BioNTech and Pfizer's BNT162 Vaccine Patent Landscape

By Mario Gaviria and Burcu Kilic[1]

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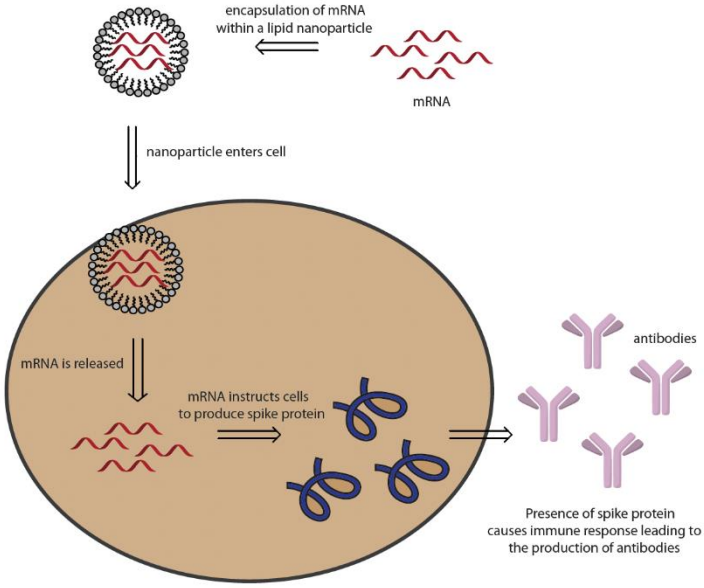
Safe and effective vaccines are key to combating the Covid-19 pandemic; however, patents and other intellectual property claims directed at vaccine technologies create legal barriers for equitable access and fair allocation. No corporation produces at scale to supply the world. Providing timely global access will depend in significant part on increasing supply, including by transferring technology to qualified manufacturers. Much of this technology is claimed as patented, proprietary, or confidential in nature.

German company BioNTech and its U.S. partner Pfizer's[2] vaccine candidate, BNT162 SARS-CoV-2, employs the use of lipid nanoparticle (NP) technology to deliver mRNA to cells. Once the lipid nanoparticle is injected into a patient, it travels into the cells and instructs them to produce the SARS-CoV-2 spike protein. The presence of this coronavirus protein is thought to trigger an immune response leading to the production of antibodies.[3] If the patient is infected with coronavirus, the antibodies will identify and bind to the virus, which triggers a series of events resulting in the elimination of the virus.



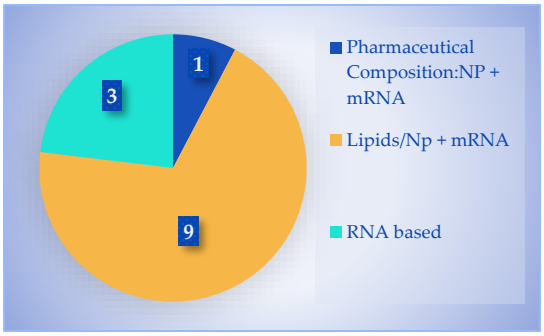
[1] Public Citizen's Access to Medicines Program

[2] All patents and patent applications identified in this study were claimed by BioNTech indicating that they are the inventor of the relevant vaccine technology, while Pfizer is acting as the innovator and leading the large-scale manufacturing, development, and regulatory approval process.

[3] https://www.nejm.org/doi/10.1056/NEJMoa2027906

BNT162 is in Phase 3 clinical trials. Pfizer announced promising but preliminary trial results on November 9th.[4]

We identified several patents claimed by BioNTech relating to the pertinent vaccine technologies.[5] We placed them in three groups based on their description and their primary independent claim:



- Patents directed at RNA
- Patents directed at Lipids/NP + mRNA
- Patents specifically directed at pharmaceutical compositions involving lipid NP + mRNA.

Below is our non-exhaustive list. In a recent financial statement, BioNTech suggested that its patent claims extend to mRNA structure, formulations, and manufacturing, and relies on trade secrets and confidential know-how to protect aspects of mRNA manufacturing technologies.[6]

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	Active	Lipids/NP + mRNA
US2020/0155671	BioNTech	January 22, 2020	Pending	Lipids/NP + mRNA
US2020/0197508	BioNTech	March 21, 2018	Pending	RNA immune response
US2019/0153428	BioNTech	August 24, 2016	Pending	RNA immunogenicity
US2019/0321458	BioNTech	July 14, 2017	Pending	PC: Lipids/NP + mRNA
US2018/0263907	BioNTech	March 30,2016	Pending	Lipids/NP + mRNA
US2017/0273907	BioNTech	September 17, 2015	Pending	Lipids/NP + mRNA
US2014/0030808	BioNTech	December 2, 2011	Pending	RNA expression
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

[4] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against

[5] Pharmaceutical companies are not the only claimants of key technology. The U.S. government claims a patent on a key technology which may be relevant for BioNTech and Pfizer to stabilize the spike protein. *See* Public Citizen, Leading COVID-19 Vaccine Candidates Depend on NIH Technology (Nov. 10, 2020), https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology/.

[6] "Certain of our technologies, including in particular certain proprietary manufacturing processes or technologies and/or neoantigen prediction technologies, are protected as trade secrets", BioNTech SE, SEC Filing (July 21 2020), https://www.sec.gov/Archives/edgar/data/1776985/000119312520195911/d939702df1.htm.