

# EXHIBIT 14

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ARBUTUS BIOPHARMA CORPORATION )  
and GENEVANT SCIENCES GmbH, )

Plaintiffs, )

v. )

MODERNA, INC. and MODERNATX, INC., )

Defendants. )

C.A. No. 22-252-MSG

**HIGHLY CONFIDENTIAL –  
OUTSIDE COUNSEL’S EYES ONLY**

MODERNA, INC. and MODERNATX, INC., )

Counterclaim-Plaintiffs, )

v. )

ARBUTUS BIOPHARMA CORPORATION )  
and GENEVANT SCIENCES GmbH, )

Counterclaim-Defendants. )

**DECLARATION OF PROFESSOR STEPHEN BYRN**

1. I, Professor Stephen Byrn, hereby declare as follows:

**I. INTRODUCTION**

2. I am the Charles B. Jordan Professor of Medicinal Chemistry at Purdue University.

3. I have been retained by Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, “Moderna”) in connection with the above-captioned lawsuit.

**II. BACKGROUND AND ASSIGNMENT**

**A. The Suit**

4. I have been advised by counsel for Moderna that Arbutus Biopharma Corp. and Genevant Sciences GmbH (collectively, “Plaintiffs”) have asserted patents including U.S. Patent Nos. 8,058,069 (the “’069 Patent”), 8,492,359 (the “’359 Patent”), 8,822,668 (the “’668 Patent”),

9,364,435 (the “‘435 Patent”), and 11,141,378 (the “‘378 Patent”) (collectively, the “Molar Ratio Patents”) against Moderna. I have reviewed and analyzed the Molar Ratio Patents in connection with the opinions I express herein.

**B. Moderna’s COVID-19 Vaccine**

5. Moderna’s COVID-19 Vaccine, “mRNA-1273,” is an FDA-approved drug product.<sup>1</sup> mRNA-1273 contains four lipids: SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC].<sup>2</sup>

**C. The Discovery Dispute**

6. I understand that Plaintiffs have requested drug product samples from all batches of drug product of Moderna’s COVID-19 Vaccine, and specifically samples of drug product that contain 100 milligrams of lipid content per batch.

7. I have been advised by counsel that Moderna assigns “part numbers” to differentiate between formulations and processes used to make the drug product. For example, Moderna’s drug product with part number [REDACTED] is manufactured as a [REDACTED] mL vial with a specification that requires lipid content of [REDACTED] MRNA-GEN-00456568 (Exhibit #A). One drug product vial of part number [REDACTED] would comprise [REDACTED] mg total lipid content.

8. I have been further advised by counsel for Moderna that, in response to Plaintiffs’ sample request, Moderna has offered to produce 3 drug product samples for each part number that

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<sup>1</sup> <https://purplebooksearch.fda.gov/productdetails?query=125752>.

<sup>2</sup> <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f96b315c-fa57-4876-a7e5-a9b584d8e6e6>

has been manufactured in the U.S.<sup>3</sup> and has objected to the production of the volume of samples requested by Plaintiffs on the grounds of relevance and disproportionality to the needs of the case.

9. I have been further advised by counsel for Moderna that Plaintiffs have filed an application to the Court in this case seeking an order compelling Moderna to produce samples from all batches of drug product of Moderna's COVID-19 Vaccine in response to Plaintiffs' RFP seeking "50 vials of the Accused Product from each lot referenced in Biologics License Application 125752 or that has otherwise been manufactured by or on behalf of Moderna." I understand that Plaintiffs have requested sufficient vials to comprise "100 mg of lipid" for each lot.

**D. Assignment**

10. I have been asked by counsel for Moderna to consider (1) whether "100 mg of lipid" for each batch is necessary to conduct testing for lipid content (2) whether Plaintiffs' justification that they need samples in order to determine the lipid content in individual LNPs is scientifically sound.

11. To answer these questions, I have considered the materials identified herein, and rely on my education, professional training, and expertise in medicinal chemistry as well as my general knowledge of chemistry, which I have developed in over 50 years of experience as a professor of medicinal chemistry.

12. I am being compensated for my time spent working on this matter at a rate of \$850 per hour. I have no financial interest in the outcome of this case.

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<sup>3</sup> I have been informed that Moderna transitioned from drug product vials to single-dose syringes and that for such batches Moderna would provide an equivalent number of syringe samples.

### III. PROFESSIONAL BACKGROUND & TESTIMONY

13. I received a Ph.D. in Chemistry from the University of Illinois in 1970 and was a post-doctoral fellow at UCLA from 1970 to 1972. In 1972, I became a professor in the Medicinal Chemistry and Pharmacognosy Department at Purdue University. I was Head of the Department of Medicinal Chemistry and Pharmacognosy at Purdue University in the School of Pharmacy and Pharmaceutical Sciences from 1988-1994. I was the Director of the Center for AIDS Research at Purdue from 1988 until 1998, and I was the Head of the Department of Industrial and Physical Pharmacy from 1994 to 2009. I became the Charles B. Jordan Professor of Medicinal Chemistry in 1992.

14. I am an author of over 225 peer-reviewed publications in technical journals on topics relating to solid-state chemistry, analysis, formulation, X-ray crystallography, stability, medicinal chemistry, chemistry, and the like. I am also co-author of the three leading books in the field of solid-state chemistry of pharmaceuticals. My most recent book was published by Wiley in 2017 and is entitled "Solid State Properties of Pharmaceutical Materials." Under my supervision, over 50 students and post-doctoral associates have published numerous papers and theses on many different compounds and formulations.

15. I have taught numerous courses as outlined in my Curriculum Vitae, attached as Exhibit B. At Purdue I co-authored a book entitled Quantitative Pharmaceutical Chemistry and lectured on HPLC. I have continued to lecture and work with HPLC since then. I have also taught at the federal Food and Drug Administration and have given I have also given over 270 invited lectures and symposium talks and presentations on solid-state chemistry, analysis, polymorphs, and similar topics.

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