EIP

T 0192/22 - Is a first medical use claim a magic bullet?

The EIP team was pleased to receive the BoA Decision on T 0197/22 earlier this month, providing the reasons for revocation of Translate Bio's EP 3318248 B1 at the oral proceedings held in March, where we represented one of the Opponents.

The patent related to mRNA transfer vehicles, with the **Main Request broadly being directed towards mRNA encapsulated in a liposomal formulation for use in therapy .** This technology is highly relevant to those working in the field of mRNA-based therapies.

~~Is a first medical use claim a magic bullet?~~

Should a Proprietor be entitled to bar others from using a prior art transfer vehicle to deliver a nucleic acid for use in any therapy if their use together was not disclosed, despite how variable the resulting products' mechanisms of action can be in vivo depending on the therapy?

This case was particularly interesting due to the **atypical first medical use claims** at issue. First medical use claims under Articles 53(c) and 54(4) EPC typically spring to mind language such as "substance X for use as a medicament", wherein "substance X" is an active ingredient (having a clear chemical composition) that has not been used in therapy before.

In this case, however, **the claims did not define what protein the mRNA should encode, what disease it should treat, or the composition of the liposome (other than its size and broad categories of required lipids).** Indeed, all of these play a crucial role in achieving the desired therapeutic effect. Proteins encoded by mRNA molecules can have drastically different mechanisms of action depending on their purpose, which can range from

vaccines to replacement therapies. This is in contrast to a new class of antibiotics, for example, where the members usually share the same mechanism of action.

It is not generally required for a patent to show that a compound is suitable for each and every disease in order for a first medical use to be sufficiently disclosed. That said, how far can one exploit this without falling foul of Article 83 EPC? In the present case, as mentioned, the claims left the nature of the intended therapy, the encoded protein and liposome composition to be determined. This means that the patent sought to claim an entire platform of mRNA-based therapies, whilst only disclosing very limited data and no quantification of expression of any therapeutic protein.

Ultimately, in the Decision, the Board came to the conclusion that the patent did not provide sufficient proof of concept regarding the suitability of the claimed formulations for use in therapy. The issue regarding how broadly one can define a genus composition in a first medical use claim while making only a single therapeutic effect plausible for one member of the genus is perhaps ripe for further clarification by the Boards of Appeal.