

Self-amplifying RNA vaccines

Patent Landscape Analysis – February 2023

*How can saRNA revolutionize mRNA treatments?
Are mRNA vaccines leaders positioned on this new saRNA technology?*

REPORT OUTLINE

- saRNA vaccines
- Patent landscape analysis
- February 2023
- Ref.: KM23002
- PDF > 100 slides
- Excel file: 392 patent families
- €4,990 for a multi-user license



REPORT'S KEY FEATURES:

- **IP trends**, including time evolution of published patents, countries of patent filings and patents' legal status
- Ranking of **main patent assignees** & analysis of their patented technologies
- **Key players' IP position** and **relative strength** of their patent portfolios
- **Summary of the therapeutic applications:** cancer, SARS CoV2, influenza, hepatitis, HIV, veterinary.
- **Summary of the carriers used to saRNA encapsulation:** VRP, LNP, liposome, CNE, polymer.
- Identification of **newcomers** and **start-up firms**.
- **Analysis of collaborations and EP patent oppositions.**
- **Key patent selection** (highly cited & granted patents with broad claims)
- **Excel database** containing all patents analyzed in the report, including segmentations + **hyperlink to updated online database** (legal status, documents etc.)

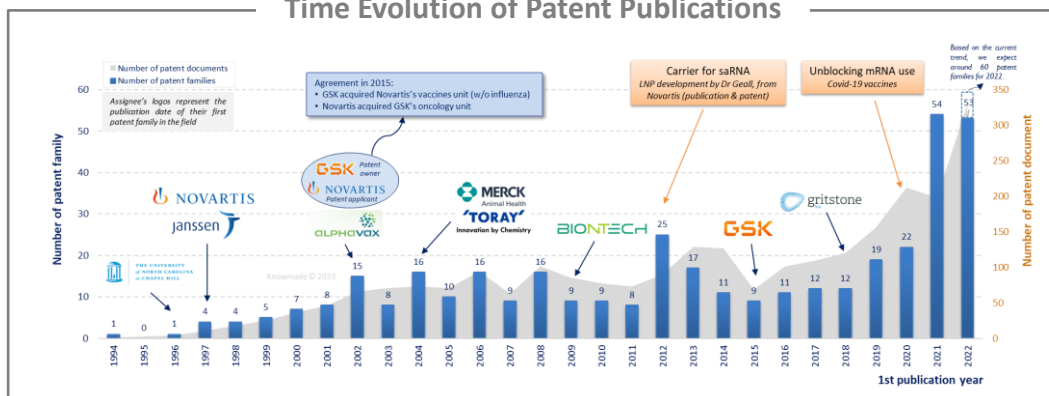
LINKED REPORTS

- [mRNA Cancer Therapies Patent Landscape 2022](#)
- [RNA vaccine Patent Landscape 2021](#)
- [Circulating Tumor Cells: isolation & detection – Patent Landscape 2020](#)
- [Circulating DNA/RNA – Patent Landscape 2021](#)
- [Cancer Diagnostics – Startup identification 2020](#)

saRNA vaccine, a more effective descendant of mRNA vaccine?

The pandemic has led to research effort and global coordination, resulting in the rapid development of mRNA vaccines and human clinical trials. Currently, there are 2 main types of mRNA vaccines: conventional non-amplifying mRNA and self-amplifying mRNA (saRNA or replicons). saRNAs are larger than non-amplifying mRNAs and maintain auto-replicative activity derived from an RNA virus vector. saRNA vaccines contain an antigen-encoding sequence and viral RNA polymerase-encoding sequence required for replication. The advantage of the self-replicating approach is that significantly higher amount of antigen can be expressed with lower doses of mRNA, and it achieves longer term expression of the antigen. In addition to clinical benefits such as stronger immune responses, lower vaccine doses and reduced adverse effects, saRNA would have advantages at manufacturing levels. The saRNA vaccine platform may have higher manufacturing productivity and lower cost per dose compared to mRNA vaccines. In human saRNA vaccine, the most advanced application is therapeutic vaccination against cancer or SARS-CoV2, with saRNA encoding tumor antigens (specific or associated) or spike proteins, respectively. Moreover, this innovative and less expensive therapy tends to apply to the veterinary area with treatments for companion animals and livestock. Main other applications of saRNA vaccine are directed against infectious diseases such as influenza, hepatitis and HIV. Currently, there are less than 100 clinical trials in progress, but this number is increasing, reflecting the interest in this topic as well as the economic stakes for companies. However, to date, there is still no product on the EP and US markets, but some patent oppositions have already been initiated against key patents. Thirteen EP opposition proceedings have been identified herein, most of which were filed in the past 5 years and are still pending. With these initial tensions concerning patents and in a swiftly growing technological environment, it is essential to comprehend the Intellectual Property (IP) stance and strategy of these different players. Such insight can help spot business risks and opportunities, foresee forthcoming technologies, and enable strategic decisions to bolster market position.

Time Evolution of Patent Publications



The analysis of the time evolution of patent publications shows that interest in saRNA began in the early 1990s, but it did not gain significant traction. However, in 2012, some scientists seized the first opportunity to encapsulate large saRNAs in lipid nanoparticles (LNP) instead of using viral particles. This was strongly proposed by Novartis researchers who showed that a 9 kb saRNA encapsulated in an LNP elicits broad, potent, and protective immune responses comparable to those of viral delivery technology, but without its inherent limitations. The second decisive event was the use of mRNA in human therapy during the COVID-19 pandemic in 2020, leading to the development of the first mRNA COVID-19 vaccine. These two events allowed saRNA technology to fully develop and led to a significant increase in the number of patent families published in 2021 and 2022, which doubled from 2021 to 2022.

Companies mentioned in this report (non-exhaustive list):

ALPHAVAX, ARCTURUS THERAPEUTICS, BIONTECH, BOEHRINGER INGELHEIM - ANIMAL HEALTH, CSL – SEQIRUS, GRITSTONE BIO, GSK, JANSSEN, MERCK MSD, MERCK MSD - ANIMAL HEALTH, NOVARTIS, PFIZER, REPLIKUN BIOTECH, SANOFI, TENGAN BIOMEDICAL, TIBA BIOTECH, TORAY INDUSTRIES, etc.

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