

VACCINATION WOES

PUBLIC POLICY. VIRULENCE. TECHNOLOGY. HUMANITY. PREDICTION. RISK. MORTALITY. ACCLAIM. \$\$.

By Denise Shaw & Inan Gupta

The COVID-19 pandemic delivered devastating sickness, strife, and upheaval worldwide in 2020.

However, long before the emergence of this recent scourge, scientists had been working diligently to protect humanity from pestilence by dedicating themselves to the field of vaccine development.

Dramatis personae

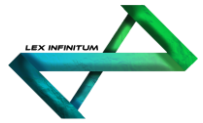
Professor Tahani al-Jamil and Dr. Moira Rose, a wife and wife duo of scientists co-founded the biotechnology company TurTec in 2013, focusing on development and manufacture of active immunotherapy modalities for the treatment of diseases. Before the advent of COVID, the commercially available offerings of the company were modest. However, it was recognised by investors for its cutting-edge research. On the back of this investor confidence, TurTec went public in 2018 at a valuation of USD 600 million: a meagre sum in the corporate world but representing the largest IPO in the biotech sector. In 2022, it posted revenues of USD 18 billion. This year, they were also proud to welcome back Dr. K Kodaline as Research Director of TurTec. Dr. Kodaline had been instrumental in delineating the research trajectory of TurTec in its early days before leaving for a tenured position at the University of Pennsylvania. In 2023, Dr. Kodaline, along with her associates, won the Nobel Prize for Physiology or Medicine for developing techniques allowing the use of mRNA for therapeutic purposes. Though Dr. Kodaline doesn't own the techniques, they are widely credited to her.

Mr. Doe is the CEO of MODA Inc, a legacy pharmaceutical giant with an enterprise value of USD 92 billion. MODA was amongst the first companies globally to develop a vaccine against COVID-19 and the first to develop an mRNA-based one.

From the apple of my eye

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TurTec was the proprietor of two key pieces of research.

First, TurTec developed and refined several techniques (including Dr. Kodaline's) relating to the use of mRNA tech in vaccines. This included methods that increased the immunity coverage provided by the vaccine and the stability of the product.

Second, TurTec possessed a proprietary computational design programme. This AI-based tech represents a radical departure from traditional vaccine development methods and allows for significant optimisation of the research process. The programme expedites and can reduce the time spent in lab trials by up to 80% and in controlled animal trials by 45%. It can also aid the analysis and the dosing effects of the vaccine by gender, race, ethnicity, and age.

To the apple of discord

In January 2020, Tahani and Moira read about the outbreak of COVID-19 and reasoned that their extensive research on mRNA therapy against cancer and other transmissible diseases could apply to vaccine models effective against COVID-19. They were aided in their research by their proprietary predictive algorithms program. In the view of Moira and Tahani, it is a privilege to work for the greater good of humanity, especially as immigrants who are aware of and treasure the opportunities they got.

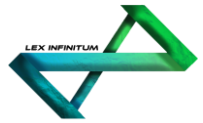
However, in 2020, TurTec was still a research-oriented company with limited market presence. With COVID lockdowns disrupting supply chains and owing to limitations in terms of resources, networks and downstream processing, TurTec's development of a vaccine hit a roadblock in April 2020. In May, recognizing its limitations, TurTec licensed rights over its research into mRNA vaccines to MODA Inc. for USD 20 million. Importantly, the computational design programme was not licensed.

At the height of the first wave, in a review, the Surgeon-General's office found MODA to be amongst the most promising candidates for the development of a

vaccine. Therefore, MODA was granted permission to violate any third-party patents required for the manufacture of the vaccine.

MODA came out with its vaccine in December 2020, shortly after the first-ever COVID vaccine was announced. The mRNA platform formed the basis of the vaccine. However, instrumental to the miraculously quick rollout of the vaccine was the synergy between the mRNA platform and the computational design algorithm. In





2022, in the context of effectiveness of the vaccine against COVID variants, Mr. Doe, the CEO noted, "The agility of our mRNA platform has enabled us to update, Moda's COVID-19 vaccine, to target XBB variants with speed and clinical rigor."

MO(O)DA swings

In 2021, MODA made a USD 50 million "pledge" to provide academic credit and or financial remuneration to researchers and scientists, in academia, government, and corporations who played a verifiable and substantial role in the discovery of the COVID-19 vaccine. In reliance on this promise, many women and men did their best but have not received the professional recognition or the money in the form of cash or research grants. However, failure to honor a pledge is not an actionable breach under the law.

MODA also continues to focus on public health efforts to increase vaccination rates globally. MODA has undertaken significant marketing and awareness campaigns, working closely with vaccinators and others to drive a robust vaccination season, including by activating the medical community, supporting and re-engaging customers (including those who deferred updated vaccination due to recent infections), and amplifying the voices of credible influencers.

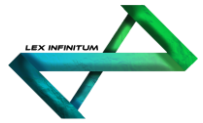
However, at the same time, MODA has registered its opposition to any government-mandated price caps on the product. It has also filed infringement lawsuits against two pharmaceutical companies and a research institution for using components of its COVID-19 vaccine that MODA claims proprietary rights over.

The dispute

At the heart of these disputes is the answer to an important question: Who can claim to have invented an essential element of the COVID-19 vaccines, and what does that entitle them to?

In January 2024 TurTec filed a suit against Moda for patent infringement for the use of its AI-based computational design algorithm, which is an indispensable component and instrumental to the strongest available immune response, variant tracking, and the understanding of clinical and experimental trial data. It has sought damages of USD 8 billion unpaid royalties based on global COVID-19 vaccine sales payments since 2020. Separately, it has also sent MODA a notice stating its desire to revise the license fee payable for the mRNA platform.





Both parties have agreed to mediate the dispute under the auspices of the ICC. TurTec will be represented by Moira Rose and Maya Sarabhai, the a leading attorney in the field of cross-sectional IP disputes and TurTec’s Counsel. MODA will be represented by Mr. Doe and the General Counsel of MODA. Both party representatives have full authority to settle.

