Paper No. ____
Filed: March 9, 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 OBJECTIONS TO PETITIONER'S REPLY EVIDENCE

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner submits the following objections to Moderna Therapeutics, Inc. ("Petitioner")' Exhibits 1020, 1023, and 1024 and any reference to or reliance on the foregoing Exhibits in the Petition or future filings by Petitioner. Patent Owner's objections are made pursuant to the Code of Federal Regulations ("C.F.R.") governing this proceeding, including without limitation 37 C.F.R. §§ 42.61-42.65 and § 42.6(a)(3). As required by 37 C.F.R. § 42.62, Patent Owner's objections below apply the Federal Rules of Evidence ("F.R.E.").

II. OBJECTIONS.

1. Objections to Exhibit 1020, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 401, 402 (Irrelevant Evidence Inadmissible), 403 (Excluding Evidence for Prejudice, Confusion, Waste of Time, Duplication, or Other Reasons), F.R.E. 702, 703 (Expert Foundation and Opinions), F.R.E. 802, 803, 805 (Inadmissible Hearsay).

EX1020 is the declaration of Petitioner's proffered expert, Dr. Anchordoquy. Patent Owner objects to the declaration in its entirety. First, Dr. Anchordoquy is not a qualified expert in the relevant field and does not even meet Petitioner's definition of the ordinary artisan. Dr. Anchordoquy is a zoologist, not a lipid chemist with formal training in the subject matter at hand. EX1020, ¶9.

Moreover, Petitioner and Dr. Anchordoquy define the ordinary artisan as someone who "would have specific experience with lipid particle formation ***and use in the context of delivering therapeutic nucleic acid payloads***." EX1020, ¶25; *see also* Institution Decision ("Inst. Dec."), 11-12 (discussing the level of ordinary skill in the art). Dr. Anchordoquy, as support for his expertise in the field, specifically discusses his first issued patent, U.S. Patent No. 7,914,714, which he asserts "described a process by which lipid bilayers could be formed around a solution of nucleic acids, effectively surrounding the nucleic acids to achieve complete encapsulation within a lipid vesicle." EX1020, ¶14. That patent, however, claims a "method for making an encapsulated droplet … of an agent to be encapsulated…through electrostatic atomization…." This technology is neither the same nor similar to the technology at issue. Indeed, it does not seem that Dr. Anchordoquy has any relevant patents or patent applications at all. Furthermore, Petitioner does not demonstrate that Dr. Anchordoquy has any significant expertise in the technology at issue through his publications or academic studies. Accordingly, although Dr. Anchordoquy is the rare zoologist who *may* potentially have some degree of experience with lipid formulations, he is not an expert and it is apparent that he does not have the requisite experience with delivering therapeutic nucleic acids as required by Petitioner's definition of the ordinary artisan and as adopted by Dr. Anchordoquy.

Second, even if the Board were to find Dr. Anchordoquy an expert in this case, his declaration is irrelevant for the purposes proffered by Petitioner. Dr. Anchodoquy's declaration is used as a means to assert new argument and obviousness theories unsupported by the petition. The petition was based on a faulty application of the relevant caselaw and, as detailed in the Patent Owner Response, lacked critical evidence to support an obviousness charge. In Reply, Petitioner now attempts to submit evidence that is required to have been submitted with the petition materials. 37 CFR § 42.23(b). Petitioner did not do so, but instead, now attempts to abandon arguments and explanation proffered by its previous expert in order to advance different and new obviousness arguments.

Third, Dr. Anchordoquy fails to describe the underlying facts or data on which his opinions are based, thereby failing to provide a proper foundation for his opinions. There is no basis in the Board's rules or opinions, nor in the case law of the Court of Appeals for the Federal Circuit, that requires a fact finder to credit the unsupported assertions of an expert witness.

Accordingly, what little (if any) probative weight to which the declaration is entitled is outweighed by the its prejudicial effect.

2. Objections to Exhibit 1023, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 401, 402 (Irrelevant Evidence Inadmissible), 403 (Excluding Evidence for Prejudice, Confusion, Waste of Time, Duplication, or

Other Reasons), F.R.E. 802, 803, 805 (Inadmissible Hearsay), F.R.E. 901 (Authenticating or Identifying Evidence).

Dr. Anchordoquy describes EX1023 as the "label for Onpattro from the FDA. EX1020, ¶139. Neither the exhibit itself nor Dr. Anchordoquy, however, point to the source of the electronic record or to how or when it was obtained.

3. Objections to Exhibit 1024, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 106 (Remainder of or Related Writings or Recorded Statement), F.R.E. 401, 402 (Irrelevant Evidence Inadmissible), 403 (Excluding Evidence for Prejudice, Confusion, Waste of Time, Duplication, or Other Reasons), F.R.E. 802, 803, 805 (Inadmissible Hearsay), F.R.E. 901 (Authenticating or Identifying Evidence).

Exhibit 1024 is entitled "Liposomal Formulations for Nucleic Acid Delivery," and is identified as "Chapter 9." Neither Dr. Anchordoquy's declaration nor Petitioner's reply identify the source of the exhibit. *E.g.*, Reply, iii (identifying EX1024 as "Ian MacLachlin, Liposomal Formulations for Nucleic Acid Delivery (2007), but not identifying the source); EX1022, ¶29 (merely referencing EX1024).

III. CONCLUSION

The aforementioned exhibits were filed on March 2, 2020. These objections are made within 5 business days of institution pursuant to 37 C.F.R. § 42.64.

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