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First to file? How to handle post-experimental data

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Is it best to file as early as possible with very broad claims to make sure your innovations are protected? This is an often-employed strategy in which additional results are added in a later stage to back up the application. The Board of Appeal of the European Patent Office (EPO) recently decided that such post-experimental data would not be taken into account to assess the inventive step of the claims of a patent filed by Bristol-Myers Squibb. What does this ruling mean for an optimal filing strategy?

The curious case of EP 1 169 038 B1

Why did the EPO reject the use of post-experimental data in this case? They argued that the technical effect relied upon by the appellant had not been plausibly demonstrated in the patent. The claims of the patent were meant to protect a small molecule, called dasatinib, which Bristol-Myers Squibb asserted is a protein tyrosine kinase (PTK) inhibitor with potential for use as an anti-cancer drug. However, the description of the patent was very generic.

It disclosed a huge number of small molecules defined using a generic chemical formula. This encompassed millions of compounds, some of them not even structurally related to each other. Thus, a skilled person would find it unlikely that all of these compounds could exhibit a substantial amount of PTK inhibitory activity. Furthermore, only a broad list of the compounds' potential targets was provided. Finally, the patent lacked experimental data or concrete values. No specific assays were disclosed that had been used to evaluate the small molecules; instead, the patent merely stated that these compounds had shown activity in one or more of a given set of assays.

In the absence of any verifiable technical facts, the Board held that Bristol-Myers Squibb's broad disclosure as to the alleged activity of these compounds, and even dasatinib, was not sufficient to render their suggested effects plausible.

When are you ready to file?

This decision should be a wake-up call for applicants willing to gather an almost infinite number of compounds in a single prophetic application in order to reduce their patent costs and win some time for the identification of the key compound(s).

There are two main reasons that patents are filed (too) early. First, the European patent process is a "first-to-file" system, where patent rights are granted to the applicant with the earliest valid priority date. Second, the career of most researchers is driven by publications. This forces them to protect their work in an early phase so that they can publish their results as soon as possible without jeopardizing their patent applications.

Nevertheless, being the first to file doesn't necessarily mean you will be granted a (strong) EP patent. Including experimental data is not mandatory in an EP application. However, the application should convince a skilled person that the technical problem underlying the invention has been solved. The application should at least contain a proof of concept that can be later backed up by post-experimental data. Such a proof of concept doesn't need to be clinical or in vivo data. It typically includes in vitro cell experiments evaluating a parameter that reflects the activity of the compound in question.

The optimal strategy

If the number of potentially interesting compounds is very large, and it is not yet clear which ones are the most promising, the best solution is to delay filing and keep the invention secret. This is not without risk because others may file or publish before you.

If a short list of the most promising compounds relevant to your problem already exists, each of these compounds should ideally be protected in a separate first filing. Each of these filings should comprise a proof of concept. At the end of the priority year, you can decide which first filings to pursue in a follow-up application. Usually, all the interesting compounds will be protected in a single international follow-up application, claiming priority over all the related first filings. Doing this grants the applicant flexibility. If some of the initial compounds are not withheld, they will not pollute the final application, and nobody will know that they were selected initially.