Paper No. ___
Filed: April 29, 2019

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 PRELIMINARY RESPONSE PURSUANT TO 37 C.F.R. § 42.107

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I. INTRODUCTION

The Board should not institute *inter partes* review of claims 1-22 of U.S. Patent No. 8,058,069 (the '069 patent) because Moderna Therapeutics, Inc. ("Moderna" or "Petitioner") fails to show that it has a reasonable likelihood of prevailing.

The nucleic acid-lipid particles claimed by the '069 patent have achieved tremendous recognition in the field of genetic therapy. The '069 patent is now listed in the FDA's Orange Book as protecting the patisiran commercial product—tradename "Onpattro." EX2025. Patisiran received regulatory approval in the U.S. and Europe and has been designated by the FDA as a "first-in-class" drug. EX2023; EX2024.

As an initial matter, the petition (2-3) cites to Petitioner's pending challenge (IPR2018-00739) of Patent Owner's related U.S. Patent No. 9,364,435, but fails to appreciate that its serial attacks actually weigh against institution here. Petitioner asserts similarities between the cases, but does not explain why it sat on the present challenge for 10 months while using prior Board decisions and Patent Owner's briefing as a roadmap for drafting the current petition. Despite this advantage, Petitioner ignores the evidence presented in the '739 IPR directly pertinent to numerous issues presented here—evidence that should have been addressed but was not. *Infra* Sections VII-VIII. This includes, *inter alia*, extensive experimental

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