

VACCINE PATENT DISPUTE

MODERNA V. PFIZER/BIONTECH

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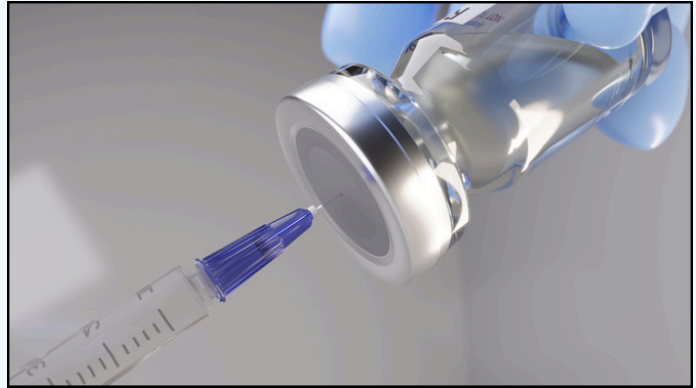
On 2nd July 2024, a High court judge issued a mixed ruling in an ongoing patent infringement case between competing developers of Covid-19 vaccines Moderna, Pfizer and BioNTech. The pharmaceutical giant Pfizer along with its partner manufacturer BioNTech have been embroiled in conflict with vaccine producer Moderna, concerning the use of messenger RNA ('mRNA') technology in Covid-19 vaccines.

Timeline of previous events surrounding dispute :

Date	Event
October 2020	Moderna issued Pledge.
March 2022	Moderna updated their pledge
August 2022	Moderna sued Pfizer and BioNTech in US and Germany.
December 2022	Countersuit by Pfizer and BioNTech.
August 2023	Pfizer/BioNTech requested in partes review from the United States Patent and Trademark Office (USPTO).
November 2023	Moderna patent declared invalid by the European Patent Office (EPO).
April 2024	Court in Massachusetts granted Pfizer and BioNTechs motion to put on hold Moderna's lawsuit.
May 2024	EPO upheld validity of one of Moderna's patents.
July 2024	Mixed ruling regarding Moderna's Pledge from the UK High court. <ul style="list-style-type: none"> i) Moderna's EP 3 718 565 patent confirmed invalid following their appeal to EPO boards of Appeal. ii) Moderna's EP 3 590 949 patent held to be valid and thus infringed by BioNTech and Pfizer.

Background of Patent Dispute:

Moderna sued BioNTech and others who were in partnership with Pfizer, alleging that the partnership copied mRNA technology that Moderna had patented long before the rise of COVID-19 existed, and therefore infringed their patents filed between 2010 and 2016.



In August 2022, Moderna sued Pfizer and its German partner in relation to their Comirnaty vaccine, arguing that it was due compensation for products that were manufactured after 07 March 2022. The lawsuit concerned two specific elements of the Comirnaty vaccine:

1. Its approach to encode the spike protein packaged inside of a lipid nanoparticle; and
2. The particular mRNA modification which was claimed to be identical to Moderna's Spikevax.

Moderna alleged that neither company out of the duo had Moderna's level of experience in mRNA vaccines and thus could have only produced their Comirnaty vaccine by following Moderna's lead. Pfizer and BioNTech denied infringement, with both companies seeking the "revocation" of two of Moderna patents, claiming they were "invalid".

In August 2023, Pfizer and BioNTech took the fight to the U.S. Patent Trademark Office (USPTO) requesting an inter partes review of Moderna's patents, with the aim of having them declared invalid. According to Pfizer and BioNTech, Moderna protections were too broad and tried to claim ownership of knowledge that existed before 2015. This was the priority date of Moderna's patents. Stating in their counterclaim that Moderna's patent was "unimaginably broad" and that Moderna "Co-opted an entire field of mRNA technology."

In November of 2023, the EPO declared Moderna patent invalid which covered coronavirus vaccines using RNA polynucleotides. The patent in question was one which covered betacoronavirus vaccines that use a minimum of one RNA polynucleotide that contains an open reading frame encoding at least one betacoronavirus antigenic peptide.

In May 2024, The European Patent Office ('EPO') had upheld the validity of one of Moderna's patents by way of an oral decision, handing Moderna a win for this ongoing vaccine dispute. The EPO maintained the validity of "Patent '949" belonging to Moderna, which describes and protects certain alterations to mRNA molecules that are designed in order to lower its immunogenicity, bypass the immune system and boost translation in the body (as well as the potential uses of the modified mRNA)

Pfizer and BioNTech still have not appealed this decision despite initial talks of doing so.

The UK Dispute:



The 2nd July 2024, judgement resulted in a mixed ruling regarding Moderna's pledge.

- 1.Moderna's EP 3 718 565 patent was confirmed invalid following their appeal to EPO boards of Appeal.
- 2.Moderna's EP 3 590 949 patent was held to be valid and thus infringed by BioNTech and Pfizer.

The pledge:

"We feel a special obligation under the current circumstances to use our resources to bring this pandemic to an end as quickly as possible. Accordingly, while the pandemic continues, Moderna will not enforce our COVID-19 -related patents against those making vaccines intended to combat the pandemic. Further, to eliminate any perceived IP barriers to vaccine development during the pandemic period, we are also willing to license our intellectual property for COVID-19 vaccines to others for the post-pandemic period."

In parallel proceedings to the Moderna v Pfizer/BioNTech dispute, the main concern was with Moderna's "Patent pledge," and Pfizer/BioNTech's purported obligation to pay damages to Moderna. In October 2020, a pledge was issued by Moderna stating that "whilst the pandemic continued, they would not be enforcing any of their COVID- 19 related patents against those making vaccines which were intended to combat the pandemic."

In March of 2022,Moderna altered this pledge. Rather than their initial pledge above, they "withdrew" from their commitment not to enforce patents against vaccine manufacturers and limited their pledge to relevant parties that had manufactured those vaccines for use in 92 low- and middle-income countries exclusively.

The pledge trial dealt with whether Moderna's pledge was in fact withdrawn in March 2022 argued by Moderna, or on the 5 May 2023 according to Pfizer and BioNTech. The judgement from the High court Judge Jonathan Richards was that Pfizer and BioNTech had "non-contractual consent to perform acts that would otherwise infringe the patents between 8 October 2020 and 7 March 2022." Resulting in BioNTech and Pfizer having to pay damages to Moderna from the 8th of March 2022.

Final thoughts:



Both parties expressed mixed opinions towards the mixed judgement. Moderna mentioned that they were pleased that the High Court confirmed the infringement of their patent EP 949 and that the defendants were not entitled to use Moderna's patented technology after 7 March 2022, however they disagreed with other aspects of the decision and would consider appealing. Pfizer and BioNTech made similar remarks stating they believed in their own intellectual property and stand firm with the belief that neither patents are valid and therefore they will also be seeking to appeal the decision for EP 949.

The outcome of any further appeal will likely have huge impacts for both companies considering all the similar and/or parallel proceedings currently going on across multiple jurisdictions.

RT Coopers aim to provide up-to-date information on these proceedings and any further changes to the Multi-jurisdictional dispute between Moderna and vaccine manufacturers.