Munich Milan Lugano

MODIANO & PARTNERS
European Patent and Trademark Attorneys

EUROPEAN PATENT NEWS

Since 1950 IP Protection in the Heart of Europe

No. 05 - May 19, 2021

WAIVER OF PATENTS ON COVID-19 VACCINES: A EUROPEAN PATENT PERSPECTIVE

Currently there is a great deal of discussion on the possibility of waiving the patent rights for authorized COVID-19 vaccines in order to accelerate vaccine availability, particularly for countries that are more heavily affected by the COVID-19 virus at this time.

The question of whether waiving those patent rights, even temporarily and/or only for certain countries, would solve the problem of vaccine availability must be analyzed also in terms of the amount of information contained in the relevant patent applications, and when that information will become available.

Let's start with when the information contained in the patent applications will become available. The genetic sequence of the COVID-19 virus was established and published in January 2020. Therefore, prior to that time, it was not possible to develop a COVID-19 vaccine. This in turn means that any patent applications directed at COVID-19 vaccines were likely filed in January 2020 at the earliest, and probably later. Assuming that those patent applications were indeed filed in January 2020, they will be published no earlier than July 2021 (18 months after their filing/priority date). So already for this reason, none of the information contained in those patent applications is available now, even if the rights resulting from those patent applications were waived immediately.

Of course, the European Patent Convention allows applicants to request that their patent applications be published before the normal 18-month period. However, even if the companies that have developed the now authorized COVID-19 vaccines decided to have their patent applications published now, this would not necessarily help. The reasons for this are as follows.

Firstly, the European patent system is a 'first-to-file' system. It is therefore to be expected that the European patent applications relating to the currently authorized COVID-19 vaccines were filed at a time when the related research was still at the laboratory stage, and had not yet been scaled up to the industrial-level manufacturing that is required for addressing a pandemic. Therefore, those European patent applications can be expected to contain information that, at best, would enable third parties to manufacture those vaccines only on a laboratory scale. Since COVID-19 vaccines are based, one way or another, on complex biotechnological techniques, scaling up their manufacture from the laboratory stage to the industrial-manufacture stage requires, in and of itself, significant research and know-how the results of which cannot be expected to be contained in patent applications that were filed at a time when the efforts required for scaling up the level of manufacturing had likely not even started.

Secondly, it is to be expected that the European patent applications directed at COVID-19 vaccines were drafted in line with the current case law of the Boards of Appeal of the European Patent Office (EPO) on biotechnological inventions, particularly as regards the requirement of sufficiency of disclosure, essentially corresponding to the enablement requirement of US patent law. That case law has established that a European patent application discloses, e.g., an antibody class defined by a particular functional requirement – i.e., an invention based on complex biotechnological techniques – in a sufficient manner if *"the skilled person [is] able **in a possibly time-consuming but straightforward manner** to provide antibody variants having the functional requirements indicated in the claim."* Similarly, still in the field of biotechnological inventions, the EPO case law has established that a European patent application need not contain every single detail on how to manufacture the claimed invention if *"the skilled person [has] at his disposal, **either in the specification or on the basis of common general knowledge**, adequate information leading necessarily and directly towards success…"*. Thus, the EPO case law does not require that a European patent application disclose in detail every single embodiment of the claimed invention, still less that it disclose in detail the manufacture of every single embodiment or how to manufacture those embodiments on an industrial scale. Again, this is in line with the EPO's first-to-file system.

As a result, when looking at the question of a patent waiver on COVID-19 vaccines from a European patent perspective, it seems fair to say that the patent waiver as such is not the real solution to meeting the international demand for COVID-19 vaccines, and it would instead simply represent a detriment to the long-term benefits of the patent system, which are the constant push for research and innovation, including for new and better pharmaceutical treatments and new and better vaccines.

GERMANY
Thierschstrasse, 11 - D-80538 Munich
tel +49 89 221.216 - fax +49 89 225.809

ITALY
Via Meravigli, 16 - 20123 Milan
tel +39 02 8590.7777 - fax +39 02 863.860

SWITZERLAND
Via E. Bossi, 1 - CH-6900 Lugano
tel +41 91 922.9214 - fax +41 91 922.9215

info@modiano.com www.modiano.com