ACCURA

August 2017

IPR & LIFE SCIENCE NEWS

Stay up-to-date with the lastest news from
Accura's IPR and life science experts.

In this edition, you can read about the introduction and expected launch of the Unified Patent Court and about the new Danish guide on pre-launch of medicinal products.

www.accura.dk

THE UNIFIED PATENT COURT: INTRODUCTION AND EXPECTED LAUNCH

In this and a series of follow up articles you can learn about the Unified Patent Court and the Unitary Patent. New readers may start here.

The introduction of a new system for making patent protection across Europe easier, more transparent and more effective has been in the pipeline for years. The new Unitary Patent system introduces the most significant changes to European patent law in 40 years including setting up a supranational common court in the form of the new Unified Patent Court (UPC).

Shortly before the summer holidays, UPC's Preparatory Committee announced that uncertainty had arisen as to the timeline for the launch of the new system. This uncertainty is mainly due to an unspecified lawsuit brought before the German constitutional court (Bundesverfassungsgericht) and the resulting delay in Germany's ratification of the UPC agreement. However, the launch is still widely expected in the first half of 2018.

Now is the right time for companies operating in Europe within patent-reliant industries to take the time to inform yourselves about the new UPC system and assess the possible implications for your European patent strategy. Towards the entry into force of the UPC, Accura will highlight certain areas of importance in relation hereto. In this first article, we will explain what the unitary patent and the UPC are. We also suggest the first preparatory steps to take as a company.

The Unitary Patent

The unitary patent package consists of two EU Regulations which create a new European patent with unitary effect (unitary patent) and an agreement between the 25 contracting Member States which sets up the UPC as a single and specialised patent jurisdiction (the UPC Agreement). Together with the already existing European Patent Convention, these new instruments provide an alternative to the traditional European patent. In terms of filing and prosecution, unitary patents will be similar to the traditional European patents granted by EPO. However, within 30 days after the patent is granted by the EPO, the proprietor may designate the patent as having unitary effect. In that case, the unitary patent provides the proprietor with patent protection in all 25 contracting Member States and the patent will also be enforceable in all contracting Member States.

While the current European patent system remains in place, the unitary patent aims to be a cheaper alternative as the proprietor is not required to submit translations into a language of each contracting state and will only have to pay a single renewal fee to renew the patent.

The Unitary Patent Court – UPC

The UPC will be a part of the judicial system of the contracting Member States. It will have exclusive competence in respect of European patents and unitary patents. For traditional European patents, the exclusive competence is, however, subject to exceptions (further about this below).

The UPC's rulings will have effect in the territory of all the contracting Member States, e.g. an injunction will stop infringements in all the contracting Member States. This provides a more efficient enforcement system than the current EPO system where proprietors need to instigate legal proceedings in each individual Member State to stop an infringement. In this regard, proprietors should keep in mind that a UPC revocation order will also take effect in all contracting Member States. Hence, the UPC system can become a double-edged sword to some.

The UPC will have no competence with regard to national patents which will remain under the jurisdiction of the national courts.

Ratifications should be monitored

When the unitary patent system is launched, it is critical to note that, in the beginning, unitary patents will only cover countries having ratified the UPC Agreement at the given time where unitary effect is registered. Subsequent ratifications will not extend the scope of a pre-existing unitary patent and so proprietors must monitor ratifications closely and consider whether additional validation as a traditional European patent for the remaining Member States is required.

Should you consider to opt out?

The UPC Agreement prescribes a seven-year transitional period (which may be prolonged up to a further seven years). During this transitional period, infringement actions or revocation proceedings regarding traditional European patents or supplementary protection certificates (SPC) issued for such patents may still be brought before national courts.

In addition, during the transitional period, the patent proprietor or applicant will have the possibility to opt out a traditional European patent/patent application/ SPC from the jurisdiction of the UPC. It is important to note that a decision to opt a patent out will have effect for the entire life of the patent (in so far as it will be possible to withdraw an opt-out, unless an action concerning the European patent has already been brought before a national court). Further, it is critical to note that the possibility of opting out only exists during the transitional period for as long as an action has not been brought before the UPC, and that cases decided by a national court prior to the UPC Agreement will preclude withdrawal of the opt out for the given patent. Naturally, there will be no possibility to opt out unitary patents.

There are many things to consider when deciding whether to opt out the entire or part of your company's patent portfolio. For example, you may consider opting out if you wish to be able to pick and choose where to enforce your national validations of European patents or wish to enforce the validations differently in different European countries. Further, if the patent is critical to your business, e.g. if the patent covers a core part of a commercially important technology, the risk of central revocation by the UPC across all validated jurisdictions may point towards opting out.

However, it is not possible to generally say whether patent proprietors should opt out their patents or not. This will indeed depend on specific analysis of the given company's patent portfolio and patent protection strategy.

In order to allow proprietors the chance to file opt-outs for their existing European patents before the UPC opens for business (which would place proprietors at the risk of third parties filing centralized attacks with the UPC immediately after the court becomes operational), a sunrise period is due to be implemented. During this sunrise period, patent proprietors will be able to file requests to opt European patents out prior to the launch. This sunrise period will last 3 months and is currently expected to start early 2018.

In terms of practicalities, a request for opting out a patent must be made by logging in to the UPC Case Management System, which will require that the proprietor register as a user and provides certain documentation. Currently, the Case Management System runs in a test version but the possibility to register is expected to open soon.

Preparations before opting out are required

Patent proprietors should take time to consider the full implications for opting existing European patents or SPC's out of the UPC, as it will best be done before the UPC opens to avoid the risk of losing the opportunity, e.g. due to a third-party revocation action.

An opt out must be applied for by the legal owner of the patent. In many cases the legal owner is not the same as the individual identified as the owner on the Patent Register. To clarify such discrepancies, it will be necessary to upload documentation of the legal ownership to the UPC Case Management System. In this regard, proprietors should note that an opt out will not take effect until it is registered. Consequently, proprietors who wish to opt out their European patents should prepare and be ready to file the necessary documentation and information as early as possible in the sunrise period to ensure that there is sufficient time to deal with any queries that may arise.

For patents owned by joint proprietors, a valid opt out requires that all proprietors of the patent and all holders of existing SPC's join in the application to opt out of the UPC. The party filing the request to opt out must be able to demonstrate that all proprietors have agreed to file the request and that it is authorised to act on the other's behalf.

License agreements

Licensees are well advised to contact the patent proprietor(s) to check what the plans are in terms of the opt-out option. Many proprietors who have licensed their rights to others may not have the patent in question at the top of their agenda. However, it will be in the licensee's best interest to ensure that any necessary action is taken by the proprietor in a timely fashion.

Under the UPC Agreement, an exclusive licensee is entitled to enforce the patent without the proprietor's consent unless otherwise agreed. This makes the proprietor vulnerable to counterclaims for revocation of the patent with effect for all the contracting Member States. Consequently, proprietors may also want to review such license agreements and limit the licensee's right to enforce the patent before the UPC opens. A holder of a non-exclusive license is not entitled to enforce the patent unless this is expressly permitted in the license agreement.

Contact Accura's team of experienced patent specialists, if you would like further information and/or advice with regard to the UPC system. Accura monitors the developments of the UPC closely. Please find our contact information on the last page.

DK GUIDE ON PRE-LAUNCH OF MEDICINAL PRODUCTS

In the first half of 2017, the Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI) published a new guide on pre-launch.

More specifically, the guide regards the question of which information pharmaceutical companies can legally provide to healthcare professionals about (future) medicinal products prior to obtaining a marketing authorisation.

Medicinal products which have not (yet) been granted a marketing authorisation for the Danish market may not be advertised for or be part of promotional activities for medicinal products. Such illegal advertisement is called pre-launch. In this regard, the distinction between providing (scientific) information and actual advertising (pre-launch) is very important, and ENLI's guide provides a much needed help when it comes to assessing whether certain information or activities are considered as pre-launch or not.

As a general rule, ENLI considers pharmaceutical companies' mentioning of scientific studies and data related to phase I and II of a clinical development study program for potential future medicinal products to be outside the scope of the rules on advertisement for medicinal products and, thus, legal. Naturally, this presupposes that the information from such studies is presented in a neutral (and non-promotional) way. On the other hand, the mentioning of information and data from phase III studies is very often considered advertising by ENLI and, thus, illegal pre-launch. The reason for this is that an application for a marketing authorization is much more imminent, when a pharmaceutical company is presenting information or data from phase III studies than from phase I and II studies.

Despite these general considerations, the assessment will very much depend on the specificities of the communication in question and the context in which the information is provided. This is where ENLI's guide on pre-launch provides a help. The guide includes different relevant scenarios where a pharmaceutical company may or may not mention studies in phase I, II and III in its communication with healthcare professionals. In connection hereto, ENLI lists five factors which strongly point towards advertising and, thus, illegal pre-launch. Further, the guide includes a Q&A-part with relevant "scientific information vs. pre-launch"-related questions on the following topics:

(i) Products in the pipeline,

(ii) Meetings with health care professionals,

(iii) Consultantships, including advisory boards, and

(iv) Market Analysis.

The guide is currently only available in Danish and can be found here.

Contact Accura's team of experienced life science specialists, if you have questions regarding your company's communication with healthcare professionals, including the mentioning of information and/or data related to clinical studies. Please find our contact information on the next page.

CONTACT

Morten Bruus

Partner, Attorney-at-Law

IPR, Life Science
M: +45 3078 6695
morten.bruus@accura.dk

www.accura.dk

ACCURA Advokatpartnerselskab
Tuborg Boulevard 1 · 2900 Hellerup/Cph. · Denmark · CVR no. 3303 9018
Phone +45 3945 2800 · Fax +45 3945 2801 · accura.dk