The Life Sciences sector is highly competitive. The input of a patent attorney specialized in this field is highly recommended.

Plausibility in patenting Life Sciences inventions

Great care should be taken when deciding whether and when to file a patent application and how much experimental data a patent application should contain.

BY GILLES PFEND, PH.D SWISS & EUROPEAN PATENT ATTORNEY AND PARTNER WITH KATZAROV

PARTNERSHIP

The so-called «first-to-file» patent system, in which the first to file the application will have the right to a patent, has advantages but also some disadvantages, particularly in the highly competitive Life Sciences sector.

One of these disadvantages concerns the risk of filing a patent application for an invention for which little or no experimental data exists. There is a substantial risk that this application, during its examination by the European Patent Office (EPO), will be objected to for lack of sufficiency or inventive step, trough lack of plausibility or credibility.

Although plausibility is neither a patentability criterion nor a ground for opposing (or invalidating) an EP patent, Examiners of the EPO are increasingly probing a patent beyond the standard novelty and inventive step requirements to ask whether the patent is plausible in the context of both sufficiency and inventive step.

If an invention lacks reproducibility because its desired technical effect, as expressed in a claim such as e.g. in a claim related to a compound for use in the treatment of disease X, is not achieved, this results in a lack of sufficient disclosure. Otherwise, i.e. if the effect is not expressed in the claim but is part of the problem to be solved, there is a problem of inventive step.

Let's consider the two following scenarios.

Scenario 1: Technical effect is mentioned but not supported by data in the application as filed

This is the most common situation. The applicant files a patent application for an invention for which he has not yet been able to prove experimentally that it solves the technical problem it is supposed to solve.

A typical example is a chemical or biological compound X which is supposed to be useful in the treatment of disease Y.

Although nowhere in the European Patent Convention (EPC) does it state that examples are necessary, the EPO faced with such a situation will not fail to question the applicant on the plausibility of this claim, either during the examination of the patent application or during opposition or appeal proceedings when this issue is raised by a third party.

The applicant or owner will then have to show or make plausible that the technical problem has been solved at the filing date of the patent application.

In the absence of any data, experiments or post-filing data which demonstrate the technical effect in the application at the date of filing, it may still be possible to demonstrate plausibility based on prior art or common general knowledge.

Thus, if the chemical or biological compound X is known from the prior art to act on a particular pathway and if the invention relates to the discovery of the involvement of this pathway in disease Y, the applicant may argue that the plausibility requirement is met as of the filing date of the patent application.

However, if the patent application provides no more than a vague indication of a possible medical use for a chemical compound yet to be identified, post-filing evidence or common general knowledge cannot be used to remedy the fundamental insufficiency of disclosure of such subject-matter at the filing date.

In any case, it must be borne in mind that the use of prior art or common general knowledge can be double-edged.

Scenario 2: Technical effect is mentioned, and the application contains some data in the application as filed

This is the case, for example, when the compound X is claimed as a Markush claim. A Markush claim is defined by a common structure, i.e. if an essential structural element (e.g. chemical structure) is common to all variants, or if all variants belong to a recognized class of chemical compounds in the field to which the invention belongs.

The EPO, in general, admits that certain variants or compounds do not have the claimed technical effect (non-working embodiments). Of course, it depends on the number of non-working embodiments. Indeed, if the claim recites 10 compounds and 4 of them do not display the technical effect, there is little chance that the claimed invention will be considered plausible. On the other hand, if the claim is a Markush claim encompassing a large number of alternatives, only some of which corresponding to non-working embodiments, it seems sufficient that the patent application contains information on the relevant criteria to identify the working embodiments within the claimed alternatives to meet the plausibility requirement.

Are in vivo experiments necessary?

This is a question we are very often asked by applicants as it is obvious that in vivo (animal or human) data are only rarely available at the time of filing a patent application. It may be sufficient to establish plausibility that in vitro data, directly and unambiguously reflect, the therapeutic effect on which the claimed therapeutic application is based or, alternatively, that there is an established link between the physiological effects of the claimed compound and the disease in question.

If in vitro data are generated in one or more cell models commonly recognized by the scientific community as models reproducing the disease in question, there should be no problem in establishing plausibility.

In conclusion, great care should be taken when deciding whether (and when) to file a patent application and how much experimental data a patent application should contain. The input of the patent attorney is crucial at this stage of the decision as it can have important consequences on the patentability of the invention and ultimately on obtaining a strong patent protection in all the jurisdictions of interest.

The topic of this article was the subject of a MINTT workshop organized by the Technology Transfer Office (TTO) of EPFL on June 12, 2020. The author would like to thank the organizers as well as the participants for this stimulating event.