



American Intellectual Property Law Association

Serving America's Legal and Creative Community

BIOTECH BUZZ

International Subcommittee

Contributor: Holger Tostmann

***"Early Certainty from Examination"*-Initiative of European Patent Office Complicates Life Sciences Patent Prosecution in Europe**

Summary

The purpose of this brief article is to provide information about a recent "formal" development that has been implemented by the European Patent Office (EPO), which may have significant impact on how applicants in the area of life sciences are able to, or have to, prosecute their patent applications before the EPO.

"Early Certainty from Search"

The EPO has recently put strong emphasis on increasing "efficiency" of patent prosecution. This initiative is meant to reduce the time required for prosecution (up to grant, including opposition) and to also reduce the "backlog" of applications.

The first stage of this initiative is the "Early Certainty from Search" module, in accordance with which the EPO now routinely produces search results within six months from the filing of an EP application, or the entering of a PCT-EP application into the regional phase before the EPO. In our view, this "early search"-approach is generally in the interest of applicants because the prior art search performed by the EPO, which is usually more comprehensive than the prior art search performed in parallel proceedings elsewhere, often provides a better basis to judge the chances of success for the application, including the scope which allowable claims may eventually have.

"Early Certainty from Examination"

In a second step of this overall "efficiency" initiative, the EPO is now phasing-in the "Early Certainty from Examination"-module, which proposes that, in general, a given application should lead to grant (or refusal) within an average time frame of twelve months, counted from the start of examination [which, in case of PCT-EP applications, typically occurs a few months after the response to the Communication pursuant to Rule 70(a)2 EPC has been filed].

Consequences

In essence, and in our experience as of today, this means that Examining Divisions are urged by EPO management to either issue the Communication pursuant to Rule 71(3) EPC ("Notice of Allowance"), in case the application is seen as generally allowable, or to summon to Oral Proceedings (which then leads to an "up or down"-decision on the patent application), also within the same time frame of twelve months, in case no claim set has been submitted that is seen as allowable, in principle.

In our experience, at the moment, this means that, in an increasing number of cases, an application is allowed no more than two "rounds" of material amendments. Often, the first "round" of material exchange with the Examining Division is already provided by the claim amendments and arguments exchanged in response to the Communication under Rule 70a(2)/(1) EPC as issued during the search phase, i.e. before examination even starts. Therefore, in principle, it may be possible that only one Communication pursuant to Art. 94(3) EPC ("Office Action") is issued, before the Examining Division summons to Oral Proceedings.

This "speeding-up" of the proceedings as not requested by the applicant may be beneficial for some applicants, in particular applicants more interested in the quick grant of a patent. This initiative may also be reasonable for specific areas of technology, in particular areas of technology that have short development phases and/or that relate to relatively simple subject-matter. However, this forced "speeding-up" of examination, in our view, is generally detrimental for applicants in the area of the pharma / life sciences area since development cycles are typically long and the final product of commercial interest is often not fully known at an early stage of patent prosecution. Also, obviously, in many cases, the subject-matter is so complicated that it is simply unrealistic to expect that all issues will be addressed in one or two "rounds" of Office Actions.

As a consequence of this "Early Certainty from Examination"-initiative, in more instances than previously, Oral Proceedings are scheduled, which forces the applicant (early and perhaps unduly) to narrow the application simply to avoid refusal of the application at the end of Oral Proceedings.

Extensive discussions about this topic are ongoing in the industry (see, for example: <http://kluwerpatentblog.com/2017/04/05/the-epo-and-the-problem-of-the-right-speed-ii-examination-proceedings/>), in particular the European biotech industry, which generally views this development as detrimental and points to the fact that applicants may be forced to pursue their patent applications in other venues, for example on the national level. Lobbying efforts to change this strict regime are under way and it is rumored that the initiative may be retracted once management at the EPO changes.

Solutions

For the time being, however, both clients and their representatives have to deal with the situation and determine possible strategies to avoid or mitigate the effects of this forced speeding-up of the proceedings. In those cases, in which budget limits

are not a primary concern, the possibility always exists to file a divisional application, which, in principle, allows the proceedings to be drawn out until the expiration of the patent term. For example, one approach may be to narrow the claim in the parent case, in order to avoid Oral Proceedings, and to then pursue a broader set of claims in a divisional application, which should "buy" an additional two to three years of pendency, depending on how the claims are amended and whether or not full use is made of extensions of time, which are available in proceedings before the EPO.

An alternative (or supplementing) approach would be to argue against (unduly) early summoning to Oral Proceedings, for example by pointing to the fundamental right to be heard, which should also include sufficient time to conduct experiments or to present comparative data, which is required in an increasing number of cases.

Holger Tostmann is a partner of *Wallinger Ricker Schlotter Tostmann* in Munich, Germany
<http://www.wallinger.de>