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Update Regarding Initiation of Patent Litigation Against Moderna

February 28, 2022

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GENEVANT

Genevant and Arbutus have Jointly Filed a Complaint against Moderna Asserting Patent Infringement

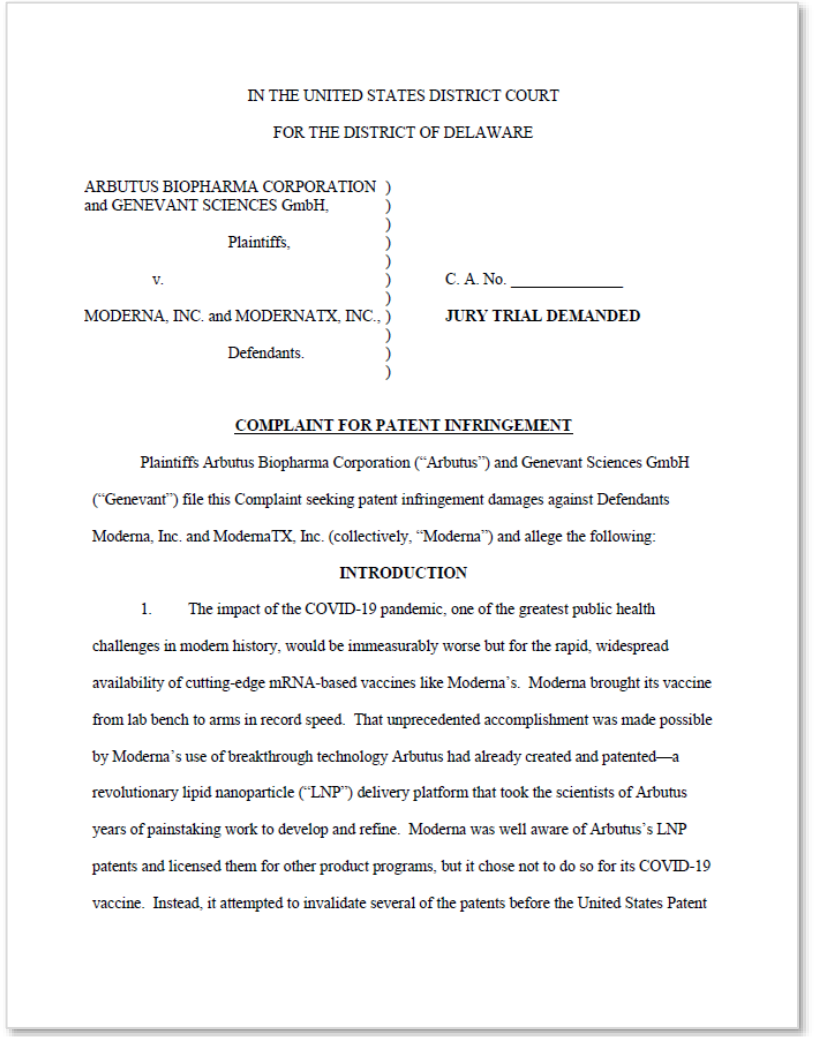
Today, Genevant and Arbutus jointly filed a complaint against Moderna in the US District Court for the District of Delaware asserting infringement of six patents

Genevant and Arbutus do not seek an injunction or otherwise to impede the sale, manufacture, or distribution of Moderna's COVID-19 vaccine

We recognize the important work of Moderna that helped lead to a lifesaving vaccine in record time

That success was built on, and made possible by, the substantial advances and contributions of Arbutus and Genevant scientists

Genevant has out-licensed its LNP technology on multiple occasions; the filing of this lawsuit was necessary because Moderna has not meaningfully engaged in licensing discussions



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. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

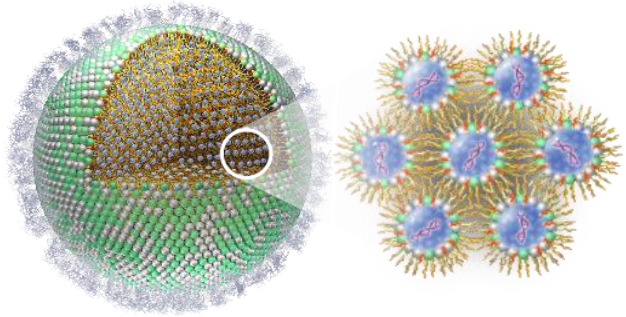
Plaintiffs Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") file this Complaint seeking patent infringement damages against Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") and allege the following:

INTRODUCTION

1. The impact of the COVID-19 pandemic, one of the greatest public health challenges in modern history, would be immeasurably worse but for the rapid, widespread availability of cutting-edge mRNA-based vaccines like Moderna's. Moderna brought its vaccine from lab bench to arms in record speed. That unprecedented accomplishment was made possible by Moderna's use of breakthrough technology Arbutus had already created and patented—a revolutionary lipid nanoparticle ("LNP") delivery platform that took the scientists of Arbutus years of painstaking work to develop and refine. Moderna was well aware of Arbutus's LNP patents and licensed them for other product programs, but it chose not to do so for its COVID-19 vaccine. Instead, it attempted to invalidate several of the patents before the United States Patent

Genevant is a Leading Nucleic Acid Delivery Solutions Company

- Genevant was formed in 2018 by Roivant and Arbutus and licensed Arbutus's LNP technology and patent portfolio
- Deep expertise in delivery systems for mRNA and other nucleic acids
- Without adequate protection, nucleic acids degrade quickly in the body before accessing their target cells – long known to be a significant obstacle to accessing their therapeutic potential
- Many years ago, a team of research scientists at an Arbutus predecessor company began to take on this challenge
    - Years of effort led to the innovative solution — tiny particles made of four carefully selected lipid types, now commonly known as **lipid nanoparticles** or **LNP**
    - Genevant's technology became the first LNP to be included in an FDA-approved RNA product in 2018, Alnylam's Onpattro® developed under LNP license from Arbutus
- Today, LNPs have emerged as the primary means for delivering the industry's mRNA pipeline, as well as a key delivery approach for gene editing
- Core members of the team behind the early LNPs now lead Genevant's R&D efforts, collaborating with leading companies to develop innovative nucleic acid medicines



Genevant Collaborates with Leading Companies for Access to its LNP Technology to Develop Medicines for a Variety of Diseases and Disorders, Including COVID-19

Collaboration Partner	LNP Collaborations Outside of COVID-19	Publicly Disclosed Financials*
Sarepta Therapeutics	Gene editing therapeutics for specified neuromuscular diseases, including DMD[1]	Royalty rate: mid-single to low-double digits† Near-term: $50M + significant milestones
Takeda	Nucleic acid therapeutics directed to specified targets in HSCs to treat liver fibrosis[2]	Royalty rate: undisclosed Upfront and milestones: $600M
Takeda	Nonviral gene therapies for up to two rare liver diseases[3]	Royalty rate: undisclosed Upfront and milestones: $303M
2seventy bio	Gene editing therapies for hemophilia A[4]	Royalty rate: mid-single digits† Upfront and near-term option: $10M + milestones
gritstone bio	Self-amplifying RNA for an unspecified indication[5]	Low to mid-single digits† Initial payment and milestones: $73M
BioNTech	mRNA for a specified number of oncology targets; co-dev in up to five rare diseases[6]	Milestones and royalties (amounts undisclosed); 50:50 on co-development programs

Collaboration Partner	LNP Collaborations for COVID-19	Publicly Disclosed Financials*
gritstone bio	Self-amplifying RNA COVID-19 vaccine program[7]	Royalty rate: mid-single to mid-double digits† Upfront + milestones: $192M/product
ST Pharm	mRNA COVID-19 vaccine program in specified Asian countries[8]	Royalty rate: 8% Upfront + milestones: $133.75M
Providence Therapeutics	mRNA COVID-19 vaccine program	Undisclosed
Chula Chulalongkorn University	mRNA COVID-19 vaccine program in specified Asian countries	Undisclosed

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*Includes publicly disclosed terms only and therefore does not reflect all payments that may be applicable and received by Genevant (e.g., reimbursements for FTE support, field expansion fees, etc.). All potential payments are contingent upon achievement of specified milestones. †Depending on the circumstances.

 1. Genevant and Sarepta joint press release, January 13, 2021. 2. Genevant press release, March 15, 2021. 3. Genevant press release, August 23, 2021. 4. 2seventy bio press release, January 6, 2022. 5. Gritstone Oncology 8-K, October 20, 2020. 6. BioNTech Form F-1, July 21, 2020. 7. Genevant and Gritstone joint press release, January 20, 2021. 8. ST Pharm Korean disclosure document, April 8, 2021.

Genevant Has an Expansive LNP IP Portfolio

- Genevant owns or licenses approximately 700 LNP-related patents and pending patent applications, including the following US patents which are licensed from Arbutus and were asserted in today's complaint:

Subject Matter	US Patent No.	Expiration Date
Particle Composition	8,058,069	April 2029
	8,492,359	April 2029
	8,822,668	April 2029
	9,364,435	April 2029
	11,141,378	April 2029
mRNA-LNP Compositions	9,504,651	July 2023

- The particle composition patents listed above are directed to compositions comprising various lipid types, including cationic lipids, phospholipids, cholesterol and conjugated lipids
  - Phospholipids and cholesterol are types of amphipathic lipids and/or non-cationic lipids; PEG-lipids are a type of conjugated lipid
  - In addition to the US, particle composition patents have also issued in the EU, Japan, Australia, Canada, China, Israel, and New Zealand, with the EU patent validated in certain major European countries
- Claim 1 of the '651 patent is directed to a lipid vesicle formulation comprising (1) lipid vesicles comprising a cationic, an amphipathic and a PEG lipid and (2) mRNA at least 70% of which is fully encapsulated in the lipid vesicles
- The patents refer to lipid vesicles or nucleic acid lipid particles, which we'll refer to as LNPs for the purpose of this presentation

Existing Disclosures Regarding Moderna's COVID-19 Vaccine Indicate Infringement of the Particle Composition Patents

1. A 2020 preprint describing mRNA-1273 development and preclinical data disclosed molar ratios of 50:10:38.5:1.5[1]
2. A 2020 study published in *NEJM* described the mRNA as encapsulated in an LNP "as described previously" and cited a prior Moderna publication that discloses the same molar ratio as #1[2]
3. An international patent application showed that the same 50:10:38.5:1.5 molar ratio was used in the Phase I trial of mRNA-1273[3]
4. Moderna has acknowledged that the "lipid carrier particle" used in its Phase I study is the same as the one that was "ultimately approved" for use in its product[4]

	Moderna Public Disclosures re mRNA-1273[6]	US Pat. No. 8,058,069	US Pat. No. 8,492,359	US Pat. No. 8,822,668	US Pat. No. 9,364,435	US Pat. No. 11,141,378
Cationic Lipid	50% SM-102 (contains a protonatable tertiary amine[5])	50 - 65%			50 - 85%	No quantitative limitation; must contain protonatable tertiary amine
Non-Cationic Lipid	PL: 10% Chol: 38.5%	PL: 4 - 10% Chol: 30 - 40%	PL: 3 - 15% Chol: 30 - 40%	Up to 49.5% (incl. Chol: 30 - 40%)	13 - 49.5% Claim 7: PL: 3 - 15% Claim 8: Chol: 30 - 40%	30 - 55% (incl. PL: 3 - 15%)
Conjugated Lipid	PEG-lipid: 1.5%	0.5 - 2%				PEG-lipid: 0.1 - 2%

PL: Phospholipid. Chol: Cholesterol.

1. Corbett et al., Preprint, 2020
2. Corbett et al., *New England Journal of Medicine*, 2020
3. International Patent Publication WO 2021/159130
4. Decl. of Shaun Ryan, US Federal Circuit Court of Appeals, February 23, 2021
5. International Patent Publication WO 2017/049245 A2
6. Corbett et al., Preprint, 2020; FDA SPIKEVAX authorization letter

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Genevant and Arbutus also Assert that Moderna's Vaccine Infringes the '651 Patent

Claim 1 of US Patent No. 9,504,651, titled "Lipid Compositions for Nucleic Acid Delivery," is directed to a lipid vesicle formulation comprising:	Moderna's COVID-19 vaccine
(1) a plurality of lipid vesicles, wherein each lipid vesicle comprises: a cationic lipid; an amphipathic lipid and a PEG-lipid	The vaccine comprises a lipid vesicle comprising a cationic lipid (SM-102), an amphipathic lipid (DSPC) and a PEG-lipid (PEG2000-DMG)[1]
(2) mRNA, at least 70% of which is fully encapsulated in the lipid vesicles	We believe the vaccine comprises a lipid vesicle formulation wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles

1. FDA SPIKEVAX authorization letter

Despite Denying Infringement, Moderna Has Unsuccessfully Attempted to Invalidate the ‘069 and ‘435 Patents

2016

Moderna’s CEO, Stéphane Bancel, publicly stated that Moderna was in the process of producing its own LNPs and dismissed Arbutus’s LNP technology (which was later licensed to Genevant) as “not very good”[1]

2017

Bancel claimed that Moderna had developed its own LNPs that would not be covered by Arbutus’s IP[2]

2018

Nevertheless, beginning in 2018, Moderna filed *inter partes* review (IPR) petitions requesting that the US Patent and Trademark Office cancel the claims of three patents licensed by Genevant from Arbutus, including the ‘069 and ‘435 patents*

2020

In July 2020, the Patent Trial and Appeal Board (PTAB) upheld all claims of the ‘069 patent; it had previously rejected Moderna’s challenge as to ten of the ‘435 patent’s twenty claims

2021

In December 2021, the Federal Circuit rejected Moderna’s appeal of the PTAB’s decision holding all claims of the ‘069 patent patentable and dismissed Moderna’s appeal challenging a similar finding of patentability of certain claims of the ‘435 patent

*Moderna also attempted to invalidate US Patent No. 9,404,127 via IPR; a Genevant/Arbutus appeal of the PTAB’s decision in Moderna’s favor remains ongoing; infringement of the ‘127 patent was not asserted in the complaint filed today

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1. Nathan Vardi, “Moderna’s Mysterious Medicines,” Forbes.com, December 14, 2016, available at https://www.forbes.com/sites/nathanvardi/2016/12/14/modernas-mysterious-medicines/?sh=26dd47526ef6
2. Nathan Vardi, “Moderna Can't Escape My Intellectual Property, Says Arbutus CEO,” Forbes.com, May 16, 2017, available at https://www.forbes.com/sites/nathanvardi/2017/05/16/moderna-cant-escape-my-intellectual-property-says-arbutus-ceo/?sh=163a7337633a

Next Steps

1. We expect that Moderna will respond to the complaint within the next several months

2. Pending Moderna's response, the court will set a schedule for further proceedings in the case

3. We expect that litigation with Moderna could take at least 2 years, but there are many factors that could affect that timeline

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