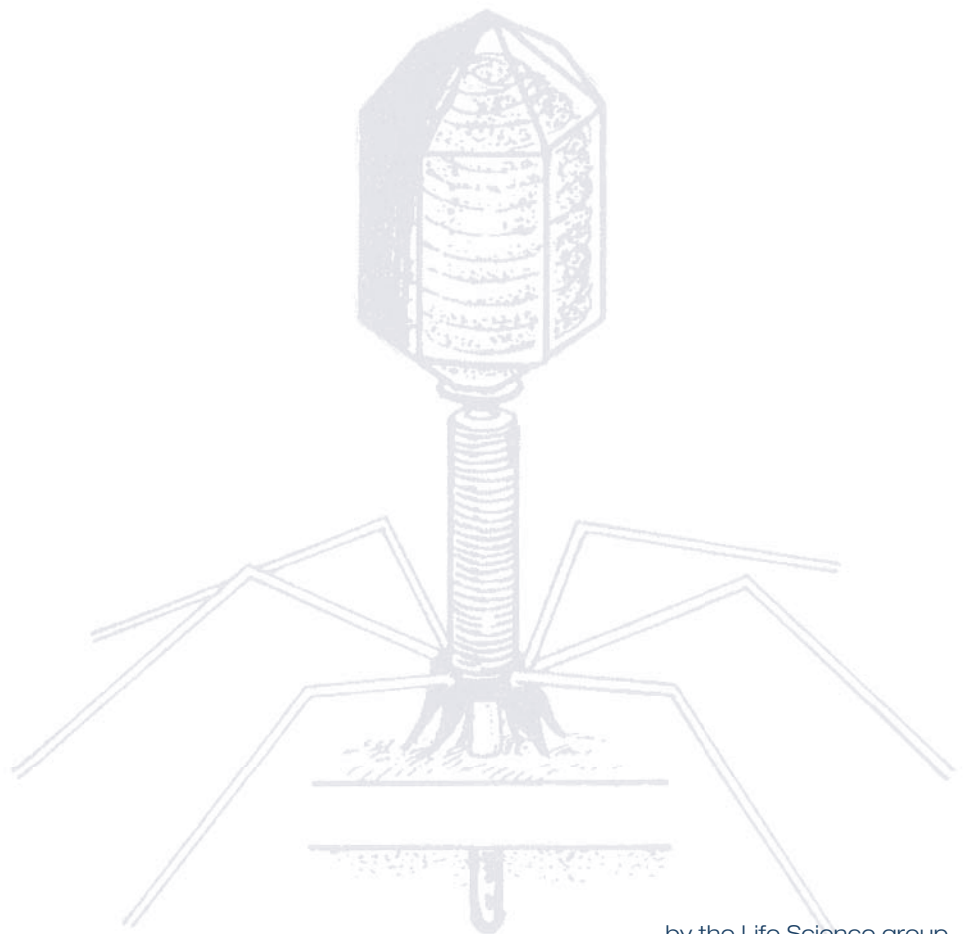
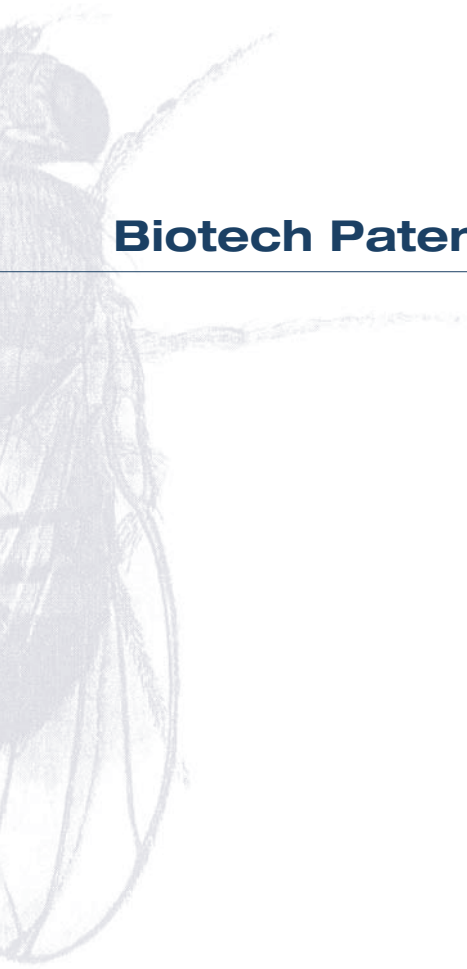


Biotech Patents





There are quite a number of patent-related problems, which can come up for innovative biotech and pharmaceutical companies.

Here are a few spotlights on some of those problems:

DID YOU KNOW THAT ...

... European Patent law has recently undergone substantial changes?

The new European Patent Convention (EPC2000) has come into force on December 13, 2007. The EPC 2000 revises and replaces the older EPC of 1973.

One of the changes in material patent law of high relevance for biotech companies is the “purpose-related product protection” for any further medical uses of compounds in addition to a first medical use that is already known (the new Art. 54 (5) EPC). That means that the applicant can get protection for any further specific medical use of a compound or formulation, e.g. “formulation A for use in the treatment of disease Y”, even if another medical use of this formulation was already known, e.g. “for the treatment of disease X”. Such claim format is much easier than the previous, rather complicated “second medical use” or “Swiss type” claim format. This should be a real incentive for biotech companies all over the world to have a closer look at protecting the various and diverse medical uses of their compounds, compositions, formulations etc. in Europe.

... you can get an enforceable “small patent” while your patent application is still pending at the patent office?

A number of EPC contracting countries in Europe offer the possibility of branching off a utility model application from an existing patent application (PCT, EP or national patent application). A “utility model” is an additional IP right that is totally separate from a patent. It is sometimes referred to as the “small patent”, as it offers protection for only 10 years and only allows for compound, composition, formulation and medical use claims (no method claims). However, the big advantage of branching off e.g. a German utility model from a pending patent application is that the utility model is immediately registered without substantial examination, so that the applicant can get an IP right very quickly, while the patent application is still in prosecution at the patent office, which may be a long and painful process. This can be a big advantage if the applicant quickly needs an enforceable IP right to take steps from against possible infringers on the national level. A number of states in Europe offer the possibility of having a patent AND a utility model in paral-

lel, i.e. two IP rights on the same invention in parallel (e.g. Germany).

... treatment regimens and dosage plans are patentable?

The European Patent Convention (EPC) does NOT allow the patenting of methods of treatment of the human or animal body in order to leave enough room for the medical practitioner. While claims directed at the “second medical use of a compound” were granted in the past, applications aimed at further variations of said second medical use that comprise specific treatment regimens (e.g. vaccination schemes, dosage plans/schedules) were rejected by the European Patent Office (EPO) as being unpatentable. This has changed since the decision T 1020/03 of one Technical Board of Appeal of the EPO, which has allowed a second medical use claim aimed at a specific treatment regime / dosage plan, since such dosage plan has to be seen as a new medical indication. This view has been confirmed by the recent decision T 0036/04 of the same Technical Board of Appeal. The question of whether or not a specific treatment regimen for a known specific medical use can be patentable is currently dealt with by the Enlarged Board of Appeal of the EPO (case G 02/08).

Basically, this decision opens a path for filing patent applications aimed at specific treatment regimes, dosage plans / schedules etc. even if the actual medical treatment as such is already known. This can be of a particular advantage for biotech and pharmaceutical companies, who have clinical trials going. Often it is only during those clinical trials that the best and therapeutically most effective treatment regimen is found. It may be that only after completion of phase II or even phase III the therapeutically most valuable treatment regimen is known. Following the above described decision, there is now the option of filing a European patent or PCT application on exactly that particular treatment regimen during or even after the clinical trials. This, however, can be seen differently on the national level (BGH, “Carvedilol II”).

... medical data acquisition methods can in principle be patented?

Diagnostic methods practiced on the human or animal body are NOT patentable under the European Patent Convention (EPC). This is stated even more clearly in the new Art. 53 c) of the EPC2000, which has come into effect on December 13, 2007. In the past, there has been a big discussion on what exactly a “diagnostic method” actually is. That means that it has not been clear so far, what features a method needs to comprise in order to qualify as a “diagnostic method”, and thus to be excluded from patentability.



The good news for biotech and pharmaceutical companies is that the recent decision G 01/04 of December 16, 2005 of the Enlarged Board of Appeal of the EPO has defined a true “diagnostic method” very narrowly, so that a lot of medical methods that were previously thought to be unpatentable can now be seen in a different light.

Specifically, the Board held that for the patentability exclusion to apply a diagnostic method claim must comprise the following three elements :

- a) the diagnosis to be made,
- b) the preceding steps of e.g. data acquisition which are constitutive for making the diagnosis, and
- c) the specific interactions with the human or animal body which occur when carrying out the preceding steps which are of technical nature.

Basically, this has opened the door for method claims that leave out e.g. the first element, the diagnosis to be made for curative purposes, so that the patenting of non-invasive data acquisition methods, which may later be used as a basis for a diagnosis, should now be possible.

... 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 in the application (Art. 83 EPC). That means that the invention (e.g. a vector, a transfected cell, a protein, a medical device, etc.) needs to be “workable” for a person skilled in the art that has read the entire patent application 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 of the application over the entire breadth of the claims.

The question is at what time the applicant, e.g. a biotech or pharmaceutical company, has sufficient data to fulfil the requirement of “enabling disclosure”. What is “too early” or “too late” for filing a patent application? 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. Moreover, such patent would also be open to opposition by third parties, since insufficient enabling disclosure is one of the grounds of opposition. On the other hand, if the applicant waits for too long until enough solid data have been acquired, it may already be too late, since another company has been quicker and has also filed a patent application in the meantime. The question of early or late filing is of particular relevance in fast moving fields of technology, such as biotechnology or pharmaceuticals. Here, the ultimate goal has to be to protect the therapeutic value

of a compound as early as possible by patents.

A recent decision of the European Patent Office (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 (decision T 609/02, AP-1 complex, Salk Institute). At least one example of the invention in the application is necessary for taking the hurdle of enabling disclosure. Said example should substantiate the claimed technical effect so that it is rendered credible. This can be a mere in vitro experiment, which provides a first indication on the therapeutical effect that may be seen in vivo later on. During prosecution, such initial in vitro experiment 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.

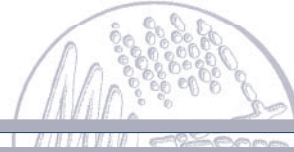
However, in the case of mere speculative applications, which simply state such effect, but do not show at least in vitro data, things are certainly different. Even if late filed data do support the initially claimed effect they cannot retroactively heal the initial lack of enabling disclosure the application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

For the daily practice of a biotech or pharmaceutical company this means 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. This is the only way to keep the option of submitting additional data later on in order to substantiate the claimed technical effect.

... we have a specialized Life Science group at GLAWE DELFS MOLL for all these problems?



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