
Patent dispute looms as a major complication for Moderna's COVID-19 vaccine

Edward Hammond

Moderna's candidate COVID-19 vaccine, mRNA-1273, on which the US government has placed one of its largest pandemic bets, appears to be ensnared in a serious patent dispute that could impact the vaccine's production and price. The problem lies in a fight between Moderna and a Canadian biotech company named Arbutus, formerly Tekmira, which holds a patent on mRNA vaccine formulations that Moderna's vaccine may infringe on.

Moderna denies that it needs a licence to Arbutus' patent in order to produce mRNA-1273.¹ But a recent pre-publication paper with Moderna co-authors² states that mRNA-1273's formulation is one that appears to squarely fall within the claims of a 2011 Arbutus patent³ that covers particular ratios of ingredients in an mRNA vaccine.

Although the pre-publication paper was released only weeks ago in mid-June, Moderna claims that the mRNA-1273 composition that it describes is a "research formulation" that will be replaced with an alternative when the vaccine goes into production. Asked to describe the new formulation, Moderna declined, telling *Forbes* magazine that "we are not disclosing our proprietary ratios at this time."⁴

Before the pandemic, Moderna was working with United States government support on a vaccine against MERS (Middle East Respiratory Syndrome), a coronavirus "cousin" of SARS-CoV-2 that causes COVID-19. The MERS vaccine was the direct predecessor of mRNA-1273. As the MERS vaccine was moving

¹ Moderna. 2020. Statement from Moderna on Patent Trial and Appeal Board (PTAB) Ruling (press release). 24 July. <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-patent-trial-and-appeal-board-ptab-ruling>

² Corbett K et al. 2020. SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness. bioRxiv (pre-publication). <https://www.biorxiv.org/content/10.1101/2020.06.11.145920v1.full> (posted 11 June 2020).

³ US patent 8058069. <http://patft1.uspto.gov/netacgi/nph-Parser?patentnumber=8058069>

⁴ Vardi N. 2020. Moderna's Mysterious Coronavirus Vaccine Delivery System. 29 July. <https://www.forbes.com/sites/nathanvardi/2020/07/29/modernas-mysterious-coronavirus-vaccine-delivery-system/#59ac580462d9>

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through testing, in January 2019 Moderna filed a legal suit against Arbutus in the US patent court,⁵ seeking to invalidate Arbutus' mRNA vaccine formulation claims.

On 23 July, the US Patent Trial and Appeal Board ruled against Moderna's attempt to undo Arbutus' patent. The implications of the loss seemed obvious, but Moderna brushed off the setback, claiming that it did not file the lawsuit because its own vaccines may infringe on Arbutus' patent but rather, somewhat implausibly, because Moderna was performing a sort of public service for a number of companies that are developing mRNA vaccines and drugs. According to Moderna, the suit was provoked by "the longstanding aggressive posture taken by Arbutus and its predecessor company against many developers of nucleic acid-based therapeutics."

Moderna's statements that the patent dispute is not relevant to mRNA-1273 have met with wide skepticism, but will be impossible to place in context until further information about the vaccine's formulation becomes available.

Adding to the complicated outlook, Arbutus has entered into separate deals related to the mRNA patent. After an Arbutus (then Tekmira) Ebola drug sputtered and eventually flunked trials in 2018, the company changed its focus to hepatitis B. When it did so, the Canadian company accepted a US\$116 million investment from Roivant Sciences based in Basel, Switzerland.

The investment made Roivant the largest shareholder of Arbutus. Roivant then merged some of its own research programmes with parts of Arbutus to form a new company named Genevant, which is based in Cambridge, Massachusetts (US), a mere two kilometres from Moderna's headquarters.

Genevant came away from the deal with assets that include an exclusive licence for all non-hepatitis B use of the formulation patent, including control over sub-licences.⁶ The only exceptions, according to an Arbutus filing with US regulators,⁷ are pre-existing patent licences one of which is, interestingly, held by CureVac, a German company whose own mRNA COVID-19 vaccine is competing with Moderna's.⁸

Thus, for COVID, excepting CureVac's licence, the patent appears to be effectively controlled by Basel-based Roivant. Confusingly, although Roivant is a privately held Swiss company, it is controlled by the American biotech capitalist Vivek Ramaswamy. It is thus the 34-year-old Ramaswamy who will likely be calling the patent holder's shots in the ongoing dispute, and it will be his decision if Arbutus were to seek payment from Moderna or file suit for infringement.

What the future holds is difficult to predict. Given the extreme pressures of the pandemic, it seems unlikely that either company would pursue a course that would entirely prevent production of Moderna's vaccine if it proves effective in Phase 3 human trials that began in late July.

The patent dispute does, however, have economic implications with broader potential ramifications. If Moderna's final mRNA-1273 formulation arguably, or actually, infringes on the Arbutus patent, Roivant would appear to be within its rights to demand whatever licence fees it deems appropriate from Moderna and, in effect, Moderna's US government backers. If Roivant pursued this possibility, it could have the effect of significantly, perhaps dramatically, increasing the cost of Moderna's vaccine.

⁵ <https://developer.uspto.gov/ptab-web/#/search/documents?proceedingNumber=IPR2019-00554>

⁶ Roivant Sciences. 2018. Arbutus and Roivant Launch Genevant Sciences with Industry-Leading Platform to Develop Broad Range of RNA Therapeutics for Genetic Diseases (press release). 11 April. <https://roivant.com/arbutus-and-roivant-launch-genevant-sciences-with-industry-leading-platform-to-develop-broad-range-of-rna-therapeutics-for-genetic-diseases.html>

⁷ Arbutus. 2020. US Securities and Exchange Commission Form 8-K. 23 July. <https://investor.arbutusbio.com/node/15551/html>

⁸ CureVac. 2020. US Securities and Exchange Commission Form F-1. Page 96. 24 June. https://www.sec.gov/Archives/edgar/data/1809122/000110465920086354/tm2016252-11_f1.htm

Uncertainty about rights, and potentially increased prices and complex litigation may also discourage orders for Moderna's vaccine, although US "vaccine nationalism" and the company's tight relationship with US health ministry officials appear to ensure that the US government will buy a large proportion of Moderna's production at almost any price. Thus, barring unexpected behaviour by one of the companies, the "solution" to a continued dispute may lie in further large outlays of US public funds to make the issue "go away".

This would be likely to make Moderna's vaccine more expensive for all customers, and raise price expectations among other companies, to the likely detriment of access to vaccines in developing countries. Moderna is unlikely to be eager to take a haircut on its vaccine prices in relation to the dispute, as its stock's meteoric rise through the pandemic has earned its executives huge personal profits, and many stock speculators that are heavily invested at high prices could be unsettled by the prospect of thinner margins.

Moderna's vaccine is the second US government-supported SARS-CoV-2 vaccine to become embroiled in an intellectual property dispute.

Inovio, a US company whose vaccine is also supported by the US government, the Bill and Melinda Gates Foundation, and Gavi, The Vaccine Alliance, is also in limbo. Inovio's vaccine is produced using techniques covered by patents and manufacturing trade secrets owned by VGXI, an American company owned by South Korea's GeneOne Life Science. That dispute appears to have delayed planned production of Inovio's vaccine for the US defence ministry.⁹

Future scientific publications and regulatory filings will divulge the final mRNA-1273 formulation in the coming months. At that point, the next phase of the Moderna dispute will take shape. It seems likely that the patent dispute will prove costly for one or both of the companies, and quite possibly the US taxpayer, but the more important cost will be to US and international public health if the patent dispute limits availability of the vaccine through its impact on costs and/or production.

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⁹ See TWN Info Service on Intellectual Property and Health, 19 June 2020 and 16 July 2020. https://www.twn.my/title2/intellectual_property/ipr.new.htm