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The right time to file for a patent in Europe

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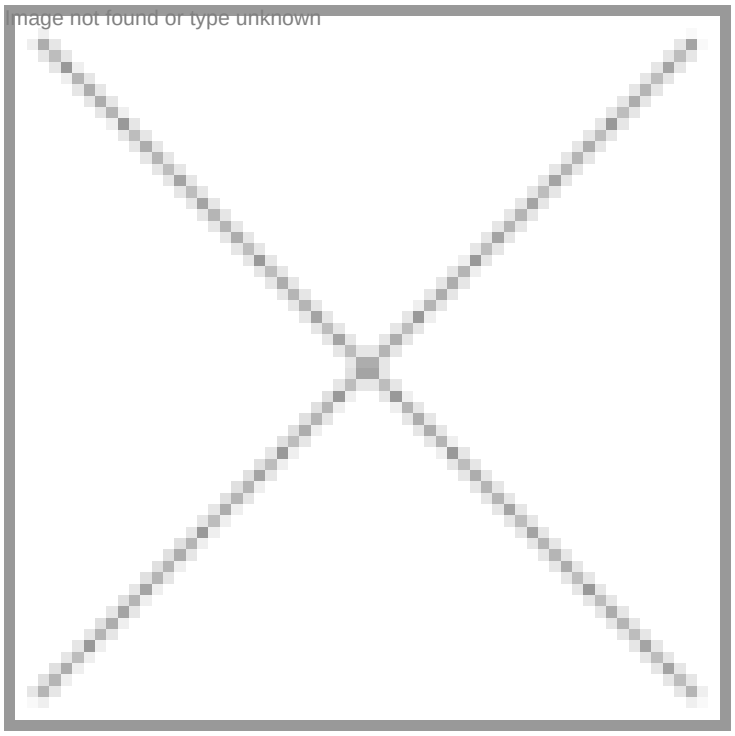

The right time to file for a patent in Europe

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The fastest biotech applications are often not the best ones. One of the hurdles for getting a patent in Europe is sufficient "enabling disclosure" of the invention that needs to be provided by the patent application (Art. 83 of the European Patent Convention, EPC). That means that the invention (e.g. a compound/composition/formulation, a nucleic acid, a protein, a vector, a transfected cell, a medical device, a method etc.) needs to be "workable" for a person skilled in the art that has read the entire patent without having to make experiments himself to find out how the invention is actually working. This "workability" of the invention needs to be mediated by the description and examples sections of the application over the entire scope of the claims on the effective date of the patent (i.e., priority or filing date).

The question is at what time would-be patentees, e.g. biotech or pharmaceutical companies, actually have sufficient data to fulfil the requirement of "enabling disclosure"? What is "too early" or "too late" for filing a patent application? This is all too often a real dilemma for companies in rapidly evolving technological fields such as Biotech. Choosing the right time to file can be especially difficult in jurisdictions such as Europe, which run on a "first-to-file" system-as opposed to the "first-to-invent" system, which is operated in the US.

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The EPO tangle

For Indian companies this is by no means a mere academic question. If an Indian biotech company files an international patent application (PCT application) in India, it will have to face this issue 31 months later on entering the European phase at the European Patent Office (EPO), where the Indian would-be patentee will have to fight out all of those problems under the EPC and the associated European case law.

A patent application that is filed too early on a more speculative basis without sufficient support for the claimed technical effects has only slim chances for grant in Europe. Moreover, such patent would also be open to attack by third parties, since insufficient enabling disclosure is one of the grounds of opposition in Europe. On the other hand, if the applicant waits for too long until enough solid data has been acquired (e.g. by clinical trials), it may already be too late, since a competitor has been quicker and has also filed his own patent application by then.

Here, the ultimate goal for the applicant has to be to protect the invention, e.g. the therapeutic value of a compound, as early as possible by getting an early patent filing date -and at the same time keeping good chances for the application by including at least some data on the technical effects of the compound. But what is "at least some data".

A recent decision of the EPO has clarified that it is not sufficient to simply verbally describe an alleged technical effect of a compound or formulation in the application in order to fulfil the requirement of enabling disclosure (key decision T 609/02 of one of the Technical Boards of Appeal of the EPO, AP-1 complex / The Salk Institute).

One important thing to also consider in the following is that the EPC allows patent claims on the "medical use" of compounds (unlike in India),-i.e., second medical use claims (the old "Swiss-type" claim format) and claims in the form of "compound X for use in the treatment of the disease Y" under Art. 54(5) of the new EPC2000 that has entered into force on December 13, 2007.

A case study

In T 609/02 the EPO Technical Board dealt with a patent claim on the use of a steroid hormone or steroid hormone analogue, which interferes with AP-1 stimulated transcriptional activation of glucocorticoid receptor or retinoic acid receptor genes, for the preparation of a medicament for the treatment of AP-1-stimulated tumor formation, arthritis, asthma, allergies and rashes. The application itself only disclosed a screening method for identifying such steroid molecules, but it failed to actually disclose such molecule and to show data of any kind indicating that such a hormone or analogue could have an effect on any of the diseases it was claimed to treat. Even though the applicant provided evidence after the publication of the patent application that steroid hormone analogues identified by the method actually worked by the mechanism described in the application, the Board of Appeal rejected this claim, stating that sufficiency of disclosure must be satisfied at the effective date of the patent (i.e., priority or filing date).

The Board of Appeal further stated that at least one example in the application that shows for instance the effect of the compound is necessary for taking the hurdle of enabling disclosure. The said example should substantiate the claimed technical effect so that it is rendered credible-the presence of a cause-and-effect relationship must be made "plausible". This can be a mere in vitro experiment, which provides a first indication on the therapeutic effect that may be seen in vivo later on. During prosecution, such initial in vitro data can be further substantiated by clinical phase I-III data, which may have become

available to the applicant in the meantime and which may be able to convince the EPO examiner. That means that if the patent application comprises at least in vitro data from the filing/priority date on that make a cause-and-effect-relationship "plausible" only then the applicant has the option of submitting more substantial, e.g. in vivo data after the effective date of the patent (i.e. post-filing).

However, in the case of mere speculative applications, which simply state such effect, but do not show at least in vitro data, things are certainly different. Even if late filed data do support the initially claimed effect they cannot retroactively heal the initial lack of enabling disclosure the application has had on the priority or filing day (T 609/02).

Practical consequences for would-be patentees

The practical advice for a biotech or pharmaceutical company has to be that all the data and results that are available on the filing day-even if they are only in vitro data-should be included in the patent application, e.g. an Indian national patent application that may be the basis for claiming a priority and, a PCT application filed in India that designates EPC contracting states. This is the only way to keep the option open of submitting additional data later on post-filing during prosecution in Europe in order to substantiate the claimed technical effect. In other words, the earliest point in time when to file a patent application in Europe (or a PCT application in India designating Europe) appears to be that day on which first, at least in vitro data are available that make the presence of a cause-and-effect relationship "plausible".