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8/18/2021 | Legal Updates

Update to the "Guidelines for Examination at the European Patent Office": Six Months On.

It has been nearly six months since the EPO updated the Guidelines for Examination at the European Patent Office ("the Guidelines"). We take a look at what two of these changes have meant and how they are affecting our daily practice before the EPO. Among the more significant changes were the addition of a section on patenting antibody inventions, and the updating of guidance on the amendment of the description of an application once the claims have been approved as meeting the requirements of the EPC.

Antibody patenting

From a life sciences point of view, it is noteworthy that this edition of the Guidelines was updated to include a section specifically on the patenting of antibodies at the EPO; section G-II, 5.6. Although this topic is now explicitly included for the first time in the EPO Guidelines, the relevant section does not contain anything surprising based on our experience in prosecuting antibody claims before the EPO for many years. Some well-established principles are confirmed in the updated Guidelines, such as the need for at least six CDRs, numbered according to a particular scheme, in order to claim a conventional antibody by its sequence, unless there is compelling evidence that fewer than six CDRs achieve the inventive effect; and that antibodies may be defined by way of their binding to a target antigen, such as, any antibody that binds to X, provided the antigen X is precisely defined. The new Guidelines also confirm that the framework sequence is required if the binding affinity is dependent on this (again subject to compelling evidence to the contrary). This last point is interesting, as this principle, in our experience, had previously not been consistently applied by different examiners at the EPO. The inclusion in the Guidelines does seem to have helped applicants gain more consistency in examination and has given applicants something to refer to if an examiner is being particularly strict or "off-script" with their objections. Referring to the new Guidelines has been a successful strategy for us in a number of cases.

Many issues arise at the EPO when defining antibodies by functional features, and unfortunately the examination of these type of claims was not completely clearly addressed in the updated Guidelines. Common practice at the EPO is for the examiners to assume prior art antibodies, if not explicitly disclosed to the contrary, have the same functional features as the claimed antibody. Examiners will often (but not always) require that the applicant proves that the prior art antibodies do not fall within the claim. The new Guidelines seem suggest that this approach would be more consistently applied when functional antibody claims are examined, and this is indeed our experience.

Finally, another point that we were hoping would result in a more consistent approach in antibody examination is the section that states improved affinity (or any other improvement) may be considered to mean the claimed antibody meets the requirements of inventive step; some examiners had been rejecting this premise by stating an improvement in affinity is merely routine trial and error and cannot be considered to be a surprising technical effect. By referring to the Guidelines, we have been able to present convincing arguments to the examiners. The flip side

to this is that the new Guidelines indicate that if relying on affinity for inventive step, the framework sequences must also be included in the claim, as these antibody regions have an influence on the affinity of an antibody and this has been consistently referred to by the examiners. However, six CDR sequences required for antibody binding should be enough for the claim to be allowed, if the technical effect is unrelated to affinity.

We are pleased to note that our hopes upon reading the new Guidelines for a more consistent approach by the examiners when determining whether the claims related to patentable subject matter have been realised. The updated Guidelines have provided us with a tool that is particularly useful for applicants needing a quick grant, albeit often with narrower claims; and a mechanism with which to push back on some more severe examiner arguments.

Description amendments

Another significant update to the Guidelines was the section relating to description amendments. This requirement, unique to the EPO and the UK IPO, means that an applicant must adapt the description too be in line with the claims before an application can proceed to grant.

This is an area that we have undoubtedly noticed the EPO becoming stricter (far stricter than the UK IPO). Before the new Guidelines were released, some examiners were accepting very minimal changes (merely deleting "incorporated by reference", for example), and others were requesting more extensive recasting to completely remove any unclaimed subject matter. We are now seeing more consistency in the firmer, more hardline, approach. We have been asked a lot more regularly to provide clarification that an embodiment, or a feature "is not part of the invention". Sometimes, labeling it as part of the *disclosure* is not enough, it explicitly must be called out as *not included in the invention*.

Again, it is helpful that there is more consistency, but we are not wholly convinced that becoming stricter in order to achieve that consistency is the correct approach for the applicant, not least due to the additional, often longwinded, burden placed on the applicant to make those amendments.