

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MODERNA THERAPEUTICS, INC.,
Petitioner,

v.

PROTIVA BIOTHERAPEUTICS, INC.,
Patent Owner.

Case IPR2018-00680
Patent No. 9,404,127

**PATENT OWNER'S RESPONSE
PURSUANT TO 37 C.F.R. § 42.120**

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I. INTRODUCTION

Moderna Therapeutics, Inc. (“Petitioner” or “Moderna”) filed a petition for *inter partes* review of claims 1-22 of U.S. Patent No. 9,404,127 (“the ’127 patent,” EX1001). The Board issued its decision instituting trial (“Decision,” Paper 13). Protiva Biotherapeutics, Inc. (“Patent Owner”) hereby requests that the Board now issue a final written decision rejecting Petitioner’s challenges and confirming the patentability of claims 1-22.

The Board should reject Petitioner’s challenges of claims 1-22 of the ’127 patent because the Petition fails to demonstrate the unpatentability of the challenged claims by a preponderance of the evidence. Specifically, each of the stated grounds of challenge fails to meet the non-lamellar morphology limitation of the claim 1, which requires *at least about 95% of the particles in the plurality of particles have a non-lamellar morphology*.

Ground 1 critically relies on the assertion that certain lipid particles in the cited art (U.S. Patent No. 8,058,069, “the ’069 patent”) were allegedly generated using “the same Direct Dilution Method” as in the ’127 patent. A review of the ’069 patent reveals that none of the lipid formulations cited are described in the reference as being generated by the “Direct Dilution Method.” The petition materials cite generally to U.S. Publication No. 2007/0042031 (“the ’031 publication”) referenced in the ’069 patent, but neither the petition nor Dr. Janoff’s declaration provides any

meaningful discussion of the '031 publication, the content of that reference, process parameters, or how it would be understood to a person of ordinary skill in the art (“POSITA”).

As experts from both parties agree, specific details of the formation process and corresponding parameters (or sets of parameters) are important in affecting the physical properties of resulting particles (such as particle morphology). As Dr. Janoff conceded during cross-examination, modifying the parameters of a given direct dilution method (e.g., flow rate, mixing parameters, temperature) would be expected to alter the physical properties of any resulting particles—defeating the alleged case of inherency. EX2028, 163:8-165:23; 191:14-17.

Grounds 2-4 were addressed in detail previously, and the Board’s Institution Decision identifies numerous reasons why these grounds are critically defective. *E.g.* Decision, 22-26. The record has not changed in any way since the time of institution to alter or otherwise cure the defects previously identified by Patent Owner and the Board.

Accordingly, the challenges presented in the petition should be rejected, and the challenged claims 1-22 of the '127 patent be found not unpatentable.

II. DR. JANOFF’S DECLARATION IS ENTITLED NO WEIGHT

As an initial matter, the Declaration of Dr. Janoff submitted with the petition (EX1007) should be accorded no weight for at least the reasons set forth below.

First, Dr. Janoff’s declaration merely adopts the attorney arguments set forth in the petition and should be weighted accordingly. The direct testimony itself characterizes the declaration as such, where Dr. Janoff repeatedly states his opinions “are based on the petition.” EX1007, ¶27 (“My opinion[s] expressed in this declaration are based on the Petition”); *see also id.*, ¶5 (“Based on studying the petition...”), ¶6 (“Based on studying the petition...”), ¶7 (“Based on studying the petition...”). During cross-examination, Dr. Janoff confirmed that his direct testimony was based on the petition. EX2028, 93:10-11 (“There is a petition. I based my opinions on the petition”); *see also id.*, 91:18-92:20 (confirming the petition was completed prior to declaration testimony), 92:21-93:11 (confirming the lawyers drafted the petition), 26:12-27:5.¹

Attorney argument is not elevated to testimonial evidence simply by virtue of being parroted by a witness. *E.g. InfoBionic, Inc. v. Braemar Manufacturing, LLC*, IPR2015-01704, Paper 11 at 6 (“We do not find the testimony of Petitioner’s expert to be persuasive or helpful as it repeats the Petitioner’s arguments and offers little or no elaboration.”)(citing 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little

¹ Dr. Janoff demonstrated a general unfamiliarity with the petition materials throughout the deposition. *E.g.* EX2028, 31:9-32:25 (unable to recall using the term “lipid particle”); 90:3-91:8 (seemingly unable to recognize the petition).

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