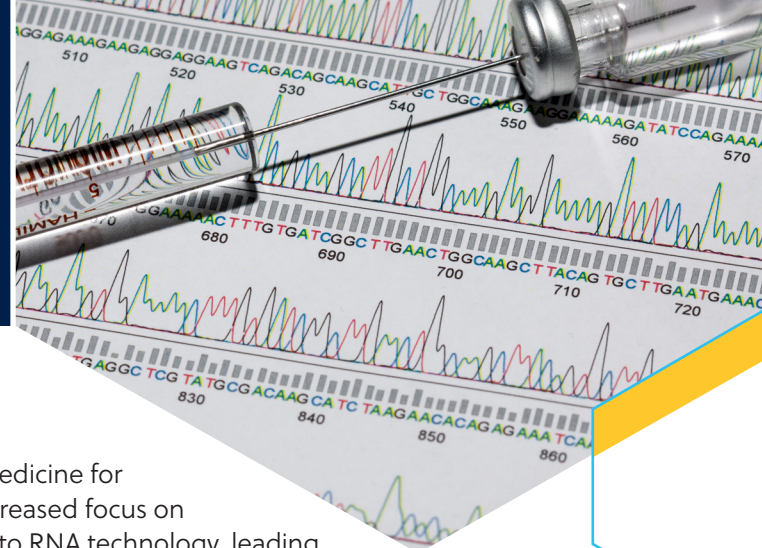


# IP TRENDS AND OPPORTUNITIES: RNA THERAPEUTICS



## Overview

Using RNA in therapeutics has the potential to revolutionize medicine for generations to come. In the last decade, there has been an increased focus on research, clinical development, and commercialization related to RNA technology, leading to a complex and competitive IP landscape. Missed scientific and IP information during R&D can put investments at risk. Organizations must enable proactive and comprehensive IP search strategies to effectively propel, secure, and protect their innovations.

**Background:** Over the last 50 years, our understanding of the types and functions of RNA has expanded, enabling the development of more stable and effective RNA medicines. This has resulted in many new therapeutic options for cancer, cardiovascular diseases, infectious diseases, and more. It has also widened the IP landscape and opportunities for new and existing companies.

**Market potential:** The global RNA-based therapeutics market is estimated to reach \$25.1 billion (USD) by 2030, growing at a compound annual growth rate of 17.6% between 2021 and 2030.<sup>1</sup>

With the cost-effectiveness, ease in manufacturing, and opportunity to target previously “undruggable” sites, RNA can potentially treat a many diseases, from the common to the extremely rare.

**Opportunities:** The success of the mRNA COVID vaccines led to a massive influx of investor funding flowing into RNA therapeutics and vaccines since 2020. However, the number of patents published between the two different time periods (2012-2016 versus 2017-2021) increased only modestly.

**Key benefits:** Leveraging RNA's diverse biological functions can lead to new therapies, diagnostic biomarkers, and clinical targets, offering extensive IP opportunities such as securing patents for novel treatments, formulations, and delivery methods.

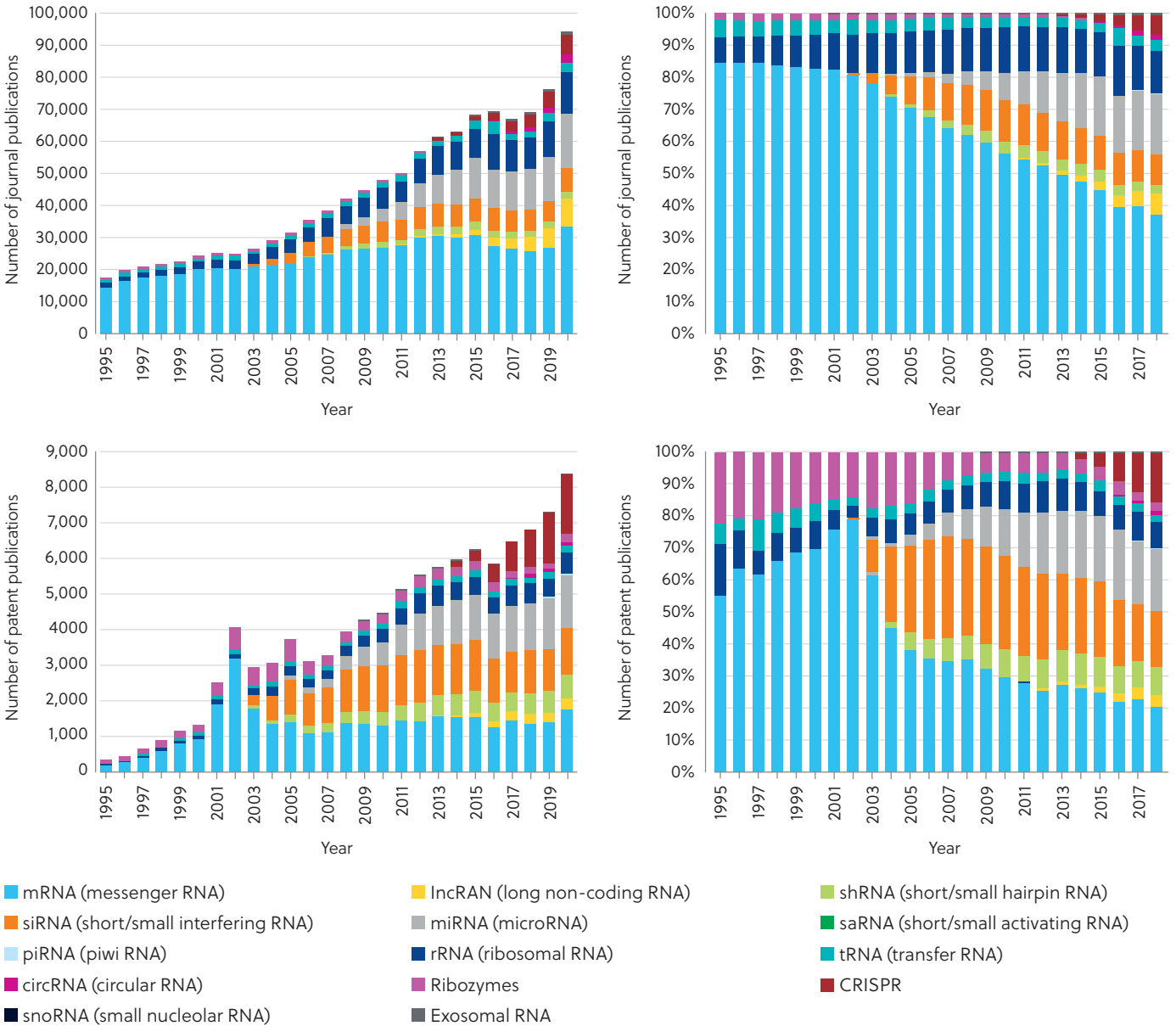
**Key challenges:** Precise and efficient IP searching remains a challenge. Analysts and innovators performing RNA IP searches face the growing complexity and volume of information.

Navigating non-standard RNA terminology across patents, experiencing limited precision for searching sequences and chemical modifications, and monitoring changes in the IP landscape in a rapidly growing industry is driving the need for industry-specific search platforms.

# Publication trends reflect the diversification of RNA types and increasing CRISPR technology patents

As RNA innovation is becoming increasingly diversified, CRISPR technology accounted for a sizable 20% of RNA-related patent applications in 2020, indicating a burgeoning market for innovation and investment.<sup>2</sup>

## Publication trends by type of RNA



## Infectious diseases and cancer dominate RNA patent growth

Infectious diseases and cancer are the most common health concerns addressed through RNA-based interventions. Despite slight shifts, the annual number of patent publications for infectious diseases and cancer remains relatively high, while eye and cardiovascular disease patents have remained stable since 2011.<sup>2</sup>



## Fast-paced RNA technology developments demand precise IP search

Pharmaceutical companies are mainly investing in mRNA and siRNA technologies amidst the complexity of RNA-based therapeutics for multiple diseases. This approach will require close IP monitoring to ensure freedom to operate while avoiding infringement.

### siRNA

Since 2018, when the first siRNA drug was approved, four new drugs – one per year from 2019 to 2022 – received U.S. FDA approval.<sup>3</sup> The foundation of this rapid success was laid by the discovery of the RNAi mechanism 20 years before, in 1998.

### ASO

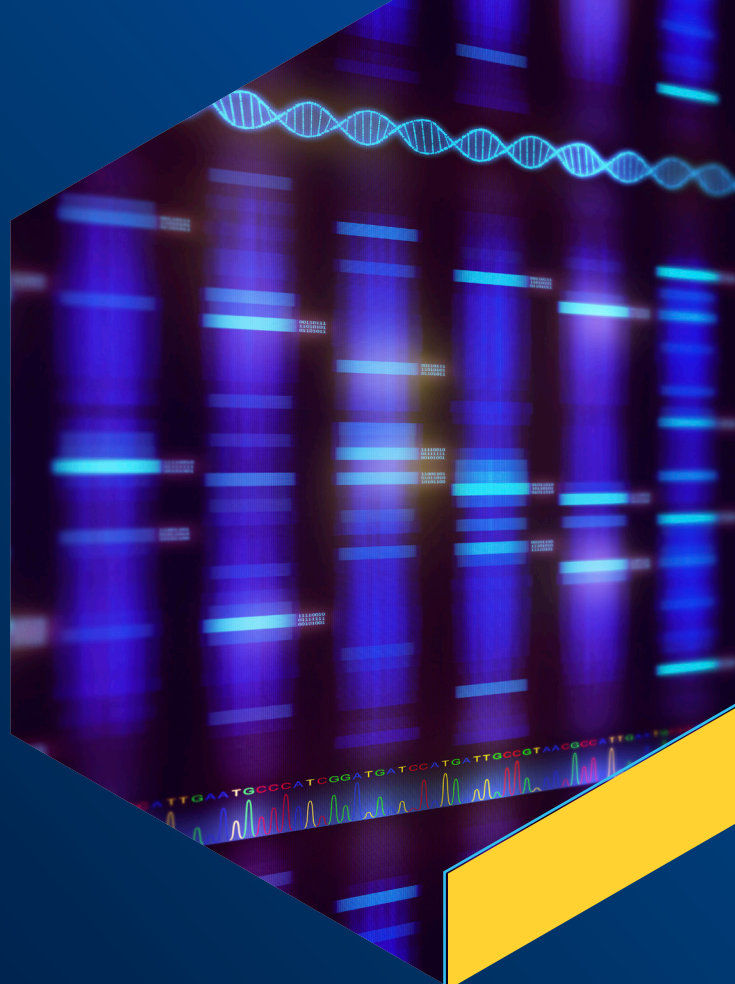
The triumph of antisense oligonucleotides (ASOs) since the 1998 approval of the first therapeutic initiated a series of ASO drug approvals, demonstrates their expanding role in clinical settings. Fifteen ASO therapeutics have already been approved in the U.S. for treating various rare diseases.<sup>4</sup>

### CRISPR

With CRISPR technology emerging as a dominant force in the RNA landscape, its groundbreaking gene-editing capabilities hint at a revolution in genetic interventions, potentially reshaping the future of medicine. There are 460+ pharmaceutical and biotechnology companies engaged in the development and application of CRISPR nucleases.<sup>5</sup>

### RNA aptamers

While the first RNA aptamer was FDA-approved 20 years ago, the second was only recently approved in 2023.<sup>6</sup> Despite this lag behind other RNA-based technologies, there are a few RNA aptamer molecules at various stages of development and in clinical trials.<sup>7</sup>





## Due diligence in continual IP monitoring ensures strategic innovation management

Staying up-to-date with the ever-evolving RNA-based therapeutic landscape means monitoring the research and the IP landscape. The pharmaceutical sector's focus on developing treatments for multiple diseases with their RNA technology capabilities suggests a thriving future where robust IP strategies can safeguard and advance breakthroughs.

Balancing innovation with ethical considerations, especially in CRISPR-based developments, will be essential in navigating the future, potentially marked by litigation and regulatory impositions. The foresight to continually monitor IP with precision is the key to harnessing the full potential of RNA technologies.

Learn more at [cas.org/stnext](https://cas.org/stnext)

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