

Kluwer Patent Blog

Moderna vs. Pfizer & BioNTech: French perspective

Matthieu Dhenne (Ipsilon) · Monday, September 5th, 2022

The news was announced last week: Moderna is suing Pfizer for infringement of two of its patents related to Covid-19 vaccines. These highly targeted actions are likely to spread to many other countries: here is a brief overview of the case and its potential French perspective.

In a press release dated August 26, 2022, Moderna indicated that it was filing two lawsuits against its competitor Pfizer-BioNTech, alleging that the latter had infringed two of its patents.

The actions, which were initiated in the United States and Germany – in the District Court of Massachusetts and the Regional Court of Düsseldorf – are directed at two messenger RNA (“mRNA”) technologies that Moderna alleges Pfizer and BioNTech have duplicated in the development of their Comirnaty® vaccine.

The first technology involved consists of a messenger RNA structure that Moderna began developing in 2010 and validated in human trials as early as 2015: a specific chemical modification of mRNA. Pfizer and BioNTech allegedly moved four different vaccine candidates into clinical trials, including some options that would have avoided Moderna’s inventive path. However, Pfizer and BioNTech ultimately chose to make a vaccine with exactly the same chemical modification of the mRNA as its Spikevax®.

The second technology involved the coding of a complete “Spike” protein by Moderna’s teams. Similarly, although they had other options, Pfizer and BioNTech would have preferred to replicate Moderna’s approach to encoding the full spike protein in a lipid nanoparticle formulation for a coronavirus. Moderna scientists had developed this approach when they created a vaccine against the coronavirus that causes Middle East Respiratory Syndrome (MERS).

The stakes are high: messenger RNA is a revolutionary technique that can be used in many other areas of research besides Covid-19, and already represents a paradigm shift in vaccine research, where traditional methods have involved using weakened or deactivated forms of the virus.

In fact, the infringement actions have essentially two purposes: to secure Moderna’s exclusivity on two fundamental mRNA techniques; to obtain damages, but above all to obtain royalties.

In any event, these actions are very targeted in time and space: they concern only two countries (the United States and Germany), do not include requests for preliminary injunctions (“PI”), and exclude the 92 low and middle income countries eligible to AMC (Advance Market Commitment for COVID-19 Vaccines), and the period taken into account does not begin until March 2022

(Moderna having until then undertaken to give access to its Patents free of charge, but under certain conditions with its patent pledge).

That said, there is a good chance that actions of this type will flourish in many countries. Indeed, these are particularly lengthy litigations. In Europe, if we take the case of Germany, proceedings are often blocked for several years, because the defendants ask for the invalidity of the patents, which can block the main infringement action, if the Infringement Judge decides not to rule before the Validity Judge has rendered its decision (which is far from rare in cases of such importance). On the other hand, it would not be out of the question for Moderna to bring a more prompt action in France, for example, where the validity of its patents would be directly examined by the Judges at the same time as the infringement. An action on French territory could even be enlightening, if Moderna decided to request a preliminary injunction (“PI”) in France: in this case, within a few months, a Judge would rule on the infringement and on the validity of its Patents and could even award provisional damages to Moderna.

Thus, one cannot exclude that, in the many twists and turns that this case will involve, Moderna will not consider, for example, requesting a PI in France, where, as I have pointed out, in a few months, its Patents could be recognized as valid, and Pfizer BioNTech prohibited from commercializing in France, certainly obliged from then on to negotiate, at least for this territory.

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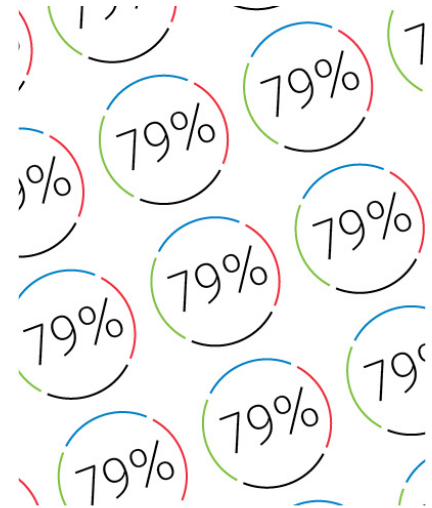
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