

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MODERNA THERAPEUTICS, INC.,
Petitioner,

v.

PROTIVA BIOTHERAPEUTICS, INC.,
Patent Owner.

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

**PETITIONER'S OPPOSITION TO PATENT OWNER'S
MOTION TO EXCLUDE**

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I. INTRODUCTION

Petitioner ModernaTX, Inc.’s¹ (“Moderna”) original expert in this proceeding, Dr. Janoff, passed away shortly after his October 2019 deposition. Petitioner engaged a new expert, Dr. Anchordoquy, to address arguments that Patent Owner Protiva Biotherapeutics, Inc. (“Protiva”) submitted in its Patent Owner Response (“POR”). Protiva now seeks to limit the record available for the Board’s consideration through its baseless motion to exclude the entirety of Dr. Anchordoquy’s opinions. Protiva’s motion, however, is both procedurally improper and substantively incorrect.

To begin with, Protiva spends much of its motion improperly arguing that (1) the Anchordoquy Reply Declaration (EX1020) goes beyond the bounds of the arguments in the Petition (Mot. 3-5), and (2) impugning the credibility of Drs. Janoff and Anchordoquy (*id.*, 5-7). The Board’s rules are clear that a motion to exclude should not “address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply” or present “arguments regarding weight” (*i.e.*, credibility). Trial Practice Guide Update, 83 Fed. Reg. 39,989, 16 (Aug. 2018) (“TPG”).

Substantively, Protiva’s motion fares no better. For example, Dr. Anchordoquy has over thirty years of experience with lipid carrier particles,

¹ ModernaTX, Inc. was formerly known as Moderna Therapeutics, Inc.

teaches doctoral level courses in lipid chemistry, and actually trained as a doctoral candidate in his lab, one of the inventors on the cited prior art. Despite this extensive knowledge base and experience, Protiva launches baseless challenges against his credentials (Mot. 1-2).

Regarding Dr. Janoff, Protiva seeks to exclude redirect testimony from his October 2019 deposition regarding the technical analysis underlying his determination that Moderna has established a *prima facie* case of obviousness. Protiva's sole basis for exclusion is that the redirect questioning was allegedly beyond the scope of cross-examination. Mot. 8-10. But, Protiva's counsel opened the door to such questioning by trying to get Dr. Janoff to agree that there was no technical analysis underling his opinion—a proposition he flatly rejected and then addressed on redirect.

II. EX1020 – REPLY DECLARATION OF DR. ANCHORDOQUY

A. Protiva's Motion Is Both Procedurally Improper And Substantively Baseless

The Board's rules state that a motion to exclude should not put forth arguments that "the proper scope of reply or surreply" was exceeded by the Reply or supporting evidence. TPG, 16. Protiva spends much of its motion arguing that Dr. Anchordoquy's declaration "introduce[s] argument that should

have been presented with the petition” Mot. 3-5. Given the Board’s guidance, this is not a proper objection for a motion to exclude.²

Even if considered, Protiva’s assertions are demonstrably false. For example, Protiva claims that issues related to routine optimization are new because “Dr. Janoff, agreed on the inapplicability of routine optimization.” Mot. 4. The Board has already rejected this false characterization of Dr. Janoff’s opinions. *See ID*, 24-25, n.11. The Petition, *e.g.*, pointed to “testing relating to the 2:40 formulation that the Patent Owner identified as a prior art formulation” as a starting point (Pet. 31; EX1008, ¶109) and argued, *e.g.*, that “determining the optimal proportion of cationic lipid for a given lipid combination would be a simple matter of varying the proportion using prior art methodologies” (Pet. 33; Ex. 1008, ¶112). Drs. Janoff and Anchordoquy thus properly expanded on arguments in the Petition in response to Protiva’s POR. While the rules state a petitioner cannot introduce new theories of unpatentability, there is no prohibition against introducing new evidence on

² Alternatively, the Board should reject Protiva’s motion as an improper end run around the page limits set for Protiva’s motion to strike and the word count for the sur-reply. Regarding Protiva’s motion to strike, Protiva requested permission to file a motion arguing that Moderna’s Reply raised “new theories and arguments.” Paper 25, 2. The Board authorized the motion and set a 5-page limit. *Id.*, 3. Protiva used the full page limit. Paper 28, 5. By trying to expand on its arguments in its present motion, Protiva is violating the Board’s limit. Similarly, Protiva should have addressed issues regarding the credibility of Drs. Janoff and Anchordoquy in the substantive briefing.

reply that supports an existing theory of unpatentability and responds directly to a patent owner's faulty response arguments. *See Genzyme Therapeutic Prods. L.P. v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. 2016) (“[T]he introduction of new evidence in the course of the trial is to be expected in *inter partes* review trial proceedings”).

Protiva also points to statements from Dr. Janoff that the field is immense, complex and unpredictable to argue against routine optimization. Mot. 4-5. Dr. Janoff's reference to an “immense” range referred to the “hundreds of cationic lipids known.” EX2033, 51:7-18. The field was unpredictable because of that immense range of available lipid species. *Id.*, 60:5-15. But, when you have a defined, efficacious system like the 2:40 formulation tested in the prior art the unpredictability in the field is minimized. *Id.*; *see also* EX1020, ¶56. Thus, Dr. Anchordoquy's opinions on routine optimization (*id.*, ¶57) do not raise contradictory positions, but properly expand on Dr. Janoff's prior opinion (Ex. 1008, ¶112) that varying the lipid component percentages using such a defined system as a starting point would require mere routine optimization.

The Board's rules also state that a motion to exclude “is not a vehicle for addressing the weight to be given evidence—arguments regarding weight should appear only in the merits documents.” TPG, 16. Despite this limit,

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