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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MODERNA THERAPEUTICS, INC.,  
Petitioner,

v.

ARBUTUS BIOPHARMA CORPORATION,  
Patent Owner.

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

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**PATENT OWNER'S RESPONSE  
PURSUANT TO 37 C.F.R. § 42.107**

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## I. INTRODUCTION

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 FDA's Orange Book as protecting the patisiran—tradename “Onpattro”—commercial product. EX2025. Patisiran received regulatory approval in the U.S. and Europe and has been designated by the FDA as a “first-in-class” drug. EX2024. The therapeutic potential of genetic therapy has been appreciated for over 25 years, but effectively delivering nucleic acids to target cells without eliciting vehicle-related toxicity prevented realization of this potential. *E.g.*, EX2016, 38, 42; EX2018, 11. By 2008, the industry-wide failure to identify a solution to the delivery problem resulted in waning confidence. EX2019, 2, 10; EX2018, 11; EX2023, 291-292.

The nucleic acid-lipid particle formulations of the '069 patent met a long-felt need for compositions that could safely and effectively deliver nucleic acids to patient target cells. The combination of effectiveness and low toxicity that characterizes the claimed compositions surprised many in the field, and finally solved the delivery problem that hindered the field for decades.

The petition is a poorly conceived challenge, relying on erroneous legal analysis in each of the under-developed obviousness (Grounds 1-3) and anticipation (Ground 1 and 3) challenges.

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