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The Covid-19 vaccine battle just got interesting

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A patent claim against Arbutus is thrown out, threatening parts of Moderna's mRNA technology – including its Covid-19 vaccine.

Be careful what you wish for. Moderna had fired the first salvo against Arbutus over two years ago, seeking to assert the position of its lipid nanoparticle (LNP) technology, but in the event it has come off worse: yesterday a US court deemed that a key Arbutus patent stands, sending the tiny biotech's stock up 120%.

Remarkably, Moderna has not issued a formal statement about the ruling, presumably not wanting to give away anything about its possible implications. The LNP tech is thought to underlie most of its mRNA work – including the high-profile Covid-19 vaccine project mRNA-1273 – but Moderna evidently does not want to spell this out.

The ruling concerns the third of three Arbutus patents Moderna had challenged through inter partes reviews; Moderna had prevailed in the first and got a mixed verdict on the second. Regarding the third, concerning US patent 8,058,069, a judge yesterday ruled that Moderna had "not shown by a preponderance of the evidence that claims 1–22 of the patent are unpatentable".

Arbutus patents challenged by Moderna in IPR proceedings		
Patent no	**Challenged**	**US Patent Trial and Appeal Board verdict**
9,404,127	Feb 21, 2018	All of the patent's claims invalidated
9,364,435	Mar 5, 2018	Some patent claims upheld, others (including sole independent claim) invalidated
8,058,069	Jan 9, 2019	All of the patent's 22 claims upheld

Of course, appeals against the last two rulings are virtually assured, though Moderna has yet to reveal its hand. It also has to be stressed that the final outcome is unlikely to see Moderna prevented from marketing an LNP-based product. At worst Moderna might have to agree to pay Arbutus a royalty.

That is, of course, as long as the LNP tech Arbutus claims is indeed implicated in most of Moderna's mRNA work. The clinicaltrials.gov entry for Moderna's phase I Covid-19 vaccine trial states: "mRNA-1273 is a novel LNP-encapsulated mRNA-based vaccine".

Moreover, any infringement would depend on mRNA-1273 actually getting to market; based on clinical data generated so far the Moderna project lags Biontech/Pfizer's mRNA rival BNT162b1 (*Novavax keeps investors waiting, July 21, 2020*).

But investors now have to price in extra risk, and yesterday Moderna's stock lost 9%, equivalent to some $3bn of market cap.

It's complicated

How the farrago came about is complicated. Markman Advisors, a New York-based patent consultancy, has pointed out that Moderna had initially licensed LNPs from Acuitas, a small Canadian firm that had itself acquired these from Arbutus.

But Acuitas's right to sublicense became the subject of separate Arbutus litigation, which was settled in February 2018 with the effect that Acuitas was limited to four specific viral targets. Moderna thus appeared to have been frozen out, and it was then that it started challenging the validity of Arbutus's LNP patents.

In a further twist, Acuitas is the source of the LNPs that Biontech and Pfizer use in BNT162b1. This arrangement appears to have been routed through a deal between Biontech and Genevant, a venture founded jointly in April 2018 by Arbutus and Vivek Ramaswamy's holding company, Roivant Sciences.

The disparity of the Arbutus/Moderna David-versus-Goliath battle should not be underestimated: against Moderna's $28bn market cap Arbutus's valuation stands at a puny $430m, even including yesterday's surge. And in US corporate law size and financial firepower count for a lot.

Nevertheless, this marks a sudden turnaround in Arbutus's fortunes. The group, formerly known as Tekmira and until now best known for hepatitis B failures, could now have a stake in a second clinical-stage Covid-19 vaccine.