CureVac sues BioNTech over mRNA technology

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A new front has opened in the patent battle over the breakthrough mRNA technology. CureVac in July filed suit in the German Regional Court against BioNTech, seeking fair compensation for infringement of four patents CureVac claims are used to make Comirnaty, the coronavirus vaccine developed and sold by BioNTech and its partner Pfizer. The Tübingen, Germany–based CureVac, whose own mRNA vaccine stalled a year ago after showing just 47% efficacy against COVID-19 in a late-stage trial, said it was not seeking an injunction, nor did it intend to halt the manufacture, sale or distribution of Comirnaty. CureVac's intellectual property portfolio, accumulated over more than 20 years of work in mRNA technology, protects several inventions the company considers foundational to the design and development of BioNTech's mRNA COVID-19 vaccine, including those relating to the engineering of mRNA molecules — sequence modifications to increase stability and enhance protein expression — as well as mRNA vaccine formulations specific to SARS-CoV-2 vaccines. "Many years of our research have also contributed to the success of the mRNA vaccines and made that possible," says CureVac CEO Franz-Werner Haas. "From our point of view, it is self-evident to respect the associated property rights." In response, BioNTech posted a statement on its website that read, in part: "BioNTech's work is original, and we will vigorously defend it against all allegations of patent infringement."

mRNA vaccine maker Moderna is also fending off lawsuits over its COVID-19 vaccine from Alnylam Pharmaceuticals, Arbutus Biopharma and Genevant Sciences.

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mRNA printers kick-start personalized medicines for all

mRNA printers will bring low-cost vaccines and made-to-order treatments for a range of different diseases.

South Africa is setting up mRNA manufacture with new technologies that will ensure vaccines and therapeutics can be made locally and cheaply. Cape Town–based Afrigen joined forces with Belgian firms Univercells and eTheRNA. And the US-based Greenlight Biosciences is about to start a clinical trial of an mRNA vaccine in South Africa, to test a vaccine that will cost about $1 per dose—a fraction of the price of other mRNA vaccines.

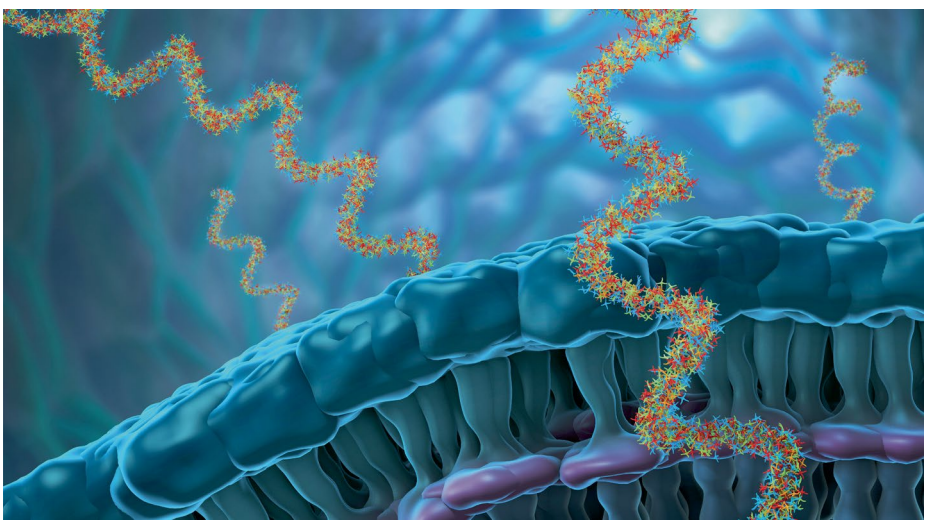
The first wave of COVID-19 vaccines came about as many biopharmaceutical firms pivoted in response to the threat. But during the initial vaccine rollouts, many low-income countries were all but abandoned, highlighting the huge gaps in global supply chains and manufacturing capabilities. "mRNA got done in one year. That's the life cycle of a new product from Apple," says Rahul Singhvi, CEO of Resilience, a biomanufacturing company established in 2020 as an explicit response to the pandemic by investor Robert Nelsen, at Arch Partners.

Yet mRNA manufacturing has not kept pace with innovation—companies often rely on "antiquated approaches," Singhvi says, as they have neither the time nor the resources to invest in better alternatives. At best, they are adding incremental improvements to out-of-date processes, and "that's never going to move the needle." Resilience has raised over $2 billion in equity financing and has big ambitions to put biomanufacturing on a similar footing to semiconductor manufacturing.

Elsewhere, a new wave of biotechs are pursuing plug-and-play approaches. Among them Nutcracker Therapeutics and Creyon Bio are incorporating automation, continuous-flow manufacturing and biochip-based microfluidics devices to accelerate the next cycle of mRNA innovation.

The goal goes beyond manufacturing at lightning speed. An mRNA printer, as popularized by vaccine developer CureVac, could make personalized point-of-care mRNA therapies affordable for more patients around the globe than at present. Although the technology to has yet to be realized, a new era of low-cost on-demand clinical-grade RNA is imminent.

Dan Gibson, chief technology officer at Codex DNA, argues that this is already a reality in research settings. While he was at Synthetic Genomics, Gibson and colleagues, including J. Craig Venter, developed an automated digital-to-biological converter to produce nucleic acids and proteins directly from DNA sequence information. Codex DNA was later spun out to commercialize



mRNA production in the cell is emulated by plug-and-play printers. Christoph Burgstedt / Alamy Stock Photo.