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COVID-19 Vaccine Patent War: Moderna's Claims Invalidated by PTAB

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The door may now be open for additional challenges to patents covering mRNA vaccine technologies, paving the way for increased competition in the mRNA vaccine space.

On Wednesday, March 5, 2025, the United States Patent Trial and Appeal Board (PTAB) sided with Pfizer and BioNTech that challenged claims in two of Moderna's patents. U.S. Patent Nos. 10,702,600 ("the '600 patent") and 10,933,127 ("the '127 patent") were invalid for being anticipated or obvious.

Previously, on August 26, 2022, Moderna sued Pfizer and BioNTech for infringing the '600 patent, the '127 patent and U.S. Patent No. 10,898,574 by selling their COVID-19 mRNA vaccines. The lawsuit was filed in a Massachusetts court (case number 1_22cv11378). In response, Pfizer and BioNTech challenged claims 1, 2, 4-6, 8-12, 16, 17, 20, 21, and 26 of the '600 patent and claims 1-3, 6-9, 11-13, 17-18 and 20 of the '127 patent in *inter partes* reexamination (IPR) proceedings, IPR2023-01359 and IPR2023-01359. Both IPRs were filed on August 28, 2023. The Massachusetts court stayed Moderna's patent infringement suit pending the outcome of the IPR proceedings.

The first independent claim of the '600 patent reads:
A composition. comprising: a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (Beta(CoV)) S protein or S protein subunit formulated in a lipid nanoparticle.

The first independent claim of the '127 patent reads:
A method comprising administering to a subject a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle in an effective amount to induce in the subject an immune response to the BetaCoV S protein or S protein subunit, wherein the lipid nanoparticle comprises 20-60 mol % ionizable cationic lipid, 5-25 mol % neutral lipid, 25-55 mol % cholesterol, and 0.5-15 mol % PEG-modified lipid.

The first independent claim of the '574 patent reads:
A method of producing a polypeptide of interest in a cell in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising a modified messenger RNA (mmRNA) such that the mmRNA is introduced into the cell, wherein the mmRNA comprises a translatable region encoding the polypeptide of interest and comprises the modified nucleoside 1-methyl-pseudouridine, and wherein the pharmaceutical composition comprises an effective amount of the mmRNA providing for increased polypeptide

production and substantially reduced innate immune response in the cell, as compared to a composition comprising a corresponding unmodified mRNA.

While the final decisions remain under seal, the PTAB docketing system indicates that all challenged claims were deemed invalid for being anticipated or obvious. References used to invalidate the claims include U.S. Publication No. 2013/0266640; PCT Publication No. WO 2012/006369; Zhi-yong Yang et al., *A DNA vaccine induces SARS coronavirus neutralization and protective immunity in mice*, 428 NATURE 561 (2004); and PCT Publication No. WO 2005/118813.

Notably, all '600 and '127 patent claims asserted in Moderna's infringement suit have been invalidated in these two IPRs. As a result, these two patents may no longer be relevant to the litigation. However, the infringement lawsuit also asserted another Moderna patent, U.S. Patent No. 10,898,574[1], thus, the battle for COVID-19 vaccine patent rights continues.

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Footnotes

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[1] As of March 6, 2025, no IPR has been filed against the '574 patent.

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