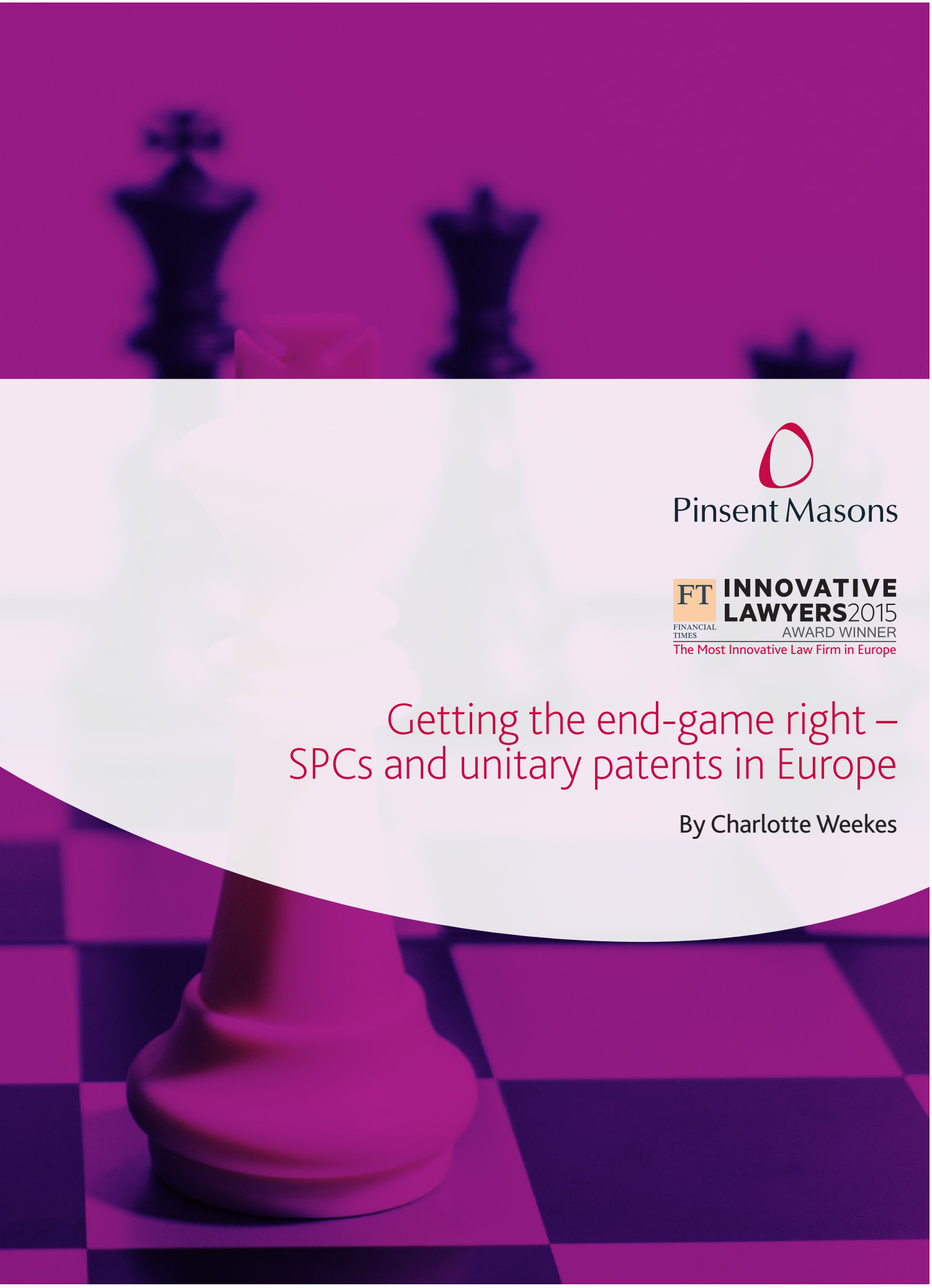

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Getting the end-game right – SPCs and unitary patents in Europe

By Charlotte Weekes

The Unified Patent Court (UPC) currently being implemented will eventually be the major forum for disputes on the validity and infringement of patent rights in Europe .

This Insight discusses the complicated business of how supplementary protection certificates for drugs might interplay with Europe's upcoming unitary patent system.

Supplementary protection certificates (SPCs) for medicinal and plant protection products in the EU are commercially valuable for the life sciences sector. Comprehensive regulatory requirements for such products mean that their marketing is often delayed by a number of years. The up to five-year period of additional patent protection that SPCs provide is compensation for this delay and acts as an important incentive for continued research into new innovative products.

The Unified Patent Court (UPC) currently being implemented will eventually be the major forum for disputes on the validity and infringement of patent rights in Europe. It will have exclusive jurisdiction for the newly created unitary patents, a single patent right with effect across all EU members states participating in the unitary patent system, as well as for traditional European patents which have not been "opted out" of the jurisdiction of the UPC. However, until an Oct. 28, 2015 communication from the European Commission[1], there had been little guidance as to how SPCs might interplay with the new unitary patent system.

The proposals

Broadly speaking, two alternative approaches to the grant of SPCs based on unitary patents have been proposed:

(i) **national SPCs** – the current system continues with a unitary patent being the required "basic patent in force" under the SPC Regulation (Regulation (EC) No 469/2009)[2] for the purpose of granting national SPCs by the relevant intellectual property offices; or

(ii) **unitary SPCs** – a new regime is created whereby a single unitary SPC is granted for all the EU member states participating in the unitary patent system (currently 25 member states[3]). Based on a unitary patent this would presumably require valid marketing authorisations in each participating member state with the SPC application centrally examined/granted by a special division of the European Patent Office (in its capacity as the registrar for unitary patents), or another new European body.

The merits of both systems are considered below.

It is worth noting that the definition of SPC in the Unified Patent Court Agreement is by reference to the SPC Regulation (and the equivalent for plant protection) and therefore any legislative amendments required to bring about SPCs based on unitary patents will either need to amend the SPC Regulation or the UPC Agreement or both, and so will take some time to implement.

National SPCs

The UK Intellectual Property Office, recently informally confirmed that it would grant SPCs based on unitary patents, suggesting it sees this as a viable option for the future.

Commentators have previously advocated national SPCs, which could be brought into force with minor modifications to the SPC Regulation creating a system where SPCs remained *sui generis* national rights, albeit within the exclusive jurisdiction of the UPC. Support for this route also comes from the UK Intellectual Property Office, which recently informally confirmed that it would grant SPCs based on unitary patents, suggesting it sees this as a viable option for the future.

The difficulty with this approach is that Article 30 of the UPC Agreement states that *"a supplementary protection certificate shall confer the same rights as conferred by the patent and shall be subject to the same limitations and the same obligations"* and this needs to be interpreted in light of the uniform protection provided by unitary patents – they have equal effect in, and may only be limited, transferred or revoked, or lapse, in respect of, all participating member states[4] (ie. all EU member states participating in the unitary patent system). Therefore a national SPC based on a unitary patent should arguably be enforceable (and challengeable) for all participating member states even if it has only been granted for one.

Given the unitary character of unitary patents, jurisprudentially can such a national right exist? For example, if an SPC was granted in the UK and refused in Germany, would the unitary SPC only provide protection in respect of the UK (and other member states with SPCs) and be unenforceable in Germany (and others without), despite the unitary scope of protection of its underlying patent?

One solution would be to amend Article 30 of the UPC Agreement along with the SPC Regulation so that SPCs remain national rights, enforced exclusively in the UPC in a similar way to European patents eg.by including all granted SPCs together in the same action, with enforcement limited to those member states in which they had been granted.

Unitary SPCs

A single body granting a single unitary SPC would provide greater certainty and transparency to both third parties and patentees, by preventing regional discrepancies in applying the SPC Regulation.

The alternative approach would be to create a unitary SPC regime, ie. a single right extending the protection provided by unitary patents. This seems to be the route favoured by the European commission, which in its recent communication[5] proposed that:

"A unitary SPC title would bring enhanced certainty to industries whose products are subject to regulated market authorisations. More specifically, a unitary SPC title would improve transparency and certainty on the protection of medicines."

On paper a single body granting a single unitary SPC would provide greater certainty and transparency to both third parties and patentees, by preventing regional discrepancies in the practice of intellectual property offices/courts of the different member states in applying the SPC Regulation and the numerous decisions on this topic by the Court of Justice of the European Union (the CJEU) ie. there would be a single decision on grant, although the UPC must make its own references to the CJEU when the law is not *acte clair*.

However, implementation of such a regime would be difficult for a number of reasons:

- The first reason is administrative and relates to the establishment of a central body to administer the grant of unitary SPCs, for example where it would be based, what languages would be used, and how it would be staffed and funded. It has been suggested that a virtual office comprising staff from each intellectual property office of the participating member states could undertake the role, or perhaps a special division of the EPO, but it will have to be both established and made competent for this role under the SPC Regulation/another instrument of law.
- The second relates to appeals against any refusal to grant an SPC. Currently these go to national courts and it would seem as if the UPC would be the natural body for any appeals against the refusal to grant unitary SPCs given that it will have the ultimate decision as to their validity. Should this be the case, though, Article 32(2) of the UPC Agreement will need to be clarified as it currently states that: *"The national courts of the Contracting Member States shall remain competent for actions relating to patents and supplementary protection certificates which do not come within the exclusive competence of the Court."* Yet given the volume of applications and the inter partes nature of proceedings before the UPC, a separate appeal division of the granting body (much like the Boards of Appeal of the EPO) might be necessary, thus increasing the time it would take to obtain ultimate clarity as to whether an SPC is granted.
- Thirdly, the SPC Regulation requires that an SPC can only be granted where there is a valid marketing authorisation (MA) subsisting in the member state in which it is to be granted, so presumably a unitary SPC could only be granted where a patentee has obtained MAs in all participating member states (much like a pediatric extension of an SPC). This could most straightforwardly be achieved for those products eligible for an MA under the EU's centralised procedure for approving drugs, but could be unsatisfactory for products with MAs obtained under the mutual recognition/decentralised and national procedures given the variance in the time it takes to obtain an MA across the different member states, delaying the grant of a unitary SPC and potentially producing a gap in protection. The alternative would be to limit the scope of protection of a unitary SPC to just those participating member states in which MAs have been obtained, but you are then left with the same jurisprudential issues as described above with national SPCs given the intended unitary character of unitary patents.
- Finally, Article 7 of the SPC Regulation provides that an application for an SPC should be applied for within six months of the grant of the MA in that member state or the grant of the basic patent on which it relies, whichever is later. At least one Advocate-General of the CJEU has considered this period as necessary for legal certainty for third parties[6] and, if this is to be preserved, a patentee would need to apply for a unitary SPC within six months of the grant of the first marketing authorisation/basic patent.

The future – does it matter?

How SPCs are to be granted for unitary patents could be a key factor for pharmaceutical companies in deciding whether to obtain a unitary patent.

In the short term, certainty as to how SPCs are to be granted for unitary patents could be a key factor for pharmaceutical companies in deciding whether to obtain a unitary patent . Given this impetus for implementation sooner rather than later, it would appear that national SPCs would be the easiest method to implement bearing in mind the current system, with no reason why a unitary SPC regime could not come into force alongside it or superseding it in the future.

Support for this approach comes from the eventual harmonisation of law that seems inevitable under the UPC's exclusive competence for infringement, declarations of non-infringement and declarations of invalidity of SPCs based on unitary patents (and these are not capable of being opted out under Article 83 of the UPC Agreement/Rule 5(2)(d) of the (now adopted) 18th draft of the UPC Rules of Procedure), and eventually all SPCs based on European patents. As the UPC will be the ultimate arbiter of the application of SPC law and CJEU decisions, it will not matter whether SPCs for unitary patents are granted nationally or centrally as the application of law would be the same.

Have your say

In its October 2015 communication, the European Commission promised to *"consult, consider and propose further measures, as appropriate, to improve the patent system in Europe, notably for pharmaceutical and other industries whose products are subject to regulated market authorisations".* As such, industry will have its chance to put forward its thoughts as to how to proceed in this key area of law.

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Contact

Charlotte Weekes
Partner
Risk Advisory Services, Intellectual Property
T: +44 (0) 20 7490 6354
E: charlotte.weekes@pinsentmasons.com

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