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Using the UPC to your benefit
in pharmaceuticals and life sciences

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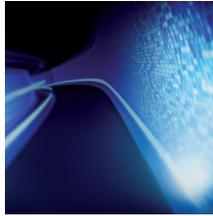
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Using the UPC to your benefit in pharmaceuticals and life sciences

By Arwed Burrichter, Natalie Kirchhofer and Tobias Hoheisel, COHAUSZ & FLORACK

The proposed Unified Patent Court (UPC) is expected to have a strong impact on patent filing and enforcement strategy in the pharmaceutical sector, because pan-European patent coverage and cross-border patent enforcement are of primary importance to pharmaceuticals. For example, validation of a European patent in each of the 38 European Patent Convention member states is quite common for pharmaceutical patents – unlike patents in other industries, where only a few European countries might be picked. Under its proposed fee structure, the forthcoming unitary patent may offer dramatic savings over the traditional European patent. In addition, a single EU patent court will be established in the form of the UPC, ensuring a more streamlined system and finally facilitating true pan-European patent enforcement and nullification.

However, despite its advantages, the new system also presents risks – particularly for the pharmaceutical and life sciences sectors. One central concern that originator companies have about the new system is the vulnerability of the unitary patent in central revocation proceedings. By putting all their eggs in one basket, originator companies could potentially allow generic companies to destroy key originator patents with one relatively inexpensive action.

This chapter explains the fundamentals of the new system, discusses its possible implications and provides recommendations on how to use the new system to your benefit.

Content and structure of UPC system

With the introduction of the unitary patent, applicants will have an additional option for protecting their inventions. In contrast to the

classical European patent – which effectively becomes a bundle of national patents subject to the competence of the national courts after grant – the unitary patent will be a single right which can be enforced (and invalidated) only uniformly through a single action before the UPC.

The European Patent Office (EPO) will be responsible for the examination and administration of unitary patents. The EPO will also remain responsible for classical European patents, which will continue to exist under the new system. In fact, applicants that want to obtain a unitary patent will need to apply for a classical European patent at the EPO. In order then to obtain a unitary patent, the patentee may choose the unitary effect up to one month after grant of the classical European patent, which will provide unitary patent protection in those states in which the UPC has exclusive competence for unitary patents. This will be at least 13 states – including France, Germany and the United Kingdom – and may be as many as the 28 European Patent Convention signatory states. In parallel, the granted classical European patent can be validated as before in states that are not covered by the unitary effect.

There will be two important differences between classical European patents validated in several countries and the unitary patent. First, for unitary patent contracting states, a single renewal fee will be required instead of several national fees. Second, no translations will be required for the validation with unitary effect, except for during a transition period of up to 12 years, during which translation will be required into English or (if the patent is in English) another language.

With the UPC, a single EU patent court will be established, ensuring a more streamlined

system and finally facilitating true pan-European patent enforcement and nullification. Its extensive rules of procedure are designed to allow for UPC first-instance proceedings to be completed within one year. The UPC will have jurisdiction over not only the new unitary patent, but also classical European patents that are presently enforceable only on a strictly national basis. The UPC will automatically affect every existing holder of a European patent that does not actively opt out of the system during the transitional period. Rulings of the UPC will have effect in the territories of participating EU member states. National patents will remain excluded from the competence of the UPC.

Brief overview of UPC structure

The UPC will comprise a court of first instance, a court of appeal and a registry. The court of first instance will comprise one central and several local and regional divisions (see Figure 1). The central division will primarily deal with standalone

invalidity actions, whereas the local and regional divisions are expected to handle the bulk of patent infringement actions, which may also include counterclaims of invalidity.

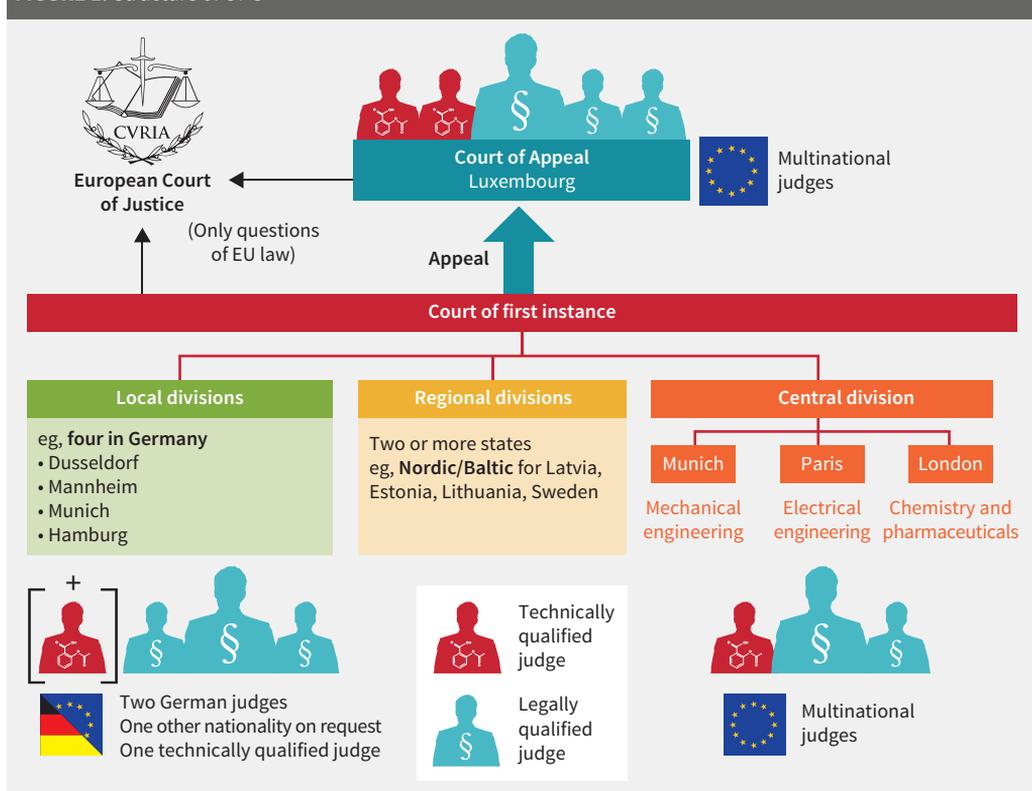
The local and regional divisions will be set up in participating member states at their discretion, with a maximum of four per country. Germany has already opted for local divisions in Dusseldorf, Mannheim, Munich and Hamburg.

Two or more contracting member states may set up a regional division. For example, Sweden, Lithuania, Latvia and Estonia have agreed to form a Nordic-Baltic division situated in Stockholm.

The central division will be divided territorially and by technical subject matter, with its headquarters in Paris (covering electrical engineering, among others) and branches in Munich (mechanical engineering) and London (chemistry and pharmaceuticals).

The UPC will also include a court of appeal in Luxembourg.

FIGURE 1. Structure of UPC



Panel composition

Since the central division is mainly concerned with revocation actions, its panels will usually comprise one technically qualified judge and two legally qualified judges. This follows the German tradition of having technically qualified judges hear revocation actions. The UPC's technically qualified judges will be allocated from a central pool on a case-by-case basis.

All of the UPC's panels will be multinational, with at least two of the three judges on the first-instance panels from different member states.

The panels of the local and regional divisions will consist of three legally qualified judges. For the regional divisions, two of these judges may be nationals of the region. For local divisions, one or two of the three judges may be a national of the state in which the division is located, depending on whether the local division hears fewer or more than 50 patent cases per year (see Figure 1). This multinational set-up is designed to help to provide training for judges from member states where little patent litigation takes place by more experienced foreign colleagues. Before the local and regional divisions, any party or the panel may request the allocation of a further technically qualified judge from the pool of judges (eg, in case a counterclaim for revocation is raised).

The panels of the court of appeal will comprise three legally qualified judges from different member states and two technically qualified judges.

Division of competence and jurisdiction within the UPC

Besides infringement and revocation actions regarding European and unitary patents, the UPC will also hear cases concerning:

- damages or compensation derived from provisional protection by a European patent application;
- prior use rights;
- compensation for licences of unitary patents; and
- motions for declaratory judgment of non-infringement.

For infringement actions, the competent division is the local or regional division of the member state in which the infringement has occurred or the defendant has a place of business. Thus, in case of EU-wide infringement activities (eg, via internet offers), the plaintiff has considerable choice of venue, opening up the possibility of forum shopping.

Usually, for parallel infringement and revocation actions concerning the same patent and parties, the local or regional division hearing the infringement may decide on both infringement and revocation, refer only the revocation action to the central division (thus bifurcating) or refer both revocation and infringement to the central division, if the parties agree.

It will be interesting to see what trends emerge in local and regional divisions. Leading German patent judges have indicated that they do not necessarily intend to continue with the German bifurcation model when sitting on a UPC panel.

Language of proceedings

Each local or regional division may specify the language of the proceedings as either an official language of the state in which the division is located or one or more official languages of the EPO – English, French and German. For example, the language of proceedings before the Nordic-Baltic division will be English. Before the central division, the EPO official language in which the relevant patent was granted will be the default language of proceedings.

Transition period for European patents

To acclimatise to the new system, owners of traditional European patents will have the chance to opt out of the exclusive jurisdiction of the UPC within a seven-year transition period, meaning that they can test out the new system at their discretion. No opt-out will be possible for the new unitary patents. European patents for which an opt-out has been declared remain subject to the existing national litigation system. For these, it will be possible to opt back into the UPC system, provided that no national litigation is pending. The most recent provisions foresee that opting out will not incur an administrative fee.

“By putting all their eggs in one basket, originator companies could potentially allow generic companies to destroy key originator patents with one relatively inexpensive action”

Court fees and costs

Under the existing fee schedule, the court fees for an infringement action before the UPC will be between €11,000 and €336,000, depending on the value of the case. On the other hand, the court fees for an invalidity action (or invalidity counterclaim) against a unitary patent will be limited to a fixed fee of €20,000, regardless of the value of the case.

Besides court fees, the costs of attorney representation, experts and translations will contribute significantly to litigation expenses. Cost-shifting provisions will require the losing party to reimburse the prevailing party for its litigation expenses.

Implications of UPC system for pharmaceutical and life sciences sectors

The UPC system is likely to be a game changer, with implications for how patent protection is obtained and how patents are enforced in Europe.

The unitary patent will allow for significant cost

savings over a classical European patent with the same country coverage. For pharmaceutical patents, which typically have a wide country coverage, the savings on renewal fees and translation costs will be particularly significant. Under the proposed fee structure, the accumulated renewal fees for the unitary patent will be less than €5,000 for 10 years and less than €36,000 for a full 20-year term – drastically less than for a classical European patent. In addition, translation costs will be dramatically reduced under the unitary patent because during the transition period, only one translation will be required for validation – and after the transition period, no translation will be required at all. As the unitary patent will be administered centrally by the EPO, administrative acts such as registering transfer in ownership will also be much easier. The resulting lower costs of obtaining and maintaining patent protection in several European countries are expected to render the UPC system particularly attractive to the pharmaceutical industry.



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Another important implication of the UPC system will be the fact that a single EU patent court will deliver rulings with pan-European enforceability on patent infringement and validity. This will significantly reduce the number of parallel litigation actions required in case of pan-European infringement. However, although the rulings delivered by the UPC will be effective within its entire jurisdiction, in order to enforce the decision, patentees will have to rely on the national authorities.

However, the introduction of the UPC system also creates risks. These risks carry particular weight in the pharmaceutical sector, where – such as in the case of blockbuster drugs – billions of dollars in revenue can depend on the validity of a single patent. First, the introduction of an entirely new court system always comes with some uncertainty: it is difficult to predict how the new system will work. Second, the UPC system provides for a single central revocation action with

which the unitary patent can be nullified for the entire jurisdiction of the UPC. Third, national prior rights in a member state of the UPC system may pose a particular threat for patentees, because they may form prior art against a unitary patent, which – unlike the classical European patent – cannot be amended for individual member states. Thus, for example, a UK national patent application with an earlier filing date that was published after filing of the unitary patent may lead to the invalidity of the unitary patent in all UPC member states.

A central concern of originator companies is the vulnerability of the unitary patent in central revocation proceedings. By putting all their eggs in one basket, originator companies potentially allow generic companies to destroy key originator patents with one action. Thanks to the fixed court fees, capped at €20,000, the costs of central revocation proceedings are expected to be significantly lower than for the multiple parallel national nullity proceedings necessary under the existing system. Since litigation costs are an important factor for many generic companies, the new UPC system may be an attractive route for generic companies to launch nullity attacks on important originator patents.

For these reasons many originator companies are likely to opt out their granted existing key pharmaceutical patents, making it more difficult and expensive for generic companies to attack their patents. Opting out is particularly attractive because it will incur no administrative fee and – unlike in the case of new unitary patent patents – there will be no cost savings for granted existing European patents under the new UPC system.

In such a scenario, provided that proceedings before a national court have not been initiated, it is possible to opt back in to the UPC system for litigation, which the patentee can decide on a case-by-case basis, thus getting the best of both worlds and allowing for extensive forum shopping.

In addition, for important patents (eg, those protecting active pharmaceutical ingredients or key medical indications), provisions for a safety net should be considered. Thus, when choosing a unitary patent for a key invention or choosing to opt back in to the competence of the UPC, it is advisable to have parallel protective rights in place. Such parallel protective rights might take the form of a divisional application (whereby the limitations of double protection must be considered), parallel national applications or utility models. National applications and utility models



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are particularly attractive because they do not fall under the competence of the UPC. Thus, they give plaintiffs additional options for forum shopping and litigation strategy.

Summary

The UPC system represents a milestone in the development of a unified European patent system. The establishment of a court with jurisdiction over one of the largest economies in the world – with a population of close to 550 million and gross domestic product comparable to that of the United States – has been long awaited by practitioners and patentees alike.

The UPC system brings both advantages and risks. The reduced costs and the pan-European patent enforcement are certainly noteworthy advantages. However, the central revocation proceedings and the danger of national prior rights to unitary patents also represent considerable risks. Nevertheless, transitional provisions will allow rights holders to safeguard their inventions against the drawbacks while testing the possible benefits of the UPC system. Clearly, the dawn of the UPC heralds exciting times for pharmaceutical companies and legal practitioners alike. *iam*

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