testimony to "lipid species" rather than ranges are unsupported attorney spin that can be disregarded. Dr. Janoff did specifically address the "numerical ranges" and "lipid proportions," and not just the number of different lipid species. *E.g.*, EX2033, 41:4-42:10. Petitioner's attempted distinction is also of no moment, as the issue is the "immenseness" of the prior art disclosure, which includes "hundreds" of lipids and much broader numerical ranges (i.e., "immense") than claimed. For example, as to the new phospholipid argument, Dr. Anchordoquy identifies a massive non-cationic range of 5-90%, and a phospholipid (optional) is only one potential sub-genus. EX1020, ¶¶44-45. Cataloguing a broad genus so massive that it is hardly a "range," the various possible different sub-genera of non-cationic lipids, and the number of lipid species in each sub-genus, and the fact that phospholipid is described in the art as optionally omitted entirely, and the prior art range is truly "immense." This further underscores the incredible nature of Dr. Anchordoquy's unsupported "routine optimization" testimony.

Petitioner falsely claims the new theory of the 2:40 formulation as a "starting point" was argued in the petition materials. Opp. 3-4, citing Pet. 31, EX1008, ¶108; EX1020, ¶56. This is incorrect, as illustrated by Petitioner's own

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citations, which do not even refer to the 2:40 formulation.

As to the lack of explanation of N/P ratio "calculations," this was hardly cured during Dr. Anchordoquy's deposition. Opp., 5. Dr. Anchordoquy admitted he did not explain the "calculations" in his declaration as required, admitted to variables he didn't know, and conceded "approximations" based on still unexplained assumptions. MTE 5-6. As to the omitted Patisiran N/P ratio calculation (*e.g.*, EX2041), Dr. Anchordoquy admitted he made the calculation but didn't include it. Withholding this conflicting evidence undermines the validity of the N/P ratio arguments specifically and the credibility of the witness generally.

The Opp. (5-6) asserts the N/P ratio aspects of Lin and Ahmad undermining Petitioner's arguments, as well as the incomplete and spurious nature of its "trend" argument go to weight, not admissibility. Petitioner's incredible arguments should be given no weight, and Dr. Anchordoquy's corresponding testimony excluded as lacking evidentiary foundation and credibility.

Finally, as to Dr. Anchordoquy's qualifications, Petitioner complains about focus on "formal training" and only one patent. Opp. 6-7. But Dr. Anchordoquy emphasized his formal training in zoology in his prepared, but non-reassuring, remarks in redirect. Patent Owner addressed the only published patent/reference Dr. Anchordoquy (EX1020, ¶14) expressly discussed. Those aspects highlighted by Petitioner and its witness simply do not provide the requisite qualifications.

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