

Vaccines Manufacturing Contracts

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- To successfully produce this vaccine at a large scale there needs to be **effective technology transfer**; therefore, lifting **IP barriers** is crucial to ensuring equitable, fair and timely access
- **Patents** are routinely used to protect the **underlying technology** used to make the vaccines
- Proprietary information for **vaccine manufacturing** is often protected through **trade secrets**

Patent/Published Application	Applicant/Assignee	Filing Date	Status	Invention Type
US 10,576,146	BioNTech	March 15, 2018	Active	Lipids/NP + mRNA
US 10,485,884	BioNTech	March 5, 2013	Active	Lipids/NP + mRNA
US 9,950,065	BioNTech	September 26, 2013	Pending	Lipids/NP + mRNA
US2020/0153671	BioNTech	January 22, 2020	Pending	RNA immune response
US2020/0197508	BioNTech	March 21, 2018	Pending	RNA immunogenicity
US2019/0153428	BioNTech	August 24, 2016	Pending	PC: Lipids/NP + mRNA
US2019/0321458	BioNTech	July 14, 2017	Pending	Lipids/NP + mRNA
US2018/0263907	BioNTech	March 30, 2016	Pending	Lipids/NP + mRNA
US2017/0273907	BioNTech	September 17, 2015	Pending	RNA expression
US2014/0030808	BioNTech	December 2, 2011	Published	Lipids/NP + mRNA
WO2016/156398	BioNTech	March 30, 2016	Published	Lipids/NP + mRNA
WO2015/043613	BioNTech	September 26, 2013	Published	Lipids/NP + mRNA
WO2013/087083	BioNTech	December 15, 2011	Published	Lipids/NP + mRNA

Patent/Published Application	Applicant/Assignee	Filing Date	Status	Invention Type
US 10,703,789	Moderna	June 12, 2019	Active	PC: Lipids/NP + mRNA
US 10,702,600	Moderna	February 28, 2020	Active	Betacoronavirus mRNA Vaccine
US 10,577,403	Moderna	June 12, 2019	Active	PC: Lipids/NP + mRNA
US 10,442,756	Moderna	December 18, 2017	Active	Lipids/NP + mRNA
US 10,266,485	Moderna	June 11, 2018	Active	Lipids/NP + mRNA
US 10,064,959	Moderna	April 21, 2017	Active	Lipids/NP + mRNA
US 9,868,692	Moderna	March 31, 2017	Active	mRNA synthesis
US2020/0206362	Moderna	October 11, 2019	Active	Lipids/NP + mRNA
US2020/0164038	Moderna	July 29, 2019	Pending	PC: Lipids/NP + mRNA
US2019/0015501	Moderna	September 27, 2018	Pending	PC: Lipids/NP + mRNA
WO2016/118724	Moderna	January 21, 2016	Published	Nucleic acid vaccine
WO2016/118725	Moderna	January 21, 2016	Published	Lipids/NP + mRNA

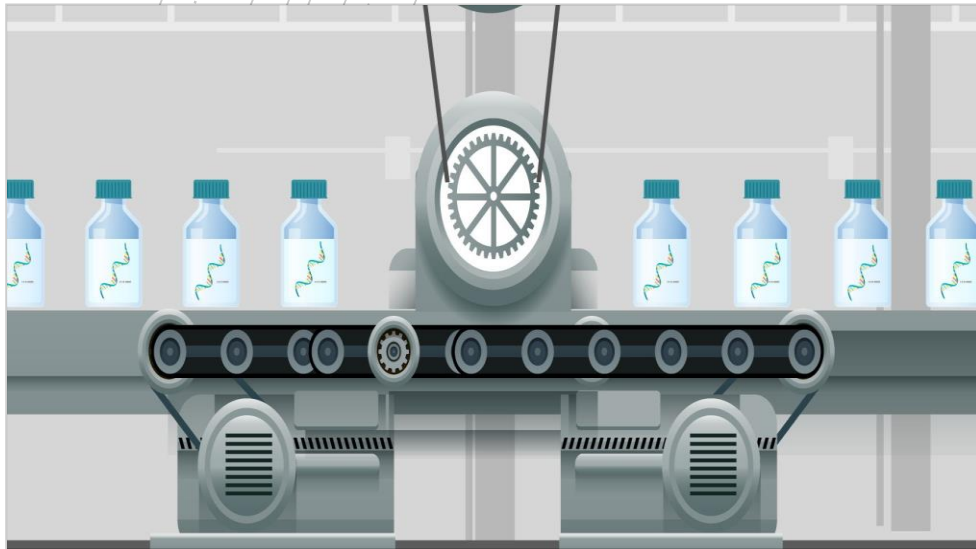
mRNA Manufacturing

As discussed below, we utilize trade secret protection for many aspects of our mRNA manufacturing technologies, including as currently utilized for production of certain of our development candidates. In addition, our patent portfolio includes certain patent filings relevant to mRNA manufacturing, or collectively, the mRNA

others. We also rely to a certain extent on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how, or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

- BioNTech: “Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents, trade secrets or other intellectual property rights that cover these activities.”
- Moderna: “We are rapidly expanding our global operations and third-party arrangements to support the worldwide manufacture and distribution of mRNA-1273, which is a complex task that we are undertaking on an accelerated timeline. Accordingly, our business and financial results may be adversely affected due to a variety of factors associated with our expanding global business, including:
 - our inability to directly control commercial activities because we are relying on third parties;
 - the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute, and the difficulty of effective enforcement of contractual provisions in local jurisdictions, and the existence of potentially relevant third-party IP rights;

moderna



LONZA

Pharma & Biotech

- **MODERNA** possesses extensive **intellectual property, proprietary technology and expertise** with respect to the research, development, manufacture and formulation of messenger RNA (mRNA) therapeutics and vaccines.
- **LONZA** possesses **world class manufacturing and process expertise** in biologics manufacturing consistent with cGMP (as defined below).
- **MODERNA Manufacturing Know-How.** Notwithstanding anything herein to the contrary, the Parties recognize **that maintaining the confidentiality and trade secret nature** of the MODERNA Manufacturing Know-How **requires an even higher level of vigilance** than other Confidential Information.
 - (...) (iii) use the MODERNA Manufacturing Know-How only for **Manufacturing and supplying the applicable Product** under the relevant Statement of Work and **for no other purpose**.

15.4. CONTRACTOR represents that CONTRACTOR and its licensors have all intellectual property rights, including but without limitation non-patented technology (know-how) and patents (when applicable) for the exploitation of the Object of this Agreement and hereby grant to CONTRACTING PARTIES a free non-exclusive license or sublicense valid in the Territory, to import the IFA and use same in the productive process of manufacturing the Finished Vaccine, to manufacture the Finished Vaccine, as well as to commercialize the Finished Vaccine in the Territory, pursuant to the terms of this Agreement. To the extent that CONTRACTOR and its licensors submit, in Brazil, patent requests related to the Object of this Agreement, CONTRACTOR agrees to notify the CONTRACTING PARTIES about this fact and to sublicense the use of such Brazilian patents to CONTRACTING PARTIES, pursuant to the terms of this Agreement, without limitation to the supply of technology object of Exhibit III.

15.5. CONTRACTING PARTIES have the right and the duty to use its own visual identity in the marketing of the Finished Vaccine, so that CONTRACTING PARTIES and CONTRACTOR use different brands and visual identities. If FIOCRUZ decides to use a trademark, it must consult CONTRACTOR in advance to verify that the trademark to be registered for Finished Vaccine does not conflict with trademarks held by CONTRACTOR or OUI.

15.2.1. Exclusively for the execution of the provisions of this clause, and subject to the success of the activities described in Exhibit I and the fulfillment of the obligations provided for in this Agreement, the CONTRACTOR will free license or sublicense, non-exclusively without the right to grant sublicenses, licensed intellectual property rights to CONTRACTOR or CONTRACTOR ownership which are required for the production of the Finished Vaccine, under the terms of Exhibit III to this Agreement.

15.3.2. Either during the Pandemic Period or Post Pandemic Period, FIOCRUZ shall cause all third parties to which FIOCRUZ sells, distributes or supplies the Finished Vaccine under this Agreement not to sell, distribute, supply or commercialize the Finished Vaccine in any other manner outside the Territory, including but without limitation to individuals or to the private market. Furthermore, FIOCRUZ shall, at its cost and responsibility, create and enforce all necessary for reasonable safeguard arrangements to ensure that none of the Finished Vaccine is sold, distributed, supplied or commercialized outside of the Territory, unless after extension of the Territory agreed to between the Parties in writing, as provided in clause 1.3 above.



THANK YOU!! Any questions??



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