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Amgen v. Sanofi: The Supreme Court tackles patent enablement

Craig Metcalf of Kirton McConkie reviews the findings in the case that has solidified the enablement requirement for pharmaceuticals in the US patent system.

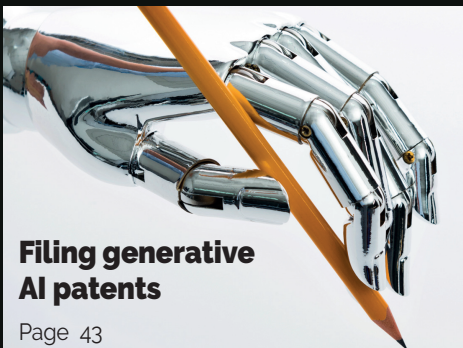
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**AIPPI 2023
WORLD CONGRESS
SPECIAL
EDITION**

The new European patent landscape: what companies should know

Dr. Michael Rüberg, LL.M., Dr. Dennis Kretschmann and Dr. Matthias Hofmann detail the successful launch of the European Unitary Patent Court, explaining strategic consideration for enforcing patents across the continent.

After more than 50 years of preparatory work and numerous setbacks, the European Unitary Patent system entered into force on June 1, 2023. For the IP world, this is a project of the century, both in terms of its long and eventful history and its far-reaching effects. It has the potential to fundamentally enhance the enforcement of patents in Europe and offers market participants numerous new options.

The European Unitary Patent system comprises on the one hand a new "European patent with unitary effect" (UP) in all participating EU member states, and on the other hand a new Unified Patent Court (UPC), which will decide on these unitary patents, but ultimately also on all conventional European patents (EP, or so-called "bundle patents").

Standardized patent protection in all participating EU countries

The aim of the Unitary Patent system is to establish a more uniform approach to the enforcement and defense of European patents in the various EU member states. The already centralized grant and opposition procedures at the European Patent Office (EPO) remain unchanged for this purpose. However, the new system adds centralized post-grant infringement and revocation procedures.

In the new system, it is possible to file a request for unitary protection with the EPO for each European patent instead of validating the patent individually in several countries. The unitary effect leads to unitary protection in all participating EU countries (17 countries at the start of the system, aimed at including, eventually, all EU member states). Therefore, only one common annual fee will have to be paid to the EPO to maintain protection in all these countries. The unitary patent will coexist with national patents and traditional bundle patents.



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Thus, once the patent has been granted by the European Patent Office, the applicant will have the choice of whether to opt for the new Unitary Patent, or not. However, it is important to note that the new patent system does not only affect newly granted patents. All validations of existing bundle patents in countries that have ratified the UPC Agreement are also subject to the jurisdiction of the UPC – and are so by default.

However, during a transitional period of at least seven years, patent owners can individually remove their patents from the UPC system – the so-called "opt-out". Then, only national courts will continue to have jurisdiction over these patents. Patent owners can also re-enter under certain conditions after they have opted out by withdrawing the opt-out. During the transition period, there will also be an option to continue to bring patent litigation before national courts for patents that have not been opted out.

As of August 2023, about one third of all European patents and applications had been opted out of the jurisdiction of the Unified Patent Court (UPC). While this is a figure far from being insignificant, it needs to be considered that it also leaves the remaining two-thirds to the present jurisdiction of the UPC.

Strategic considerations for enforcing patents before the UPC

Holders of traditional bundle patents (EP) are now faced with the question, with immediate effect and continuing during the entire transitional phase, whether and under which circumstances they should enforce the IP rights in question before the UPC, or whether preference should not be given to national proceedings. The same applies, and will apply even beyond that date, to owners of parallel national patents and Unitary Patents (UP). For the owners of traditional bundle patents (EP), this question should best be asked at an

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Résumés

Dr. Michael Rüberg, LL.M., Attorney at Law

Michael Rüberg is an attorney at law with many years of experience in patent litigation. In cooperation with patent attorneys from various technical fields, he and his team of attorneys represent clients before all infringement courts and in parallel litigation. At the same time, Michael Rüberg is involved in the coordination of numerous major patent litigation proceedings, also on an international level.

Dr. Dennis Kretschmann, Patent Attorney

Dennis Kretschmann focuses on the development and management of patent portfolios in the areas of physics, optics, electrical engineering, IT, and software. He represents clients in examination proceedings before German and international patent offices. Dennis Kretschmann also has wide expertise in patent litigation matters. He regularly conducts patent infringement and nullity proceedings before the German courts, and often coordinates cross-border infringement cases.

Dr. Matthias Hofmann, Patent Attorney

Matthias Hofmann focuses on examination, opposition, and appeal proceedings before the European Patent Office and the German Patent and Trade Mark Office. Most of his work is related to computer-implemented inventions, in particular relating to artificial intelligence. He has in-depth technical expertise in the fields of machine learning, medical imaging, video and image processing, computer architecture, telecommunications, and bio-informatics (computational genomics).

early stage during the transitional phase since there is a risk that the potential opponent may otherwise take over the decision-making (of whether to stay in the UPC or opt-out) by simply filing suit (in the form of a declaratory action for non-infringement or a validity attack) in the system to which the EP is currently assigned.

Companies must therefore know about the factors to be considered when deciding for or against national jurisdiction in comparison with the new UPC and how these should be weighted in each case. Depending on the industry, this is likely to be done with different emphases and from different perspectives. For example, one of the great promises of the new system is the possibility of obtaining a uniform injunction for the first time across all countries (in the case of a UP for all member states of the UPC, in the case of an EP for all validation states that are also members of the UPC). Also, one other important promise is to recover damages uniformly and for all countries in question. Compared to the conventional model of exemplary enforcement of patents in only one or two core markets, such as Germany in particular, this is of particular interest and importance if the distribution structure of the infringer gives reason to assume that they will continue the infringement outside the core market in question, i.e., to simply "duck away" from the enforcement.

In this regard, the UPC's simultaneous enforceability of an injunction and, where applicable, a seizure order, results in considerable commercial pressure on the infringer, in particular as no shifting of manufacturing and/or distribution to other relevant markets in Europe will be allowed for. This pressure, in most cases, will apply immediately following a first-instance decision, which will be declared provisionally enforceable as a rule before the new unified court. Not least for this reason, the new system will also be attractive to those companies whose goal is not to obtain or defend an exclusive market position, but who primarily want to monetize the IP right in question.

In addition, for those patent owners who, due to their own local manufacturing and/or sales activities, seek an exclusive position in one of the European countries that are traditionally rather reluctant or inexperienced in enforcing patents (sometimes also referred to as "patent-poor countries"), will see in the UPC a welcome opportunity to put competitors in their place even outside the usual core markets.

On the other hand, companies whose products are covered by only individual patents (such as pharmaceutical companies), will probably be afraid of the centralized, all-national parts of the EP or the entire UPC and will carefully consider whether a corresponding counter-reaction should be triggered by an action before the UPC. However,

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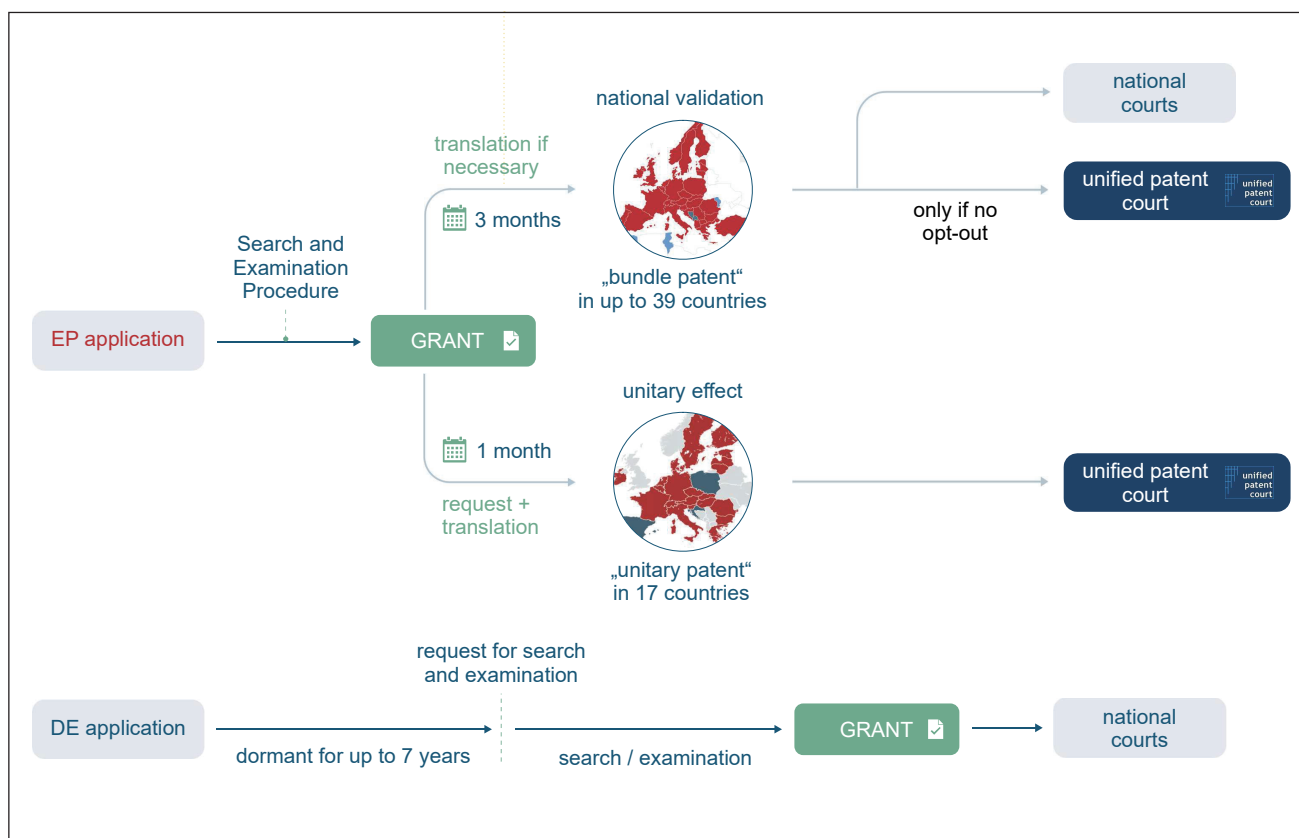
this risk can be mitigated by skillful filing strategies, in particular by exploiting the possibility of obtaining national property rights in parallel – a possibility that has been newly created for Germany, so that it does not necessarily have to discourage the use of the new jurisdiction.

One disadvantage of the new system, and this applies equally to all areas, is of course its novelty as such. This entails the unpredictability of certain decisions due to the lack of real precedents in the initial phase of the UPC, as well as the likelihood that in the initial phase almost any decision, even those of a purely procedural nature, can be appealed as long as there is no established case law practice to guide the way in this respect.

The general reluctance to be among the first to test the system seems to be confirmed by the rather low number of initial cases brought with the UPC (about 25, as of August 2023). Also, most of these cases have been brought in the German local divisions, with the apparent hope of being able to rely on the well-established German case law in patent matters for those areas of current uncertainty. While the first decisions by the German local divisions have just recently (as of August 2023) been handed down (on preliminary injunction requests), most cases will not be decided before mid-2024, so that only the UPC's own case law will start to develop. From those preliminary injunction requests decided already, one may draw the conclusion that the judges will, as expected and at least initially, follow their national tradition and concepts, to the extent allowed for in the new system.

Another factor to be weighed up when deciding on whether to use the UPC will certainly be the costs associated with enforcement, which cannot be reliably estimated at present due to a lack of practice. However, it is probably quite certain that, due to the challenges posed by the new system to the conduct of proceedings, the legal teams in the UPC will be larger than in national proceedings, as a result of which the costs will considerably exceed at least one national proceeding as a comparative figure. Whether and to what extent this will also apply to parallel national proceedings in multiple jurisdictions remains to be seen. In certain constellations, however, the traditional approach of a lawsuit in Germany, for example, followed by an out-of-court settlement for the whole of Europe is likely to remain the preferred path, also from a cost perspective.

So, in summary, there is no clear "yes" or "no" to using the new system. For some companies, "wait and see" may be the ideal way to gain initial orientation. However, whether the early phase of the system does or does not also offer real entrepreneurial opportunities should at least be considered.



Considerations on patent application practice with regard to the UPC

Patent applicants now have various options for obtaining patent protection in one or more European countries.

Anyone who only needs protection in one or two European countries achieves this most cost-effectively via national patent applications. German patent applications in particular, with an application fee of EUR 40 and an examination and search fee of EUR 350, remain very attractive.

Applicants seeking patent protection in three countries are likely to achieve their goal most efficiently with a classic European bundle patent. With an opt-out, they prevent the bundle patent from being destroyed in one fell swoop before the UPC, but by withdrawing the opt-out they still keep open the option of suing before the UPC themselves.

Once protection is sought in four or more countries, the Unitary Patent will usually be the least expensive option – which is confirmed by the fact that about 25 % of all European patents granted in June and July 2023 have been given, upon applicants' request, unitary effect.

Although the unitary patent cannot be removed from the jurisdiction of the UPC, it can be combined with a national patent, for example in Germany. An interesting filing strategy can therefore be to file a European and a German patent application in parallel. In the case of the German patent

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application, the filing of the request for examination can be waived for seven years, so that the applicant does not incur any costs during this time, apart from the filing fee and the (small) renewal fees.

Especially when protection is sought in several countries, the Unitary Patent offers a cost-effective way (compared to the previous European bundle patent) to obtain patent protection in the territory of 300 million inhabitants. Thus, there is considerable hope and trust that the Unitary Patent system will also be a success internationally.

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