

SAMPLE LANDSCAPE STUDY

mRNA Vaccines

October, 2024



INTRODUCTION (1/2)



mRNA VACCINES

Vaccines play a crucial role in preventing infections by preparing the body's immune system to combat foreign invaders, including bacteria, viruses, and other pathogens. Traditional vaccines achieve this by introducing a harmless portion of a specific bacterium or virus, stimulating an immune response. Typically, these vaccines contain weakened or inactivated forms of the pathogen. However, a groundbreaking type of vaccine has emerged that employs a molecule called messenger RNA (mRNA) instead of a component from the actual pathogen. Messenger RNA, a vital molecule for protein production in cells, is utilized in this innovative approach. Unlike traditional vaccines, which may contain live or inactivated pathogens, mRNA vaccines do not introduce any live virus or bacteria. It's essential to note that the mRNA in these vaccines does not enter the cell nucleus or alter an individual's DNA. Once cells finish using the mRNA to produce a specific protein, the mRNA is rapidly broken down and does not have a lasting impact on the recipient's genetic material.

PRINCIPLE OF mRNA VACCINES

mRNA vaccines function by introducing a segment of mRNA that corresponds to a specific viral protein, often a protein fragment located on the virus's outer surface. This mRNA serves as a blueprint for cells to manufacture the viral protein. As a standard part of the body's immune response, the immune system identifies the produced protein as foreign and generates specialized proteins called antibodies. These antibodies play a critical role in defending the body against infection by recognizing individual viruses or other pathogens, binding to them, and flagging them for elimination. Once antibodies are generated, they persist in the body even after the pathogen has been cleared, ensuring a rapid and effective immune response if the person is exposed to the same virus in the future. In the event of exposure to the virus after receiving an mRNA vaccine, the antibodies can swiftly identify, attach to, and mark the virus for destruction, preventing the onset of severe illness.



INTRODUCTION (2/2)



MARKET POTENTIAL

The global market for mRNA vaccines and therapeutics targeting COVID-19 is projected to reach approximately \$9 billion in 2024. Additionally, the market for mRNA vaccines and therapeutics for other medical conditions is expected to grow to \$1.99 billion by 2035, with a compound annual growth rate (CAGR) of 16% from 2026 to 2035. The ongoing research and development efforts being undertaken in the mRNA therapeutics market are primarily driven by the various advantages offered by these molecules, including higher biological efficacy, enhanced potent immunogenicity, and versatile delivery platforms at reduced toxicity levels, over other therapeutic modalities.

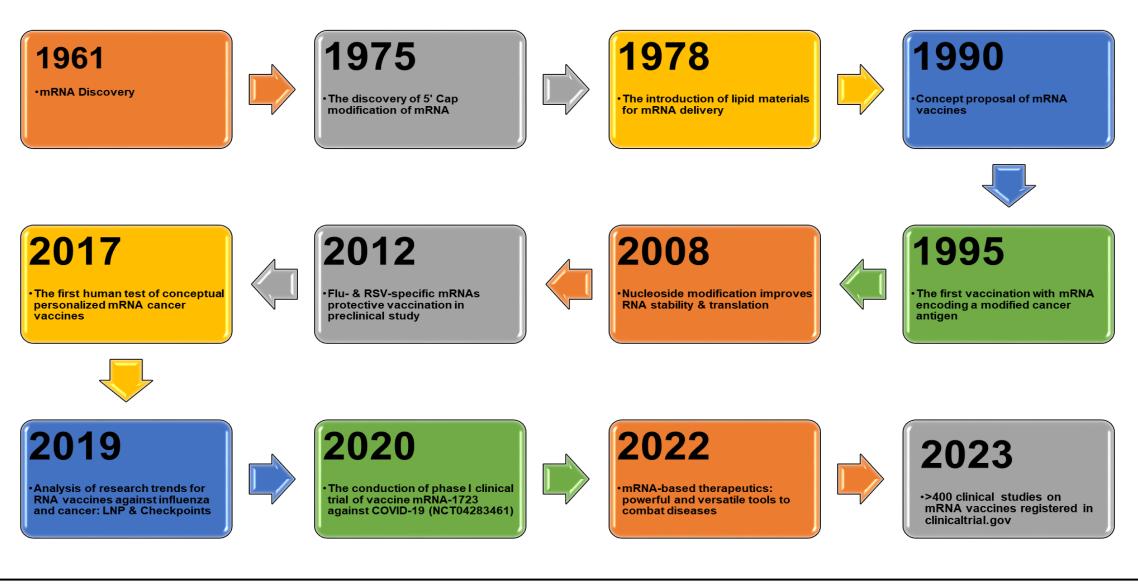
REFERENCES & CREDITS

- Jain S, Venkataraman A, Wechsler ME, Peppas NA. Messenger RNA-based vaccines: Past, present, and future directions in the context of the COVID-19 pandemic. Adv Drug Deliv Rev. 2021 Oct 9;179:114000. doi: 10.1016/j.addr.2021.114000. Epub ahead of print. PMID: 34637846; PMCID: PMC8502079.
- Verbeke R, Lentacker I, De Smedt SC, Dewitte H. The dawn of mRNA vaccines: The COVID-19 case. J Control Release. 2021 May 10;333:511-520. doi: 10.1016/j.jconrel.2021.03.043. Epub 2021 Mar 30. PMID: 33798667; PMCID: PMC8008785.
- https://medlineplus.gov/genetics/understanding/therapy/mrnavaccines/#:~:text =mRNA%20vaccines%20work%20by%20introducing,the%20virus%20by%20t he%20vaccine.)
- 4. https://www.rootsanalysis.com/reports/mrna-therapeutics-and-vaccinesmarket.html



mRNA VACCINES EVOLUTION

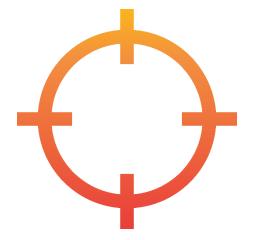




OBJECTIVES

SEARCH METHODOLOGY





- To perform a detailed analysis of granted patents and published applications pertaining to mRNA Vaccines.
- In-depth analysis of patents/applications, to categorize them and to understand focusing areas of applicants.
- Graphical representation of trends (Filing, Publication, etc.) from the mined data of relevant patents/applications.



The first step is to create and define a patent set that will serve as the basis of the study. Patent databases like PatSeer/Questel Orbit were used as our data sources. The search was carried out in the Abstract, Title, and Claims fields of patent specifications by incorporation of Keywords and International Patent Classes.



SUMMARY

- This report explores the global landscape of patents/ patent applications pertaining to mRNA vaccines.
- > A set of 450+ patent families were analyzed pertaining to mRNA vaccines.
- Patent publications have shown a notable emphasis on the development of modified mRNA-based vaccines. These vaccines utilize mRNA to encode various molecules, such as infectious and cancer antigens. These encoded molecules are then effectively delivered using lipid nanoparticles as a delivery system. This innovative approach is pivotal in advancing vaccine technology and holds promise not only for preventing infectious diseases but also for combating cancer through the induction of specific immune responses. The use of lipid nanoparticles for encapsulation enhances the stability and delivery efficiency of these mRNA-based vaccines, making them a crucial area of exploration in the field of biotechnology and medicine.
- Recently, Katalin Karikó and Drew Weissman, affiliated with the University of Pennsylvania, were honored with the 2023 Nobel Prize in Medicine. They were recognized for their groundbreaking discoveries related to nucleoside base modifications that paved the way for developing highly effective mRNA vaccines against COVID-19.

KEY REPORT FINDINGS



MODERNA is the top global innovator in this domain with 105 patent families followed by CUREVAC having 42 patent families.

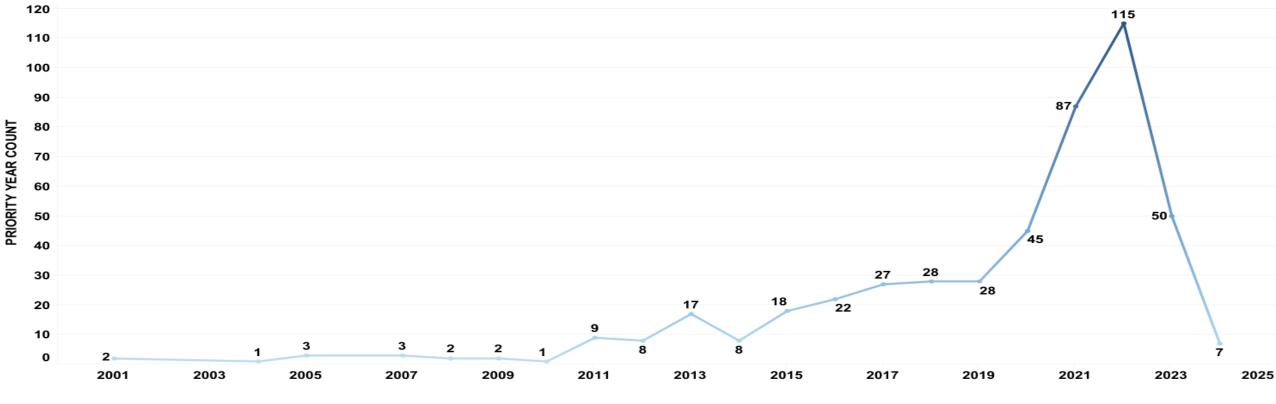


- United States (229 patent applications) is the largest filing destination.
- Vaccines leverage mRNA to encode molecules, such as infectious disease and cancer antigens.
- Use of lipid nanoparticles (LNPs) as a key delivery system.

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PRIORITY YEAR-BASED TREND ANALYSIS

ANALYSIS BASED ON REPRESENTATIVE MEMBER PER INPADOC FAMILY



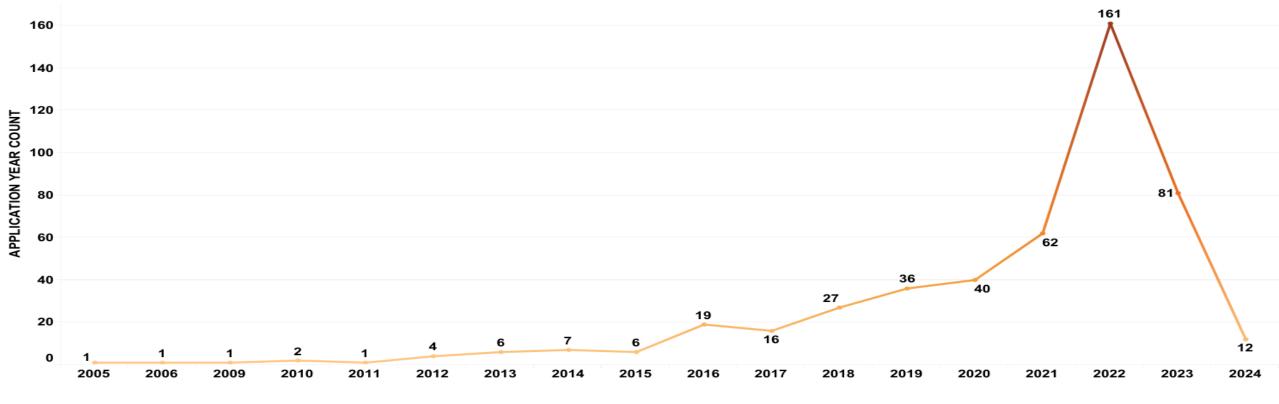
*2024 Data is Incomplete

Patent priority year trends for mRNA vaccines saw explosive growth post-2020, reflecting the technological and medical importance during the COVID-19 pandemic.



FILING YEAR-BASED TREND ANALYSIS

ANALYSIS BASED ON REPRESENTATIVE MEMBER PER INPADOC FAMILY

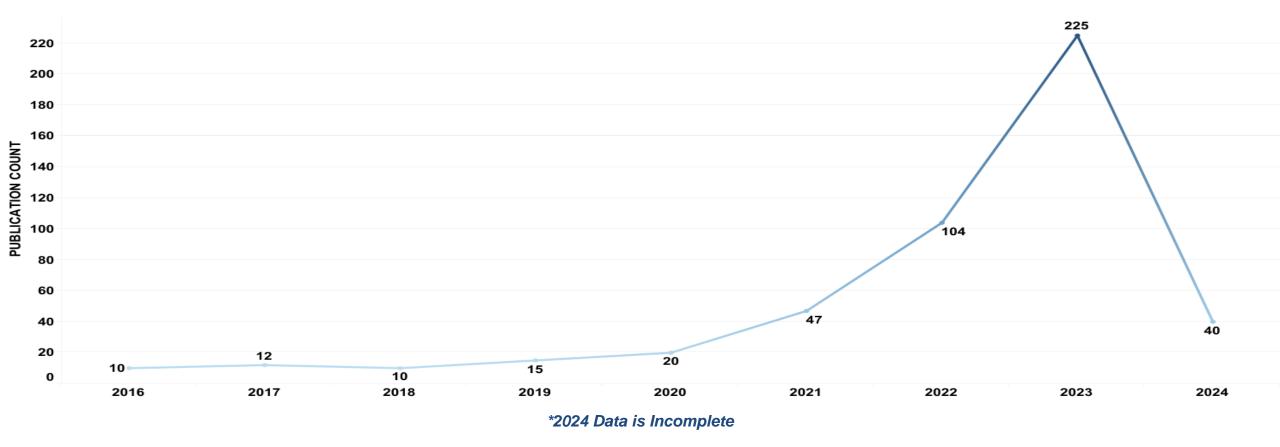


*2024 Data is Incomplete

Application trends highlight a surge in mRNA vaccine-related patents in 2022, with 2023-2024 filings potentially still being recorded, indicating that the trend could rise further.

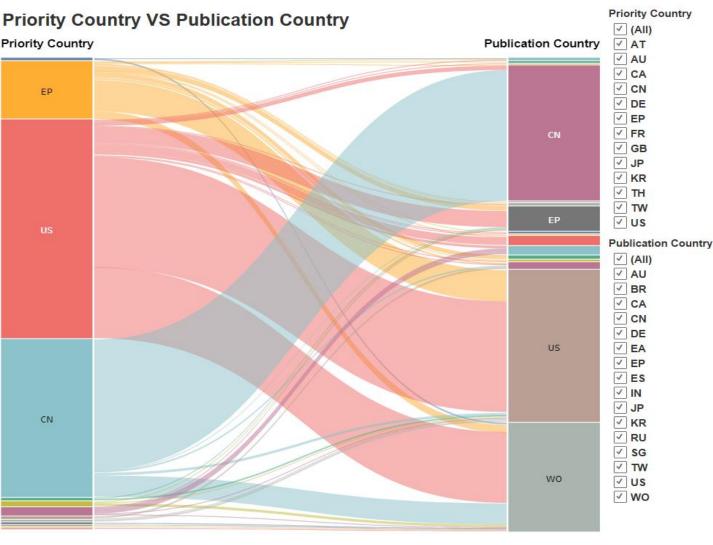
PUBLICATION YEAR-BASED TREND ANALYSIS

ANALYSIS BASED ON REPRESENTATIVE MEMBER PER INPADOC FAMILY



Application trends highlight a surge in mRNA vaccine-related patents in 2022, with 2023-2024 filings potentially still being recorded, indicating that the trend could rise further.

mRNA VACCINE PATENT TRENDS



GraphShowingPatentPriorityVs.Publication Country:This visualizes the flowof patent applications from priority countries(initial filing location) to publication countries(subsequent jurisdictions for protection).Major flows highlight the global reach ofpatents originating from key markets such asthe US, EP, and CN.

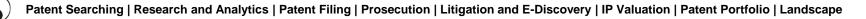


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MAJOR ASSIGNEES (BASED ON REPRESENTATIVE MEMBER PER FAMILY)

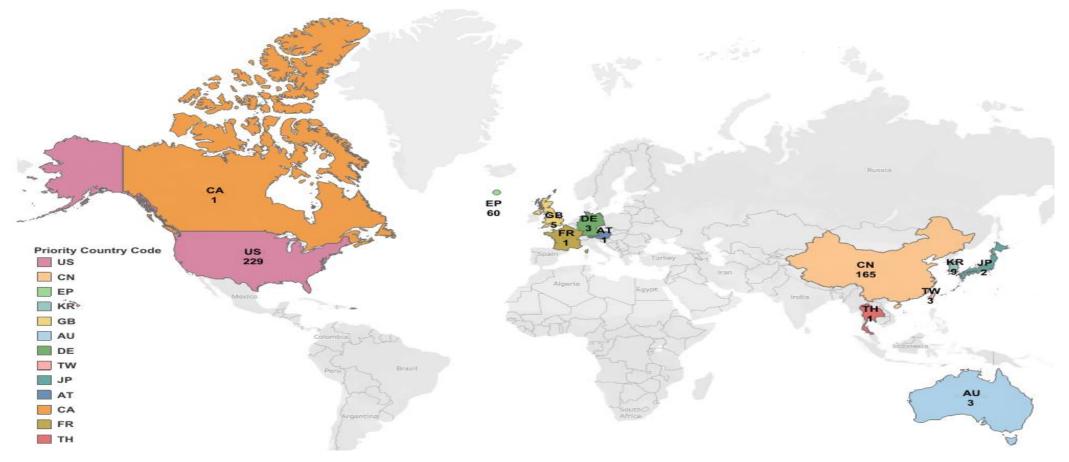


Based on the analysis, Moderna (105 patent families) is the top applicant/assignee in the mRNA vaccines domain. In addition, Curevac which works on customization of the 5' and 3' untranslated regions and the open reading frame has 42 patent families with a focus on cancer and infectious diseases.



AS TONE

GEOGRAPHICAL DISTRIBUTION OF PATENT APPLICATION FILINGS

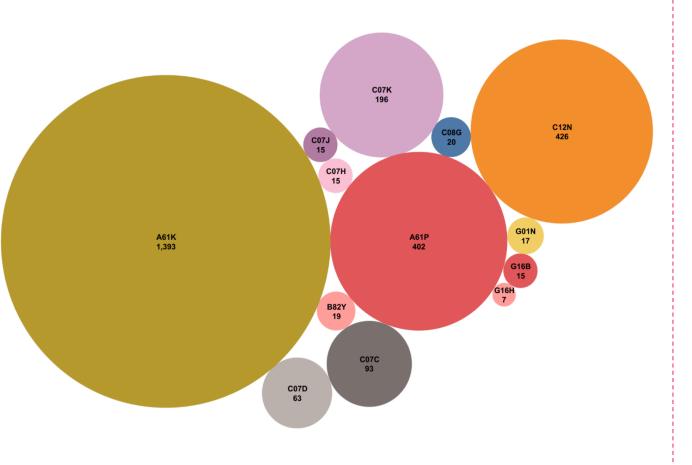


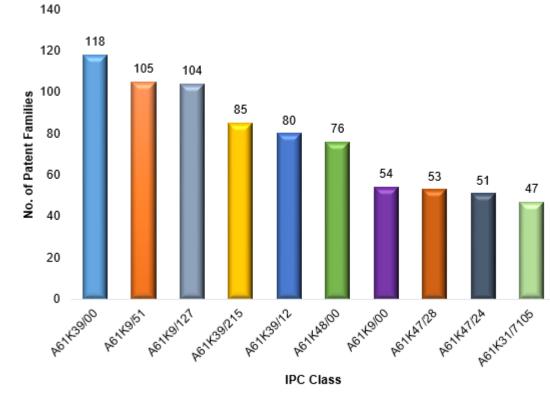
Trend related to Geographical filing demonstrates that the maximum number of filings had their origin in the United States (US) with 229 patent families followed by China (CN) with 165 patent families.



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INTERNATIONAL PATENT CLASSIFICATION-BASED TREND (1/2)





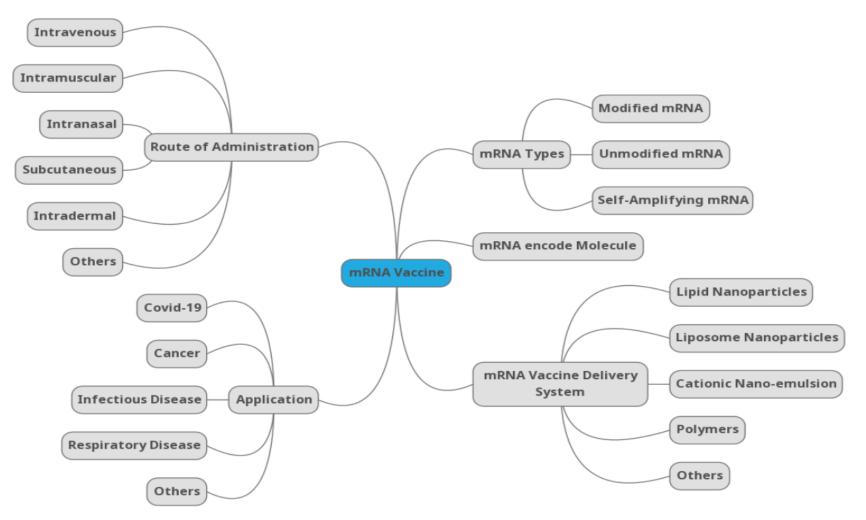


INTERNATIONAL PATENT CLASSIFICATION-BASED TREND (2/2)

IPC	DEFINITION
A61K	PREPARATIONS FOR MEDICAL, DENTAL OR TOILETRY PURPOSES
C12N	MICROORGANISMS OR ENZYMES; COMPOSITIONS THEREOF; PROPAGATING, PRESERVING, OR MAINTAINING MICROORGANISMS; MUTATION OR GENETIC ENGINEERING; CULTURE MEDIA
B82Y	SPECIFIC USES OR APPLICATIONS OF NANOSTRUCTURES; MEASUREMENT OR ANALYSIS OF NANOSTRUCTURES; MANUFACTURE OR TREATMENT OF NANOSTRUCTURES
A61P	SPECIFIC THERAPEUTIC ACTIVITY OF CHEMICAL COMPOUNDS OR MEDICINAL PREPARATIONS
C07C	ACYCLIC OR CARBOCYCLIC COMPOUNDS
С07К	PEPTIDES
C07D	HETEROCYCLIC COMPOUNDS
C08G	MACROMOLECULAR COMPOUNDS OBTAINED OTHERWISE THAN BY REACTIONS ONLY INVOLVING UNSATURATED CARBON-TO-CARBON BONDS
G01N	INVESTIGATING OR ANALYSING MATERIALS BY DETERMINING THEIR CHEMICAL OR PHYSICAL PROPERTIES
G16H	HEALTHCARE INFORMATICS, i.e. INFORMATION AND COMMUNICATION TECHNOLOGY [ICT] SPECIALLY ADAPTED FOR THE HANDLING OR PROCESSING OF MEDICAL OR HEALTHCARE DATA
С07Н	SUGARS; DERIVATIVES THEREOF; NUCLEOSIDES; NUCLEOTIDES; NUCLEIC ACIDS



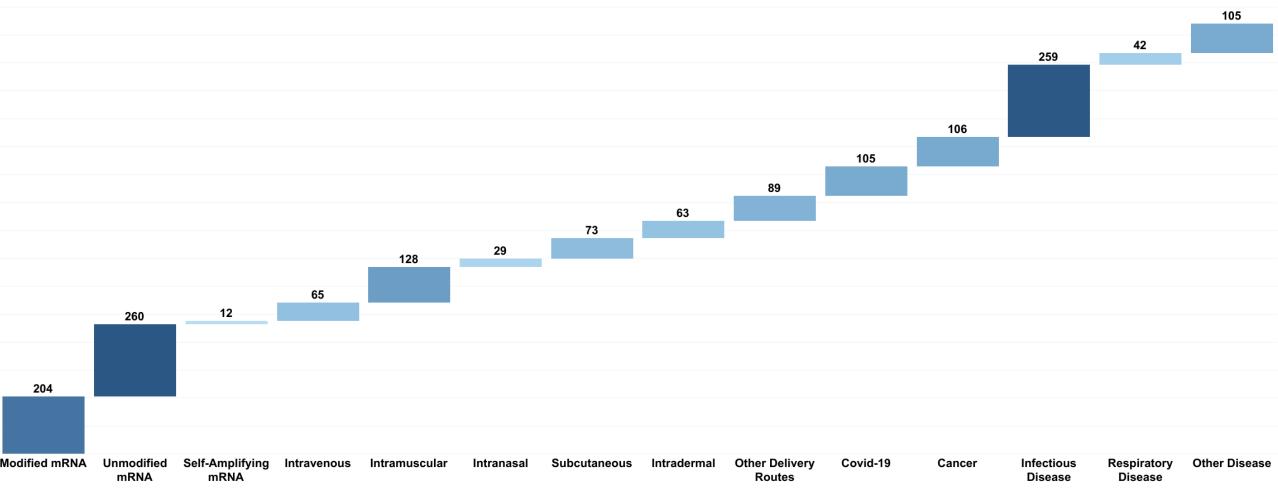
TAXONOMY DEVELOPED FOR BUCKETING OF RELEVANT PATENT DOCUMENTS



> A set of 450+ patent families was analyzed in depth to identify the focus areas of the patents related to mRNA vaccines.

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PATENT LANDSCAPE ANALYSIS OF mRNA THERAPEUTICS

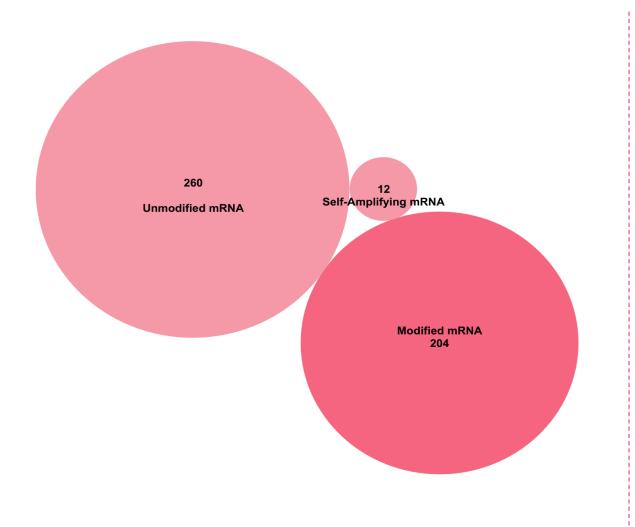


> A Visual Representation of Patent Activity Across mRNA Types, Delivery Methods, and Target Diseases

Patent Searching | Research and Analytics | Patent Filing | Prosecution | Litigation and E-Discovery | IP Valuation | Patent Portfolio | Landscape

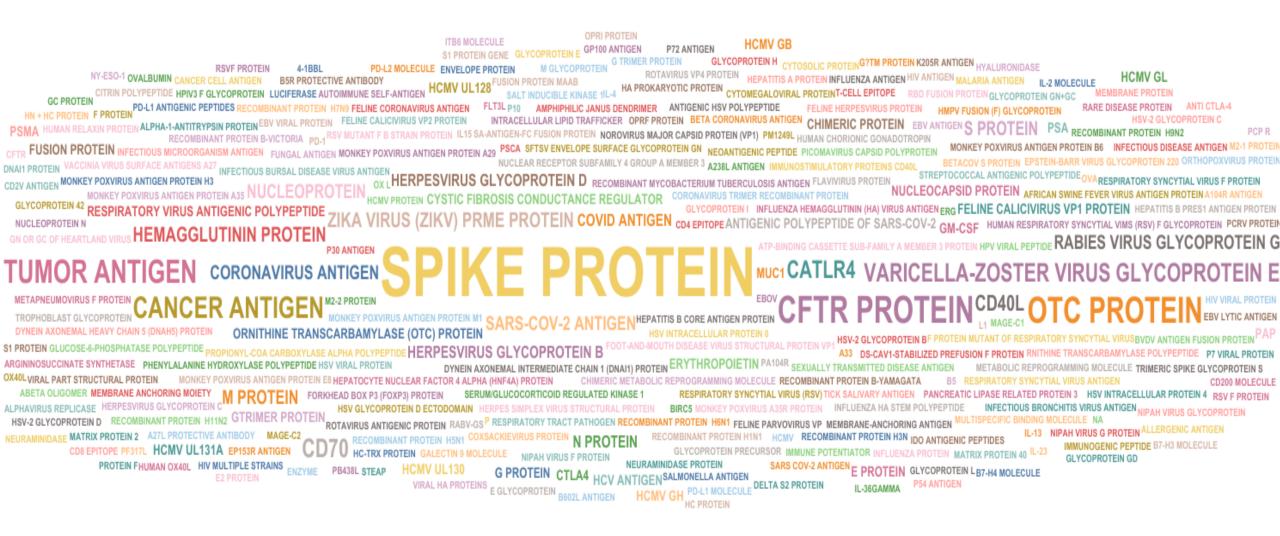


DISSECTION OF PATENTS/APPLICATIONS PERTAINING TO 'mRNA TYPES'



- Amongst the mRNA types, the maximum number of patents/applications disclose the use of unmodified mRNA for the preparation of vaccines, Further, the use of modified mRNA in vaccines is explored by key players as it provides more stability and has more favorable immunogenic effects compared to the unmodified mRNA.
- In addition, mRNA technologies encompass a range of sophisticated techniques and modifications that are employed to improve the efficacy, stability, and performance of mRNA molecules for various applications, including in the development of vaccines and therapies. Some of these key mRNA modifications and techniques include nucleoside modifications, poly A tail modification, codon optimization, and self-amplifying mRNA.

REPRESENTATION OF mRNA ENCODE MOLECULE (1/2)





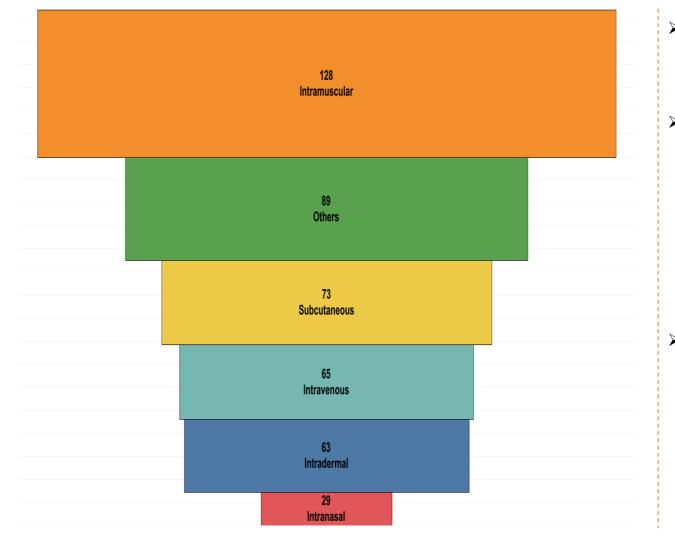
REPRESENTATION OF mRNA ENCODE MOLECULE (2/2)

- A significant portion of patent filings and applications predominantly center around mRNA-based molecules, with a particular focus on encoding entities like the spike protein of SARS-CoV-2, and infectious antigens i.e., influenza, and RSV infection. These elements play a pivotal role in the development of vaccines and therapies. Following this primary focus, the second most prevalent area of interest lies in the realm of cancer antigens encoded using mRNA technology.
- This trend underscores the growing significance of mRNA in the biopharmaceutical field, especially with regard to addressing infectious diseases and cancer. The mRNA approach enables the precise encoding of specific antigens, such as the spike protein of SARS-CoV-2 or cancer-related molecules, providing a versatile platform for vaccine and therapeutic development.





DISSECTION OF PATENTS/APPLICATIONS PERTAINING TO 'ROUTE OF ADMINISTRATION OF mRNA VACCINES'



- The primary area of focus in the realm of patents and applications pertains to the delivery of mRNA vaccines, and notably, the most prevalent method is intramuscular administration.
- This trend highlights the widespread interest and research efforts in optimizing the administration of mRNA-based vaccines. Intramuscular delivery is widely favored due to its effectiveness and ease of use, making it a practical choice for many vaccine candidates. Additionally, subcutaneous and intravenous administration, while less common, is another important route, often chosen for specific vaccine formulations and therapeutic purposes.
 - As the field of mRNA vaccines continues to advance, the choice of delivery method is crucial in determining the safety and efficacy of these vaccines. Researchers and innovators are actively exploring and patenting various approaches to ensure the successful deployment of mRNA vaccines, ultimately contributing to the development of more effective and accessible immunization strategies.

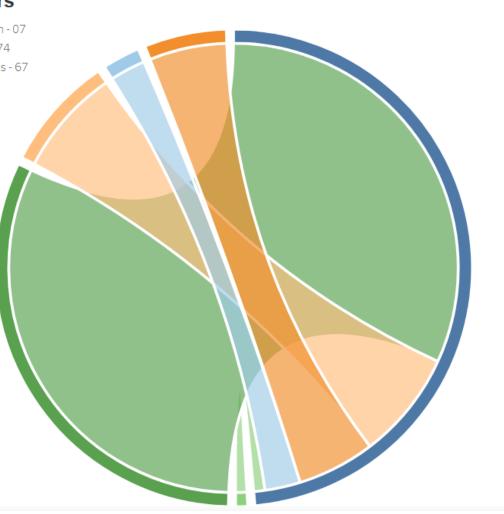




DISSECTION OF PATENTS/APPLICATIONS PERTAINING TO 'mRNA VACCINE DELIVERY CARRIERS'

Delivery Carriers

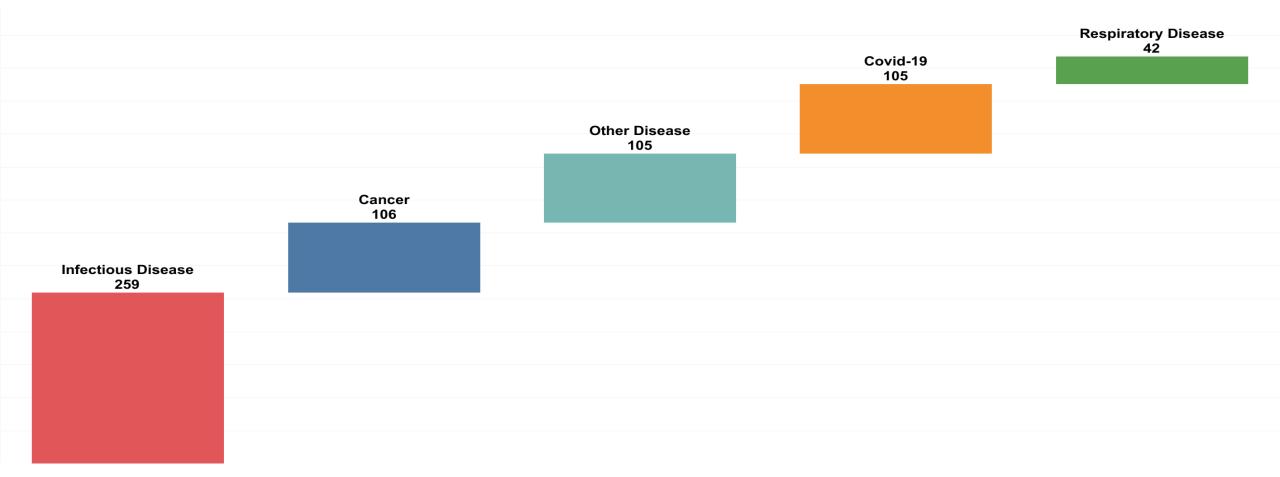
- Cationic Nano-emulsion 07
- Lipid Nanoparticles 274
- Liposome Nanoparticles 67
- Others 48
- Polymers 22
- Records



The chart clearly shows that the majority of patents and applications emphasize the utilization of lipid nanoparticles for delivering mRNA vaccines. Liposomes come next in usage. Lipid nanoparticles are essential components of mRNA vaccine technology, ensuring the secure and efficient delivery of mRNA into target cells, ultimately eliciting the intended immune response without any impact on an individual's genetic material.



PATENT LANDSCAPE ANALYSIS OF mRNA THERAPEUTICS



A significant portion of mRNA-related patents and applications focus on infectious diseases, underscoring the potential of mRNA technology in combating these threats. Cancer is another major area of interest, with a substantial number of patents dedicated to its treatment. While respiratory diseases and COVID-19 have also garnered significant attention, infectious diseases remain the primary focus of mRNA research and development.

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PATENT PORTFOLIO ANALYSIS



Heat Map Analysis Represent Major Assignee's w.r.t. mRNA Type and Application Area (1/2)

	Modifed mRNA	Unmodified mRNA	Self Amplifying mRNA	Covid-19	Cancer	Infectious Disease	Respiratory Disease	Other Disease
MODERNA	66	39		16	19	42	12	66
CUREVAC	29	13		7	19	24	4	26
TRANSLATE BIO	4	29		1	1	9		31
UNIV PENNSYLVANIA	12	3		3	2	12	2	11
INST MICROBIOLOGY CAS	5	2		4		7	1	4
RNAIMMUNE	5	1	2	4		3	1	
ZHENGZHOU UNIV	5	1		1	1	3	1	4
CANSINO BIOLOGICS	1	4		2		4	1	3
ETHERNA IMMUNOTHERAPIES	1	5			2	3		3
BIONTECH	2	4			4			2



PATENT PORTFOLIO ANALYSIS



Heat Map Analysis Represent Major Assignee's w.r.t. mRNA Type and Application Area (2/2)

- The heat map reveals a clear preference for modified mRNA among the major players. Moderna, in particular, stands out with a significant number of patents in this area, indicating a strong focus on modified mRNA technology. While companies like Translate Bio and CureVac have a notable presence in unmodified mRNA, the overall trend leans towards modified mRNA as the preferred approach.
- Infectious diseases and cancer emerge as the primary areas of interest for mRNA therapeutics. CureVac and Translate Bio have a significant number of patents in infectious diseases, reflecting the global focus on combating these threats. Moderna and CureVac, on the other hand, demonstrate a strong focus on cancer, highlighting the potential of mRNA technology in this critical area. Respiratory diseases, including COVID-19, have also garnered significant attention, with Moderna and CureVac being key players.
- While some companies, like CureVac and Moderna, have a broader patent portfolio covering multiple mRNA types and application areas, others, such as Translate Bio and RNAimmune, are making notable strides in specific areas. This indicates a diverse research landscape with emerging trends and potential future leaders. The geographic distribution of patent activity also highlights regional trends in mRNA research and development.



PATENT PORTFOLIO ANALYSIS MODEINO

This chart illustrates the prevalence

of different mRNA types in patented

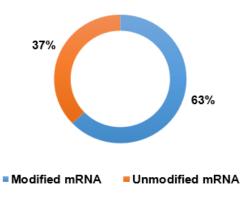
mRNA vaccine technologies,

highlighting the dominance of

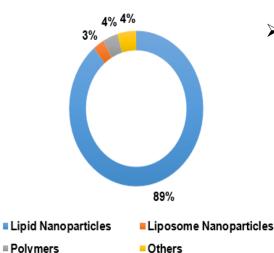
modified mRNA.

MODERNA (1/2)

mRNA Types

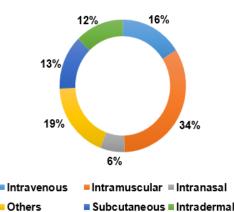


Delivery Carriers



This chart examines the delivery carriers employed in mRNA vaccine technologies, emphasizing the dominance of lipid nanoparticles.

Route of Administration



Application 18% 14% 14% 11% 16% 11% 14% 16% 41% Covid-19 Cancer Infectious Disease Respiratory Disease

Others

This chart showcases the preferred routes of administration for mRNA vaccines, with intramuscular delivery being the most common.

 This chart reveals the primary target diseases for mRNA vaccines, with COVID-19, cancer, and infectious diseases being the primary focus areas.





MODERNA (2/2)

KEY PATENTS

Patent No.	Key Features
<u>EP4355761A1</u>	The patent application relates to a mRNA vaccine comprising a modified mRNA encoding coronavirus spike proteins formulated in a lipid nanoparticle for SARS-CoV-2.
<u>US11696946B2</u>	The patent document relates to a <mark>vaccine comprising a modified mRNA encoding an influenza virus antigen formulated</mark> <u>in a lipid nanoparticle for influenza.</u>
<u>US20180243225A1</u>	The patent application relates a vaccine comprising a <u>modified mRNA encoding an Ebola virus antigen formulated in a</u> <u>lipid nanoparticle for the ebola virus.</u>
<u>US20210268086A1</u>	The patent application relates to <u>a nucleic acid cancer vaccine comprising a modified mRNA formulated in a lipid</u> nanoparticle.

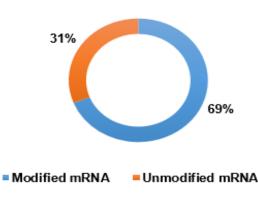


PATENT PORTFOLIO ANALYSIS



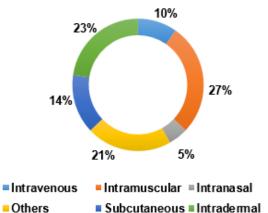
CUREVAC (1/2)

mRNA Types



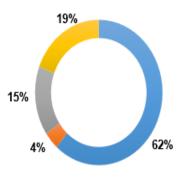
This chart illustrates the distribution of mRNA types in CureVac's mRNA vaccine technologies, highlighting the company's focus on modified mRNA.





This chart showcases the favored routes of administration for CureVac's mRNA vaccines, with intramuscular delivery being the primary method.

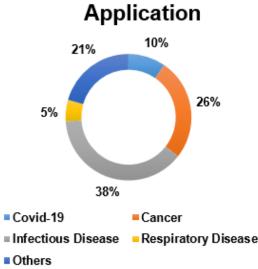
Delivery Carriers



This chart examines the delivery carriers employed in CureVac's mRNA vaccine technologies, emphasizing the dominance of lipid nanoparticles.

Lipid Nanoparticles
 Dolymers
 Liposome Nanoparticles
 Others

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This chart reveals the
primary target diseases for
CureVac's mRNA
vaccines, with COVID-19,
cancer, and infectious
diseases being the
primary focus areas.





CUREVAC (2/2)

KEY PATENTS

Patent No.	Key Features
<u>EP4147717A1</u>	The patent application relates to an mRNA vaccine comprising a coding sequence encoding a spike protein for COVID-19.
<u>US20200085852A1</u>	The patent application relates to an epidermal mRNA vaccine for the treatment of disease.
<u>US20220313813A1</u>	The patent application relates to a rotavirus mRNA vaccine wherein said mRNA is modified mRNA.
<u>US20210251898A1</u>	The patent application relates to a mRNA vaccine comprising a modified mRNA encoding coronavirus spike proteins formulated in a lipid nanoparticle for influenza or rabies.



KEY PATENTS: INSTITUTIONS VS. COMPANIES (1/2)





KEY PATENTS: INSTITUTIONS VS. COMPANIES (2/2)



- According to the analysis, Moderna, with 105 patent families, stands as the leading applicant/assignee in the mRNA vaccines field. Moderna's research encompasses mRNA and lipid nanoparticle (LNP) platforms, with a particular focus on applications in oncology and infectious diseases. Their pioneering work centers on modified mRNA vaccines, which are at the core of their innovative efforts.
- CureVac, specializing in customizing the 5' and 3' untranslated regions and the open reading frame, places a strong emphasis on addressing both cancer and infectious diseases within the mRNA vaccine domain.
- Recently, Katalin Karikó and Drew Weissman, who are affiliated with the University of Pennsylvania, were honored with the 2023 Nobel Prize in Medicine. They were recognized for their groundbreaking discoveries related to nucleoside base modifications that paved the way for the development of highly effective mRNA vaccines against COVID-19.



KEY PATENTS: INSTITUTIONS VS. COMPANIES (2/2)



GRANTED PATENTS/PATENT APPLICATIONS – UNIVERSITIES

Patent No.	Key Features
US11660332B2 JOHNS HOPKINS UNIV, UNIV PENNSYLVANIA, VANDERBILT UNIV	The patent document relates to a nucleoside-modified mRNA-lipid nanoparticle lineage vaccine for hepatitis C virus.
US20210386853A1 UNIV PENNSYLVANIA	The patent application relates to a composition comprising <u>mRNA encoding the ectodomain of a Herpes Simplex</u> <u>Virus glycoprotein</u> <u>D, where mRNA is nucleoside modified encapsulated in liposomal nanoparticles for treating</u> <u>HSV infection.</u>
CN113046369B INSTITUTE OF MICROBIOLOGY OF CAS	The patent document relates to a mRNA vaccine, wherein said mRNA is encapsulated in lipid nanoparticles for the treatment of coronavirus.
CN115969967B ZHENGZHOU UNIV	The patent document relates to a triple mRNA vaccine for preventing feline rhinotracheitis, feline calicivirus, and feline panleukopenia, comprising a mRNA expressing an antigenic protein encapsulated in lipid nanoparticles.



KEY PATENTS: INSTITUTIONS VS. COMPANIES (2/2)



GRANTED PATENTS/PATENT APPLICATIONS – OTHER COMPANIES

Patent No.	Key Features
WO2022189634A1 REDBIOTEC	The patent application relates to a vaccine composition comprising one or more mRNAs, wherein each of said mRNAs encodes a Herpes Simplex Virus (HSV) structural protein encapsulated in liposomal nanoparticles.
KR20240107033A BIOPHARMA CORP	The patent application relates to a mRNA-based vaccine composition comprising mRNA encoding an antigenic peptide formulated in the liposome.
CN114921481A SHANGHAI SERUM BIOTECH	The patent application relates to <u>a rabies virus-modified mRNA vaccine, wherein said mRNA is encapsulated in</u> <u>liposome nanoparticles.</u>
WO2023121264A1 EYEGENE	The patent application relates to a mutant SARS-CoV-2 vaccine composition comprising mRNA encoding a Spike antigen of severe acute respiratory syndrome coronavirus 2 variant (SARS-CoV-2).



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