

Considerations for US Patent Attorneys When Drafting Patent Applications to Maximize Prosecution Opportunities in Europe

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Many US practitioners draft patent applications focusing primarily on ways to position themselves for success in the US Patent and Trademark Office. Yet they often neglect to position themselves for success in the European Patent Office because many legal standards differ substantially between the US and Europe, including standards for priority, amendments, obviousness, enablement and written description. In the following, we will compare and contrast the requirements for patent applications in the US and in Europe, making specific recommendations for US patent application drafters so that they can best protect their inventions in Europe without sacrificing their US strategy.

I. Literal Approach of EPO to Reading of Documents

One of the major differences between US and European practice resides in the way documents are read. This applies to prior art, patent applications, and priority documents. The difference in reading approaches has consequences for novelty, amendments, and priority.

The EPO uses a photographic approach to reading documents, whether considering the prior art to determine if an invention is novel or evaluating a patent application to determine if the amendment introduces new matter. An invention is novel if the claims are not directly and unambiguously derivable from the prior art. An amendment is only allowable if the amended claim is directly and unambiguously derivable from the application as filed. Priority is lost if the amended claim is not directly and unambiguously derivable from the priority document.

European examiners do not read between the lines. As discussed below, examiners will not allow an applicant to combine features from across the application, unless the specification or claims linked them upon filing. The strict approach to what a document teaches presents challenges in making amendments. On the positive side there are also opportunities as the prior art is viewed under the same lens and thus often is taken to disclose less than a US examiner will find. What is not disclosed in the prior art can potentially contribute to inventive step (obviousness). Resolving any uncertainties or inaccuracies in the prior art then becomes part of the inventive process.

II. Drafting Applications With an Eye to Potential Future Amendments

Many of the approaches US practitioners are taking to position their applications for US prosecution will benefit them in Europe. Practitioners should also employ additional strategies when drafting an application that will enter Europe, with a special focus on ensuring that the EPO will accept potential claim amendments.

While the US and Europe have similar laws preventing new matter from being added into the claims by a

prosecution amendment, the two offices apply the law quite differently. The EPO requires that the limitation in question is “directly and unambiguously derivable” from the specification as filed. In other words, the original specification must offer exactly the same subject matter, providing an almost verbatim basis. This surprises many US practitioners accustomed to the more flexible approach in the US, allowing express, implicit, or inherent support in the original specification.

US applicants most frequently run into difficulty in Europe when attempting to add a specific limitation from the specification into the claims to overcome a rejection during prosecution. In Europe, the law does not allow an applicant to combine features from different portions of the specification into a single claimed embodiment. For example, to limit the claims to a feature described only in the examples would require the applicant to add any other features of the example in question to the claims, often a very undesirable result. Careful attention to disclosing various combinations, especially through the use of multiple dependent claims in the provisional and PCT applications or by writing out specific combinations, can successfully prevent this problem.

While having an excessive number of claims in Europe can result in high fees, practitioners can avoid extra claims fees by reducing the number of claims on filing or in response to a Rule 161/162 Communication. Using long lists of features and indicating that the various lists may be combined will often not satisfy a European examiner. Patent drafters should also avoid describing features of the invention, especially fallback positions, only in the examples.

When making combinations of features from the specification, a combination of features from “two or more lists of some length” generally results in new matter. In contrast, an examiner will generally allow a selection of a preferred embodiment or a preferred feature from a list of features. Therefore European practitioners favor prioritizing all fallback positions — a practice that may have negative repercussions in the US. As an alternative strategy, when possible, describe the technical effect of a given feature, making it possible to argue why selecting that particular feature is not an arbitrary selection from a list.

III. Priority

Claiming priority can also present certain challenges in Europe. In Europe, only the patent applicant or his successor in title can enjoy the right of priority. In cases where the inventors are the applicant in the US, the US practitioner may not have completed an assignment as of the provisional filing date. Nevertheless, the inventors should transfer the right to priority to the assignee during the provisional year so that the right to priority exists at the time the PCT or EP application is filed listing the assignee as an applicant. US applicants should avoid relying only on an employer-employee relationship, invention disclosure forms, or even a covenant to assign future applications in an employment agreement. In fact, case law in Europe has held that these types of agreements do not constitute an appropriate assignment agreement. Thus, execute assignment documents *before* filing of the PCT or EP application.

Priority also presents difficulties for US applicants because in order to claim priority to the US provisional application, the subject matter of the European claims must be directly and unambiguously derivable from the US provisional application. If the inventors publish a manuscript during the provisional year, that manuscript may be cited as prior art in a novelty or inventive step rejection for claims not “directly and unambiguously derivable” from the priority document. Thus, US practitioners should take extra care in drafting a US provisional application with the full scope of broad, intermediate, and narrow embodiments (with combinations presented through multiple dependent claims) in order to ward off the negative impact of a potential publication during the provisional year.

Other presentations by the inventors during the priority year, abstracts or public lectures, also count as prior art that an examiner can cite for purposes of novelty and inventive step.

IV. Novelty

As many US practitioners know, the EPO maintains an absolute novelty standard, without a grace period in view of the inventors' own publication. Only in the case of evident abuse will the EPO offer a 6-month grace period.

The EPO allows selection inventions and deems them novel if combinations are made from two or more lists of some length and if the selection results in a new technical teaching. In other words, the selection must have some

technical advantages supported by experimental data and not simply limit the invention to an arbitrary selection. When applied to ranges or intervals proffered by the prior art, a novel selection invention must provide a narrow interval, both sufficiently far removed from the end points and also resulting in a new technical teaching within but not outside the claimed range.

Understanding the European approach to novelty helps a US practitioner not only obtain claims in Europe, but also generate the strongest prior art against competitors. Unlike in the US, European applications are citable for purposes of novelty only, but not inventive step, until they publish. In order to create the most prior art impact, patent applications should contain multiple nesting and/or overlapping intervals within the scope of a given invention. Likewise, reciting a plurality of specific combinations can prevent competitors from making selections within the scope of a given invention.

V. Inventive Step

Turning to inventive step, the EPO employs a problem-solution approach to the inventive step determination. Practitioners do not need to identify the closest prior art during application drafting. The EPO will make this determination during the course of the examination, making adjustments as new prior art is recovered and the claims are amended. The closest prior art (in a way equivalent to the primary reference) addresses the same purpose (setting out to solve the same technical problem), offers the most features in common, and falls within the same or a neighboring technical field.

As the next step, the practitioner should outline the differences between the closest prior art and the claimed invention. Then, use the application to tell the story of the objective technical problem solved in view of the closest prior art. In Europe an invention is only obvious if there is a reason to modify the prior art. To this end the EPO may rely on the combination of two or possibly three documents (or common general knowledge). If the EPO might find the solution obvious, provide support for inventive step, such as unexpected results, going against a prejudice, or secondary indicia (such as old prior art, long felt need, commercial success, or failure of others).

VI. Enablement

Many US practitioners, especially those in the life sciences and pharmaceutical areas, will appreciate that the enablement or sufficiency of disclosure requirement is lower than in the US. Thus, draft claims that are broader than will be allowed in the US. The EPO will generally find sufficiency of disclosure if the specification discloses at least one way of practicing the invention. *In vitro* data are often accepted as sufficient to support method of treatment claims and later-filed evidence can demonstrate enablement.

The EPO may also be more favorable to broad claims, supported only by a few examples if it is plausible that the invention will work throughout the scope of the claims. The EPO has accepted claims with 70% sequence identity and a functional limitation on the basis of one sequence (with no showing of a structure/function relationship) so long as prior art sequences do not overlap with the scope of the claims.

The EPO is also more generous in allowing claims to treatment of groups of indications even if only one or a few are enabled. For example, data supporting treatment of a particular immunological disorder may entitle an applicant to a claim directed to immunological disorders in general. A claim to treatment of one neurodegenerative disorder may entitle the applicant to a claim to treatment of neurodegenerative disorders in general. Therefore, generalize disorders to a higher level in order to create written descriptions of them and to claim them.

Finally, in order to obtain the best claim protection and create defensive prior art, claim both broad genera as well as subgenera.

VII. Methods of Treatment, Diagnostic Uses

The EPO will issue first medical use claims on one enabled indication and second medical use claims directed to treatments of one or more indications. Thus the first inventor of a medical use of a compound can claim any medical use — “compound X for use as a medicament”. This claim covers all medical uses of the compound — including

uses that were not contemplated by the first applicant. Later applicants can pursue second medical uses of known medicaments, such as by pursuing a new disease or group of diseases, a new group of individuals to be treated, a new dosage, a new formulation, or a new treatment regimen. Second medical use claims in Europe follow the format “compound X for use in the treatment of disease Y” and the EPO no longer accepts Swiss-style claims.

Some second medical use claims limited to dosage regimens have been invalidated by the national courts. For example, a recent patent claiming a specific dosage range for a small-molecule therapeutic was invalidated by the German and French courts but upheld by the UK courts. Thus, dosage claims may not be as robust as other types of claims.

While diagnostic methods practiced on the human or animal body are not patentable in Europe, applicants can seek protection for products, substances, or compositions for use in these methods. It is also possible to claim diagnostic methods not performed on a living body, such as diagnostics on a tumor or blood sample so long as the claim does not recite the sampling step. The EPO has also excluded from statutory subject matter surgical steps that present a substantial health risk for the patient and require the intervention of a physician.

VIII. Unity of Invention

Unity of invention approaches differ significantly from US restriction practice. While US examiners often start by dividing the claims into compositions, methods of making, etc, the European examiner will often divide the application by the various compounds disclosed, allowing various categories of claims applying to each separate compound. Thus, the European examiner will not divide groups among protein, DNA, methods, etc. The EPO examiner seeks to identify claims with the same or corresponding technical feature which together provide an inventive contribution over the state of the art. These can include a common structure, the same essential structural element, a common function, or common manufacturing steps.

Unity of invention can be especially challenging since applicants may have to select an invention at the search stage and it is often prohibitively expensive to pay search fees for all inventions. Once substantive prosecution begins, the EPO will not allow an applicant to amend the claims to another invention to avoid the prior art. Protests against a unity of invention rejection, much like US restriction requirements, are rarely successful.

In order to maximize opportunities for success, place the most important invention first in the claims, providing more narrow genera and subgenera in the next claims with lists of species in the later claims. Also, find the common inventive concept amongst the embodiments and group alternatives in one independent claim, instead of offering multiple independent claims in each claim category.

Applicants should think very carefully about the prior art and the strength of the claims before deciding whether to pay additional search fees.

While the EPO previously required applicants to file a divisional application within 24 months of the first office action, it has now rescinded that confining requirement from April 1, 2014. Thus, like the US, applicants in the EPO will soon have more flexibility in when to file a divisional application.

Over past years there has been some uncertainty with respect to double patenting. Some Boards of Appeal have refused overlap between a divisional and a parent application. It now seems that the boards have realized that there are indeed no legal provisions in the EPC against double patenting. The EPO currently will object only to identical claims in a parent and divisional, not to overlap.

IX. Conclusion

If US applicants wish to pursue protection in Europe, they must draft applications with an eye towards their prosecution in both the USPTO and the EPO. Taking into account these two sometimes dissimilar regimes will help patent practitioners maximize their clients' success across the globe.

For More Information

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