VACCINEINSIGHTS

MRNA VACCINES: HARNESSING THE BENEFITS, ADDRESSING THE CHALLENGES

SPOTLIGHT

COMMENTARY

mRNA Vaccines: a growing and complex IP landscape

Robert Burrows & Ellen Lambrix

The success of mRNA vaccines against COVID-19 has fueled significant global interest in the development of mRNA vaccines against other infectious diseases and cancer. The COVID-19 pandemic has also highlighted the complex and fragmented nature of the intellectual property landscape relating to mRNA vaccines. 2022 has also seen the first significant patent infringement cases relating to mRNA vaccines. This article examines the types of patents that protect key aspects of mRNA vaccine technology and considers the impact of the existing IP landscape and recent patent litigation on future mRNA vaccine development.

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INTRODUCTION

It has been less than 2 years since the first messenger RNA (mRNA) based vaccines were approved for use against coronavirus disease (COVID-19), yet in that short time billions of doses of those mRNA vaccines have been administered globally and millions of lives have been saved as a result. This success has fueled significant global interest in the development of mRNA vaccines against other infectious diseases and cancer. Numerous companies and institutions are actively carrying out research into mRNA vaccines and a number of mRNA vaccines for indications other than COVID-19 are now being tested in the clinic. However, although the first mRNA-based vaccines have only recently been approved for use, the mRNA vaccine platforms used and under development today are underpinned by a multi-decade-long history of research and development.

As well as shining a spotlight on mRNA vaccines as a new and promising category of vaccines, the COVID-19 pandemic has also

generated significant interest in intellectual property and debate about the role that patents play in enabling or hindering innovation. This scrutiny has also highlighted the complexity of the intellectual property landscape relating to mRNA vaccines. Perhaps unsurprisingly, the number of patent applications filed relating to the use of mRNA as a vaccine for both infectious diseases and cancer increased dramatically over the five years to 2020 with patent owners ranging from large multinational biopharma companies and smaller biotech companies to universities and research institutions [1]. Given the long history of development, the platform nature of mRNA vaccine technology, and the growing number of entities conducting research in the field, it will also come as no surprise that the intellectual property landscape relating to mRNA vaccines is complex and highly fragmented.

2022 has seen the first significant patent infringement cases relating to mRNA vaccines. These high-profile cases illustrate how important it will be for anyone developing new mRNA vaccines to appreciate the complex patent landscape surrounding mRNA vaccines and the resultant need to consider intellectual property strategy and freedom to operate issues early in development.

In this article, we examine the types of patent that protect key aspects of mRNA vaccine technology. We also consider recent patent litigation and the impact of the existing intellectual property (IP) landscape on future vaccine development. This article is based on publicly available information only, is non-exhaustive, and is not intended as legal advice.

PATENTS: A BRIEF INTRODUCTION

A granted patent provides its owner (or possibly its licensee) with the right to prevent others from exploiting the invention claimed by the patent for a limited period. In the UK and the US and many other jurisdictions, the term of a patent is 20 years from the date of filing, although patent term extensions can be obtained in certain countries; such extensions, which can be up to an additional 5 years in the UK and the US, are designed to compensate the patent holder for delays to market that are caused by the regulatory approval processes for new medicinal products.

Patents are territorial, which means that a patent can only be used to prevent infringing activities in the country in which it is granted. Patent portfolios, therefore, consist of a series of national patents each covering a different jurisdiction. While some patent owners may take a global approach to patent filing, often the costs associated with filing and maintaining patents mean that patent owners will focus geographic coverage on key jurisdictions (which may vary from product to product).

The inventions protected by patents can be broadly categorized as products or processes. However, there are multiple different claim types that can be granted, and which set out the boundaries of the protected invention. With regard to mRNA vaccines, and by way of example, such claims could cover the mRNA sequence itself, the delivery system for the mRNA vaccine, the dosage regimen for the mRNA vaccine, the medical use(s) for the mRNA vaccine, processes for producing mRNA vaccines generally, and processes for the manufacture of a particular mRNA vaccine.

Although the focus of this article is on patents, it is important to appreciate that patents are not the only means by which innovations can be protected. An alternative is to rely on confidentiality restrictions and trade secrets law to protect unpatented know-how. This can be particularly useful in protecting aspects of a product, its development, or manufacture which may be difficult to obtain a patent for (such as drug discovery and development methods).

MRNA VACCINES & PLATFORM DEVELOPMENT

One of the reasons why mRNA vaccines have generated so much attention is the platform

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nature of the technology. mRNA vaccines have been described as 'plug and play'; a reference to the fact that, in theory, only the mRNA coding region need be changed in order for an mRNA vaccine to target a different indication. From a public health perspective, this is attractive because it could enable new vaccines to be developed rapidly in response to new viral threats and updated quickly to address new variants. From a commercial perspective, an mRNA vaccine platform could accelerate time spent in early development and enable more standardized large-scale production. The platform nature of mRNA technology also means that mRNA could potentially be used as a vaccine for a wide range of diseases. Illustrating this versatility, a number of mRNA vaccines for indications other than COVID-19 are now being tested in the clinic, including vaccines against Cytomegalovirus, Respiratory syncytial virus, Human immunodeficiency virus, and different cancer types including melanoma and colorectal cancer [2].

Despite the headline-grabbing stories detailing the astonishingly rapid development of both the Moderna and Pfizer/BioNTech COVID-19 vaccines, the two vaccines are in fact underpinned by decades of development work into both mRNA and delivery platforms. Importantly, from an intellectual property perspective, this means that a number of patents relevant to mRNA vaccine platforms pre-date the COVID-19 pandemic.

mRNA was discovered in 1961[3] and the possibility of harnessing mRNA as a drug or a vaccine has long been considered. However, it wasn't until the 1990s that research on mRNA began to gain momentum, and even then, the field of synthetic mRNA research encountered many challenges. Challenges that researchers developing mRNA vaccine platforms have needed to overcome include ensuring that mRNA does not trigger an adverse immune response, that the mRNA can be delivered into host cells without being degraded, that the mRNA can be correctly read by ribosomes inside a patient's cells, and that host cells express enough of the encoded antigen to have a therapeutic effect. As the field has progressed, researchers have found solutions to each of these challenges, and interest in mRNA vaccines has grown. In recent years, companies active in the mRNA field have been investing heavily in designing and optimizing their mRNA platforms to address each of these challenges. This has translated into a significant focus on, and patenting of, mRNA sequence engineering and chemistry, delivery systems (including composition and chemistry of lipid nanoparticle delivery systems) and manufacturing processes.

Nucleoside-modified mRNA

One of the key breakthroughs in the field of mRNA came in 2005, when discoveries made by Katalin Karikó and Drew Weissman at the University of Pennsylvania solved the issue of synthetic mRNA triggering an uncontrolled immune response in patients [4]. Kariko and Weissman discovered that by incorporating pseudouridine (a naturally modified mRNA nucleoside), instead of uridine, the modified mRNA could circumvent the body's inflammatory immune response to the synthetic mRNA [5]. The University of Pennsylvania, therefore, owns a number of patents relating to nucleoside-modified mRNAs and their uses. Both Moderna and Pfizer/BioNTech's COVID-19 vaccines use a modified nucleoside approach and, according to securities and exchange commission (SEC) filings, both companies have taken non-exclusive sub-licenses of mRNA patents owned by the University of Pennsylvania (via a cascade of sub-licenses from mRNA RiboTherapeutics and Cellscript). Whilst these licenses are non-exclusive, SEC filings indicate that mRNA RiboTherapeutics and Cellscript are subject to certain time restrictions on granting additional sublicenses for *in vivo* uses in humans.

While not all mRNA vaccines under development have used the same nucleoside-modified approach, disappointing trial results from CureVac's first generation

mRNA COVID-19 vaccine, which used normal uridine instead of pseudouridine, led to speculation that it was this difference which resulted in lower-than-hoped-for efficacy compared to the Moderna and Pfizer/BioNTech vaccines [6].While it is too early to know for sure, the success of the Moderna and Pfizer/BioNTech COVID-19 vaccines seems to support the case for modified mRNA, and in turn the value of the patents owned by the University of Pennsylvania (licensed to mRNA RiboTherapeutics and Cellscript).

Delivery, delivery, delivery - LNP composition and chemistry

mRNA is inherently unstable [7] and to function *in vivo* needs to be packaged inside a delivery system to ensure that it can be safely delivered into target cells without being degraded. Delivery has long been recognized as one of the key obstacles to the successful development of RNA-based technologies; as Nobel Prize-winning researcher and Alnylam co-founder, Phillip Sharp, was quoted as saying as early as 2003, the major hurdle for RNA is "delivery, delivery, delivery" [8].

Lipid nanoparticles (LNPs), used to encapsulate mRNA, are currently the most commonly used delivery system for mRNA vaccines [9]. Although other delivery systems have been developed (including lipids, lipid-like materials, polymers, and protein derivatives) [10], LNPs are currently the only delivery technology that is approved for use in mRNA vaccines (used by both the Pfizer/BioNTech and Moderna COVID-19 vaccines).

Like mRNA, LNPs also have a long history of development. Early work on LNPs was carried out by Pieter Cullis and his laboratory at the University of British Columbia and LNP technology was further developed by a number of companies associated with Cullis, including Canadian biotech companies Arbutus Biopharma Corporation (Arbutus) and Acuitas Therapeutics, Inc. (Acuitas) [11,12]. Several companies have since taken licenses of LNP patents from Arbutus and, in 2018, Arbutus spun out rights to its LNP technology (excluding rights to hepatitis B) into Genevant Sciences GmBH (Genevant) as part of a joint venture with Roivant Sciences Ltd.

Prior to the development of the mRNA COVID-19 vaccines, LNPs had already been successfully used as a delivery system for other technologies, most notably in RNAi therapeutics pioneered by Alnylam Pharmaceuticals (Alnylam) and also recently in genome editing technology. Alnylam gained approval in 2018 for the world's first approved RNAi therapeutic, ONPATTRO (patisiran), which is currently approved for the treatment of polyneuropathy caused by hereditary ATTR amyloidosis. ONPATTRO uses an LNP system that was developed by Arbutus and in-licensed by Alnylam. Alnylam itself has also developed its own proprietary LNP systems and owns several patents covering novel cationic biodegradable lipids. Patents owned by Arbutus and Alnylam have each been the subject of recent patent litigation relating to COVID-19 vaccines (discussed further below).

The LNPs used in the mRNA COVID-19 vaccines consist of four main components: a neutral phospholipid, cholesterol, a polyethylene-glycol (PEG)-lipid, and an ionizable cationic lipid [13]. Each element of an LNP affects the properties and function of an LNP system and there is, therefore, significant scope for engineering and optimizing LNPs. With research ongoing to address remaining challenges associated with LNPs (such as shelf-life and stability, targeting, optimal loading, and manufacturing challenges) [14] it seems likely that the number of patents relating to the use of LNPs in the delivery of mRNA vaccines will continue to grow. Companies involved in the development of mRNA vaccines (including Moderna and BioNTech) have been investing significant time and efforts into optimizing the chemistry and safety of LNPs and developing their own proprietary systems. SEC filings from Moderna indicate that it has an extensive portfolio of patents relating to its mRNA platform,

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including novel lipid components designed for optimal expression of both therapeutic and vaccine mRNAs.

BioNTech uses a number of delivery formulations for its products, including lipid nanoparticles and its own proprietary lipoplex (lipid carriers) formulations for which it has several patent filings in its sole name. Again, reflecting the importance of delivery systems to the success of an mRNA product, SEC filings reveal that BioNTech also has several active third-party partnerships focused on this area including a non-exclusive license from Acuitas for LNP formulations used in the Pfizer/BioNTech COVID-19 vaccine.

MRNA VACCINE PATENT PORTFOLIOS

Aside from patents covering nucleoside modification and delivery technology, there are a variety of other types of patent which may cover an mRNA vaccine candidate. These include mRNA vaccine compositions encoding antigens for specific indications, mRNA sequence engineering and chemistry (including patents directed at various features of mRNA structure), engineered protein sequence patents, and patents covering different aspects of mRNA manufacturing.

According to SEC Filings, as of December 31 2021, Moderna had more than 170 issued or allowed U.S. patents or patent applications, more than 110 granted or allowed patents in jurisdictions outside of the US, and over 430 additional pending patent applications. Moderna's SEC filings state that the company typically pursues patent protection for both product and method of use claims. Moderna has a broad prophylactic vaccine patent family including claims to lipid nanoparticle encapsulated mRNAs that encode infectious disease antigens for different indications (including COVID-19) and also includes methods using those compositions for vaccination.

BioNTech has also indicated it has a broad patent estate comprising over 100 patent families owned by BioNTech (exclusively or jointly), all of which include at least one filing in the EU or US with several pending or granted patents in multiple jurisdictions. BioNTech's SEC filings suggest that its patent estate includes patents directed to features of therapeutic mRNA structures, mRNA formulations (including its lipoplex formulations and lipid nanoparticles), mRNA manufacturing, and uses of mRNA therapeutics.

Aside from Moderna and BioNTech, there are also many other companies actively developing mRNA vaccines including CureVac, GlaxoSmithKline, Sanofi (having acquired Translate Bio in 2021), and Arcturus Therapeutics, each of which is also building patent portfolios relating to mRNA vaccines.

PATENTING CHALLENGES

Although precise requirements vary from jurisdiction to jurisdiction, as a minimum, a patent will only be granted for new and inventive products or processes. This generally means that the claimed invention cannot have been published previously. In addition, the invention cannot be an obvious iteration of something that existed beforehand. In the context of an mRNA vaccine, these requirements for novelty and non-obviousness present certain challenges to patentability. For example, if the sequence of the antigen or protein encoded by the mRNA has been published, then the coding region of the mRNA is unlikely to be patentable. Even if the translated protein has been engineered, it may still be difficult to obtain a patent for the related mRNA coding region if the steps taken to engineer the relevant antigen or protein were obvious.

Interestingly, despite the commercial success of both the Moderna and Pfizer/BioNTech COVID-19 vaccines, early patent applications filed for both vaccines are facing considerable uncertainty as to whether they will proceed to grant. International Search Reports prepared by the European Patent Office (EPO) have highlighted issues with both novelty and inventive step based on the prior

publication of the SARS-CoV-2 genome and prior publications which described specific proline substitutions (so-called 2P mutations) which had previously been made to other coronaviruses (and for which the US National Institutes of Health (NIH) has been granted a patent) [15].

These patentability challenges associated with claims for mRNA vaccines encoding previously published proteins, or proteins that have been engineered in a previously published manner, mean that some of the other types of patents relating to mRNA vaccines highlighted above (such as LNP chemistry and formulation and manufacturing patents) may become more valuable.

PATENT LITIGATION: THE START OF AN LNP PATENT WAR?

Given the number of companies active in this space and the potential commercial value of the resulting mRNA vaccines and associated technology, patent litigation in the field has seemed inevitable. This year a number of patent infringement cases relating to the Moderna and Pfizer/BioNTech COVID-19 mRNA vaccines have been reported in the UK press and specialist biotech publications. These cases are thought to be the first significant patent infringement actions relating to mRNA vaccines and it is therefore going to be interesting to see how they play out. Interestingly, three of the five cases reported this year relate to patents covering the LNPs, which may point to a broader trend in future litigation (and the types of patent it may actually be possible to obtain).

In each of these cases, the claimants are seeking damages for alleged patent infringement. However, interestingly, none of the claimants are seeking an injunction to prevent sales of the allegedly infringing COVID-19 vaccines. The lack of an injunction request is relatively unusual in patent infringement cases, but understandable given the circumstances of the pandemic; attempting to prevent the supply of the vaccines could result in a PR disaster and may also be refused by the relevant courts in any event. For example, injunctions are a discretionary remedy in the UK and there are also legal provisions such as compulsory licenses and Crown Use provisions that could potentially be relied upon to avoid patent infringement in times of emergency.

Arbutus & Genevant vs Moderna

In February 2022, Arbutus and Genevant filed a patent infringement case against Moderna in the US District Court of Delaware. Arbutus and Genevant are alleging that the production and sale of Moderna's COVID-19 vaccine infringes six US patents [16] relating to LNPs and their use. According to the claim, the relevant patents are owned by Arbutus and licensed to Genevant and relate to structural lipids, such as phospholipids and cholesterol; cationic lipids, including ionizable lipids that are positive charge-bearing at certain pH levels; and conjugated lipids, which are lipids attached to a polymer such as polyethyleneglycol (PEG).

Moderna denies infringement of the relevant patents. As an interesting aside, Moderna is also claiming that Arbutus and Genevant have brought the claim against the wrong party in the wrong court. Moderna's position is that it is a US Government-contracted supplier as part of the US' emergency pandemic response and is therefore protected from patent infringement actions under US Code Section 1498 which would require the claim to be brought against the US Government in the US Court of Federal Claims [17].

Acuitas vs Arbutus & Genevant

As mentioned above, Acuitas partnered with BioNTech and Pfizer to license the LNP used in the Pfizer/BioNTech COVID-19 vaccine (Comirnaty). In March 2022, Acuitas brought a claim against Arbutus and Genevant in the US District Court for the Southern District of New York seeking a declaratory judgment

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that the Pfizer/BioNTech COVID-19 vaccine does not infringe nine patents owned by Arbutus [18] and that the relevant patents are invalid in any event. The nine patents in question include the six US patents under which Arbutus and Genevant are suing Moderna (referred to above).

Alnylam vs Pfizer & BioNTech

In March 2022, Alnylam filed separate patent infringement cases against Moderna and Pfizer in the US District Court of Delaware. Alnylam alleges that the Moderna and Pfizer/BioNTech COVID-19 vaccines infringe one of its US patents which claims a class of cationic biodegradable lipids that can be used in the formation of LNPs for the delivery of an active agent, including mRNA. Both Moderna and Pfizer deny infringement. Moderna again is also seeking to rely on US Code Section 1498 claiming that the suit should have been brought against the US Government in the US Court of Federal Claims.

In June 2022, Alnylam filed new patent infringement suits against Moderna and against both Pfizer and BioNTech, each in the US District Court of Delaware. These latest cases allege that the companies' respective COVID-19 vaccines infringe a recently granted US patent, which also claims a class of LNPs that can be used in the formation of LNPs for the delivery of an active agent, including mRNA.

CureVac vs BioNTech

In June 2022, CureVac filed a lawsuit in the German Regional Court in Düsseldorf against BioNTech SE and two of its subsidiaries, alleging that the Pfizer/BioNTech COVID-19 vaccine infringes four of CureVac's German patents relating to the engineering of mRNA molecules [19]. The related press release by CureVac states that the patents relate to sequence modifications to increase stability and enhance protein expression, as well as mRNA vaccine formulations specific to COVID-19 vaccines. At the time of writing, BioNTech has responded, without naming CureVac, via a statement posted on its website that"BioNTech's work is original, and we will vigorously defend it against all allegations of patent infringement".

BioNTech & Pfizer vs CureVac

Following the German action brought by CureVac against BioNTech (referred to above), BioNTech has responded, together with Pfizer, by bringing a claim against CureVac in the US District Court for Massachusetts seeking a declaratory judgment that the Pfizer/BioNTech COVID-19 vaccine does not infringe three US patents owned by CureVac relating to mRNA vaccines [20].

OUTLOOK FOR THE FUTURE

The synthetic mRNA field is still relatively young, but innovation is continuing at a rapid pace. The COVID-19 vaccines have demonstrated both the extraordinary utility of the technology and the potentially phenomenal value of mRNA products. With companies investing significant sums into their mRNA development efforts and a growing number of partnerships in the field fueling development, the patent landscape relevant to mRNA vaccines is likely to become even more crowded and complex. As such, it seems likely that there will be more patent challenges and potential infringement actions in the near future as companies jostle for position in the market. For anyone involved in the field of mRNA vaccine development, the complexity of the patent landscape and the recent litigation in the field should act as a reminder of the importance of involving patent specialists early in development in order to navigate freedom to operate issues, patent filing strategies and patent licensing negotiations.

With almost inevitable freedom to operate issues and a specter of potential litigation, an

increasingly complex and fragmented patent landscape may also catalyze the formation of new collaborations and cross-licensing partnerships. Particularly between mRNA vaccine developers and companies specializing in delivery technology such as LNPs. A focus on solving freedom-to-operate issues may also lead to a degree of consolidation in the market and potentially an uptick in M&A in coming years as companies look to secure access to patents underpinning key elements of their mRNA platforms.

Finally, much has been said during the pandemic about the role that patents play in innovation and whether they enable or hinder development and access to new technologies. The pandemic has also given rise to a broader debate on issues of public interest such as access to medicines (particularly in lower-income countries), drug pricing, public funding, commercial profit, and the link between each of these issues and the patent system. While those broader issues are outside the scope of this article, the recent proliferation of patent infringement actions relating to the use of LNPs in mRNA vaccines is interesting in this context. We will have to wait to hear the outcome of those cases, but it already seems clear that the development of Moderna and Pfizer/BioNTech's COVID-19 vaccines were not impeded by patents. Even if the vaccines are shown to infringe, the claimants are not seeking injunctions to prevent sales. Ultimately then, the patent litigation in this instance should have no direct impact on the public's access to the COVID-19 vaccines. However, a large and complex patent landscape can become an issue if companies find themselves burdened with so many third-party royalty obligations that commercial incentives to bring a product to market are reduced. Similarly, if patent protection on the mRNA vaccine and its use is difficult to obtain, this could also discourage companies from developing such products for fear of not being able to recoup their investment costs during the period of any patent term. While there is no suggestion that any mRNA vaccine developers are currently in this situation, it will be interesting to see how all of these issues develop in the years ahead.

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16. US 8,058,069, US 8,492,359, US 8,822,668, US 9,364,435, US 9,504,651, and US 11,141,378

17. The effect of US Code Section 1498 is to provide that if the United States, or contractors acting on its behalf, infringes a US patent, the patent owner's remedy is an action for compensation against the United States in the United States Court of Federal Claims. It therefore generally protects US government contractors from liability for infringement.

18. US 8,058,069; US 492,359; US 8,822,668; US 9,006,417; US 9,364,435; US 9,404,127; US 9,504,651; US 9,518,272; and US 11,141,378.

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AFFILIATIONS

Robert Burrows
Partner,
Bristows LLP

Ellen Lambrix
Senior Associate,
Bristows LLP

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