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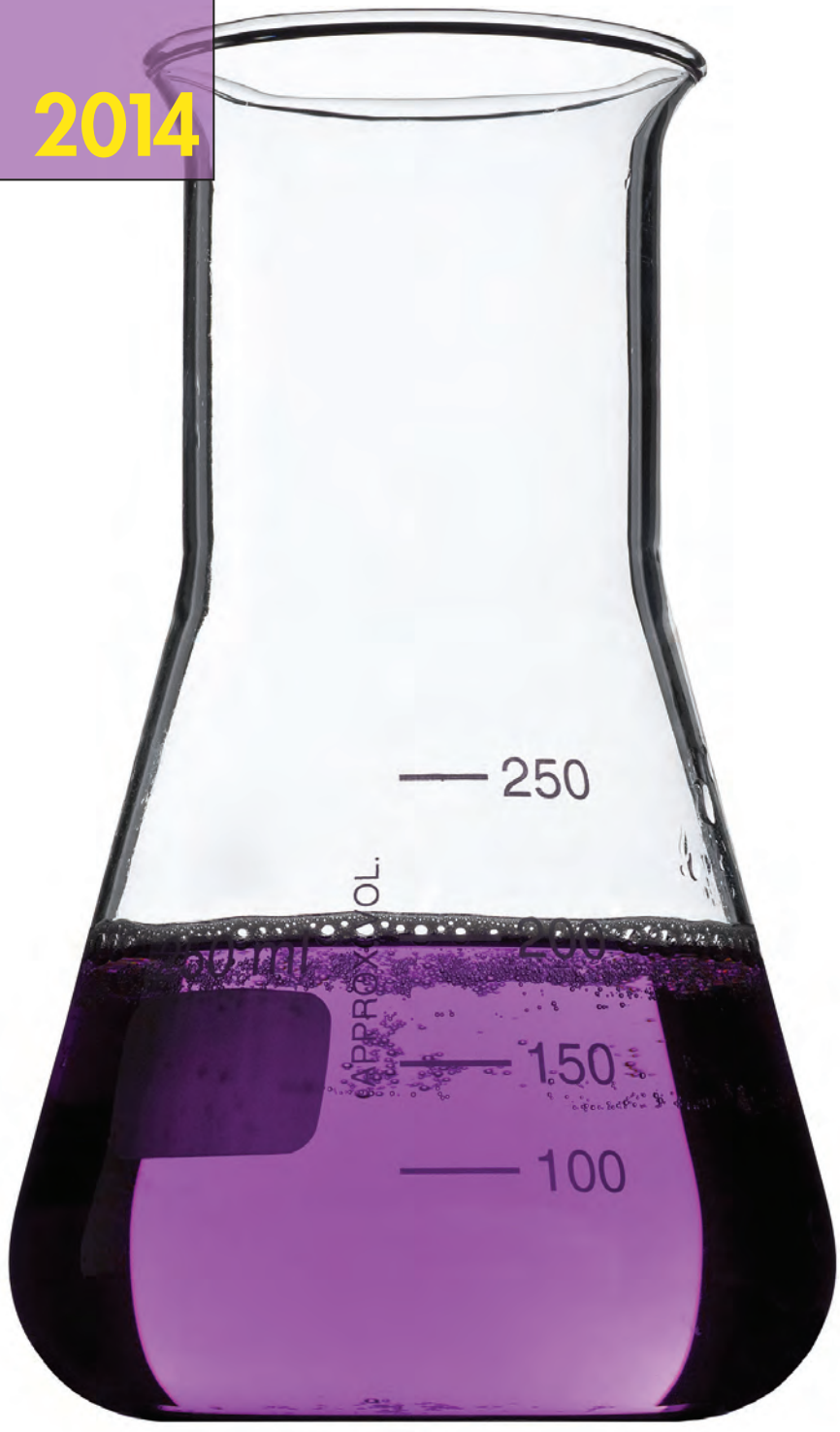

European Union

A Unified Patent Court and Potential Implications for the Pharmaceutical Industry

Europe seeks to establish a centralized patent court, finding that broad procedural changes threaten to disrupt business as usual. By Marie-Louise Jardle, Ronney Wiklund, and Ylva Skoglösa of Valea.

On the road to a Unitary Patent (UP) and a Unified Patent Court (UPC), Europe now seems to offer a beneficial unified market place. The intention of the UPC Agreement (UPCA) is to provide a **legally predictable, cost and time effective** pan-European litigation system, in which a single court decision may e.g. provide an injunction effective in all UPC states. But, the road to blissful harmonization is often flanked by uncomfortable needs for compromise and the introduction of new rules nearly always meets disbelievers. In particular, concerns have been raised by the pharmaceutical industry about the **risk** of litigating patents with high commercial value in a non-tested new court system by potentially "inexperienced" judges and the risk of losing a "crown jewel" patent in all UPC states by a single court decision. Thus, during an initial 7-year transition period, innovating pharmaceutical companies might find it more attractive to "opt-out" from the UPC (Article 83 UPCA).

The aim of this article is to identify areas relevant to the pharmaceutical industry where national variations exist and a harmonized approach can be expected. Whether the harmonization, once achieved, will be an improvement or not lies in the eye of the beholder.

Court praxis

An often discussed question is whether a UPC division would tend to follow the practice of the country where the division is placed. It stands to reason that litigations on pharmaceutical patents that are referred to the London-based Central Court division will be influenced by UK court practice. Thus, foremost German experts tend to foresee that the enforcement of pharmaceutical patents before the UPC will be slower and more costly than their German national counter-parts. In general though, the UPC aims at providing a faster procedure than most of the UPC states offer today. For instance, according to Article 62 UPCA and Rule 211 of the recently published 16th draft UPC Rules of Procedure (UPCR), **interim injunctions** may be granted in all UPC states by one court decision. Still, an issue of concern is how long it will take to obtain such a decision. Furthermore, Article 33 UPCA provides for **bifurcated proceedings** that enable an alleged infringing act to be decided on before the patent's validity, which may be beneficial to the pharma originator. A **discovery process** is presently not uniformly provided for in all UPC states. Noteworthy, UPCA allows for this, even though it will be very limited compared to that provided, for example, in the UK today (Articles 59 and 60(1) UPCA).

Articles 25-30 UPCA

Articles 25-30 UPCA provide rules on the scope of protection for patents brought before the UPC. The UPCA however, is silent on how these provisions will be applied. Will variations persist in the UPC Divisions or will there be a harmonized approach? According to the existing patent law in most UPC states, both the supply of an essential element of the patented invention and the act of putting the invention into effect must occur in the same state for **contributory infringement** to occur. However, Article 26 UPC instead reads "within the territory of the Contracting Member States in which the patent has effect", which seems to imply that the two acts may occur in separate UPC states. Furthermore, presently there are variations among UPC states as to whether an injunction due to secondary liability for off-label prescriptions of a generic drug is granted based on a second medical use patent. At present, there are also significant variations in the interpretation of the **experimental use exemption** in the different national jurisdictions, which may affect e.g. research tool patents. Some countries, such as the UK, have applied a narrow interpretation, while others, such as Germany, have taken a more expansive view. Article 27(b) UPCA provides for such exemption, but, again, how will it be interpreted in practice? These variations in the scope of research exemption have consequently lead to the **"Bolar" provisions** (Article 10(6) of Directive 2001/83/EC as amended by 2002/98/EC, 2004/24/EC and 2004/27/EC), having been implemented differently by the EU states. Some countries, like Sweden, the Netherlands and the UK, have implemented the Directive narrowly, covering only studies and trials required for generic drugs, while other countries, like Germany, France, and Denmark, have applied the "Bolar" provisions more broadly, covering studies and trials also on new indications and innovative drugs. Interestingly, the UK Government announced in 2013 its intention to change the UK Patents Acts to also exempt clinical trials for innovative drugs. Article 27(d) UPCA refers to the "Bolar" Directive, but is silent on the interpretation thereof.

Article 69 EPC and its interpretation

Article 2 of the Protocol on the Interpretation of Article 69 EPC states that when determining the extent of protection conferred by a European patent (EP) "due account shall be taken of any element

which is equivalent to an element specified in the claims". However, whether a **"doctrine of equivalents"** is applied, and if so to what extent, differs between the UPC states. This may be of particular relevance for the practice of third party's follow-on inventions, such as drug derivatives and substance manufacturing processes. It is to be expected that local Divisions will be guided by pre-existing national praxis, at least in the near future.

Validity

There have also been national variations on the validity of **dosage regime patents**. The UK has taken the same view as the EPO (G2/08), but in Germany, such patents have been revoked due to lack of novelty, whilst France has considered the subject-matter as a non-allowable therapeutic method in general.

Unitary SPC?

It is less likely that there will be a single "unitary **SPC**" giving rights in all UP states, since a market authorization must have been granted in the jurisdiction where the SPC is sought (Article 3(b) of Regulation (EC) 469/2009). More likely, there will be a bundle of national SPCs granted by the national patent offices, on the basis of a UP, since this approach would require less significant amendments to the existing SPC Regulation. According to Article 30 UPCA, the UPC will have exclusive jurisdiction for actions on SPCs granted on the basis of UPs and non-opted out EPs. Rule 5.2 UPCR clarifies that an application to opt-out an EP shall extend to any SPCs based on the EP. Although the recent years have brought us plenty of referrals to the Court of Justice of the European Union (CJEU) in order to clarify the terms of the SPC Regulation and to provide for a harmonized European treatment of SPC rights, there are still several unresolved questions. Adding the UPC into the equation will hardly make navigating the SPC legislation more predictable.

Be brave

In summary, there will certainly be some years of unpredictability before the UPC will function as intended. In the meantime, we can only hope that some of us will actually be brave enough to test the waters.

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