

SPCs: ambiguity over the Unified Patent Court's jurisdiction and opt-outs

As identified in further detail below, analysis by our SPC team has identified several areas of uncertainty concerning the application of the UPC Agreement to SPCs in circumstances where the 'basic patent' underlying the SPC has expired prior to entry into force of the UPC Agreement.

These uncertainties are likely to be especially relevant during the early years of the UPC's operation, and should be taken into account by SPC holders when deciding whether to opt their SPCs out of the UPC's jurisdiction. Although it is not completely clear whether the UPC will have jurisdiction over SPCs in the circumstances identified below, and if so, whether such SPCs can be opted out of that jurisdiction using the mechanism currently provided under the Rules, a precautionary approach might nevertheless be appropriate to attempt to use that mechanism to opt such SPCs out if it is desirable to avoid the UPC's jurisdiction.

Uncertainty no. 1: which SPCs will fall under the UPC's jurisdiction?

The UPC's foundational legal text, the UPC Agreement (formally the <u>Agreement on a Unified Patent Court, or 'UPCA'</u>), defines the UPC's jurisdiction as relating to the following types of patents and patent applications:

- European patents with unitary effect, also known as 'Unitary Patents' (Article 3(a) UPCA);
- European patents which have not yet lapsed at the date of entry into force of the UPCA, or which are granted after that date (Article 3(c) UPCA); and
- European patent applications which are pending at the date of entry into force of the UPCA, or which are filed after that date (Article 3(d) UPCA).

These provisions (and particularly Article 3(c)) seem to exclude the UPC from having any jurisdiction over previously granted European patents which are no longer in force when the UPC launches. Here we assume that the term "lapsed" in Article 3(c) should be interpreted as encompassing both those patents which have ceased to have effect prior to their maximum term, e.g. due to non-payment of renewal fees; and those patents which have expired upon reaching their maximum lifetime of 20 years from filing. For the consequences of alternative interpretations, see "Uncertainty no. 2" below.

When it comes to SPCs, however, the UPCA simply defines the UPC's jurisdiction as relating to any "supplementary protection certificate issued for a product protected by a patent" (Article 3(b) UPCA).

Unlike the provisions of Article 3(c), the definition of "patent" employed in Article 3(b) is not qualified by any requirement that the patent should not have lapsed when the UPCA enters into force, or that it should be granted after that date. Indeed, the term "patent" as employed generally in the UPCA, such as in Article 3(b), is defined in Article 2(g) UPCA as meaning simply a European patent and/or a Unitary Patent, with no restrictions on its date of filing, grant or expiry. Thus, the wording of the UPCA as far as SPCs are concerned does not clearly and explicitly preclude the UPC having jurisdiction over:

- (i) SPCs which are already in force when the UPCA enters into force; or
- (ii) SPCs which have previously been granted, but which are no longer in force when the UPCA enters into force,

as long as such SPCs are based on a European patent (i.e., not a patent granted through a national route bypassing the EPO).

Given that an SPC only comes into force upon expiry of the underlying 'basic patent', these scenarios (i) and (ii) therefore create the potential for the UPC to have jurisdiction over an SPC even though the relevant (European) basic patent would presumably fall outside the UPC's jurisdiction due to its expiry (Article 3(c) UPCA) – and, in scenario (ii), even though the SPC itself has also expired.

The uncertainty as to jurisdiction is compounded when considered in light of the UPCA's 'opt-out' provisions ("Uncertainty no. 2" below); and (in scenario (ii) at least) in light of the absence of a clearly-defined statute of limitations for certain actions under the UPCA ("Uncertainty no. 3" below).

Strictly speaking, the wording of the UPCA also fails to rule out the jurisdiction of the UPC over SPC applications which are pending when the UPCA enters into force. However, this is likely to be of lesser concern, since in most such cases the (European) basic patent should still be in force. Such a patent would clearly fall within the UPC's jurisdiction unless opted out, with the UPC's jurisdiction over the SPC application or any eventually granted SPC following its jurisdiction over the patent (Rule 5.2 – see below). Nevertheless, the absence of any language relating to SPCs which explicitly mirrors the provisions of Article 3(d) UPCA is striking.

Uncertainty no. 2: do the Rules provide an effective implementation of the 'opt-out' procedure for all SPCs?

The default position is that the UPC automatically has jurisdiction for anything falling within the scope determined by Article 3 UPCA. However, it should be well known by now that during a transitional period lasting at least seven years from entry into force of the UPCA, it will be possible to 'opt out' of the UPC's jurisdiction with respect to European patents and SPCs based on European patents (Articles 83(1) and 83(3) UPCA). It will also be possible to pre-emptively register such opt-outs during a 'sunrise period' of approximately three months prior to the entry into force of the UPCA. This period is currently expected to start in January 2023.

Article 83(3) UPCA states that "a holder of a supplementary protection certificate issued for a product protected by a European patent" shall have "the possibility to opt out". This defines the SPC in terms essentially identical to those of Article 3(b), without further qualification. Thus, it appears that Article 83(3) confers a general power to opt out any SPCs which otherwise fall under the UPC's jurisdiction, notwithstanding the status of the underlying patent.

However, the mechanism for opting-out is governed by the <u>Rules of Procedure of the Unified Patent Court</u>, and specifically Rule 5. Notably, under the Rules as they stand at present, there is no separate opt-out procedure for SPCs. Rather, the status of an SPC is determined by the status of the basic patent underlying the SPC – thus, if a patent is opted out, any SPC based on that patent is also opted out (Rule 5.2).

The requirement to opt out a patent in order to opt out an SPC based on that patent arguably creates uncertainty about whether SPCs falling under scenarios (i) and (ii) above can be opted out of the UPC's jurisdiction using the mechanism provided in the Rules, assuming that the UPC does indeed have jurisdiction over such SPCs by default.

In either scenario, the SPC in question is based on an expired patent which – by virtue of Article 3(c) UPCA – presumably cannot itself fall under the jurisdiction of the UPC. It is therefore questionable whether, under the current Rules, an opt out can validly be registered for that expired patent in order to opt out an SPC based on that patent.

Rule 5.1 does explicitly permit the registration of an opt-out for a European patent that has expired. This seems to be intended, among other things, to allow opt-outs to be registered for European patents which expire after entry of the UPCA into force to enable opting out of SPCs based on those patents. This rule does not, itself, expressly preclude the registration of opt-outs for patents which expired before entry of the UPCA into force, so it is arguable that Rule 5.1 could be employed to register opt-outs in respect of SPCs in scenarios (i) and (ii) above.

However, the Rules are intended to implement the UPCA and, as such, are subordinate to the provisions of the UPCA itself (Article 41(1) UPCA, Preamble 1 to the Rules, and Rule 1.1). It is therefore legally questionable whether Rule 5.1 can permit the registration of an opt-out in respect of a European patent which (according to Article 3(c) UPCA) is not otherwise subject to the UPCA, even if only to facilitate the opting out of an SPC based on such a patent.

To the extent that SPCs in scenarios (i) and (ii) might fall under the UPC's jurisdiction, there is potentially therefore a conflict between Article 83(3) on the one hand – which states that SPCs falling within the UPC's jurisdiction shall be eligible to be opted out – and, on the other hand, Rules 5.1 and 5.2 when read in light of Article 3(c), which arguably preclude the patents underlying such SPCs from being opted out and therefore fail to provide a mechanism to achieve the SPC opt-out prescribed by Article 83(3). If such a conflict exists, this might suggest that Rules 5.1 and 5.2 in their current form are invalid – or, at least, require further clarification – to the extent that they relate to SPCs deriving from patents which are no longer in force when the UPCA enters into force.

Alternatively, it might be argued that the UPC does not have jurisdiction for SPCs corresponding to scenarios (i) or (ii), in which case an opt-out is unnecessary. However, the legal basis for such a position also seems to be unclear, at least based on the literal wording of the UPCA, given the differences between the term "patent" as employed in Article 3(b) UPCA concerning jurisdiction over SPCs vs. the qualifications provided in Article 3(c) UPCA concerning jurisdiction over European patents.

As a further option, it might be argued that the use of the term "lapsed" in Article 3(c) is intended to provide a clear distinction vis-à-vis the term "expired" in Rule 5.1. An "expired" patent under Rule 5.1 may be intended to denote a patent which has ceased to have effect due to reaching its maximum 20-year term, whereas a "lapsed" patent under Article 3(c) may be intended to denote a patent which has ceased to have effect before that date due to e.g. non-payment of renewal fees. As such, a narrow interpretation of "lapsed" in Article 3(c) might help to reconcile Rule 5.1 with Article 3(c) and Article 83(3): under this interpretation, Article 3(c) would not preclude the UPC's jurisdiction over patents which expired prior to entry into force of the UPCA, so allowing Rule 5.1 to apply to such patents and thereby permitting opt-outs to be validly registered in order to opt out SPCs in scenarios (i) and (ii) above. However, in the view of the present authors, this interpretation seems unlikely to be correct, not least in view of the seemingly absurd consequence that this would bring historical expired patents in general within the competence of the UPC even where such patents had not served as the basis for an SPC. Similarly, a narrow interpretation of the term "expired" in Rule 5.1 would appear to prevent the valid registration of opt-outs for patents which are allowed to lapse (rather than expire) after entry into force of the UPCA. While such lapsed patents (under a narrow interpretation of the term "lapsed") could never serve as the basis for an SPC, there may nevertheless be a legitimate interest in opting lapsed patents out of the UPC's jurisdiction in order to avoid retroactive invalidity actions under any applicable statute of limitations.

Needless to say, none of these possible interpretations of the UPCA or Rules appears to be completely self-evident from the wording of the texts, or completely satisfactory in its consequences, and ultimately it is likely that this issue will need to be resolved by the Court. Here we note that, if Rules 5.1 and 5.2 are deemed to be in conflict with Article 83(3) UPCA, a mechanism is provided under Article 41(2) UPCA for the Rules to be amended "by a decision of the Administrative Committee, on the basis of a proposal from the Court and after consultation with the European Commission". Thus, it is possible that Rules 5.1 and 5.2 could be amended in due course in order to provide an effective implementation of the SPC opt-out required by Article 83(3) for SPCs based on patents which expired prior to entry of the UPCA into force. However, neither the UPCA nor the Rules provide any details of the circumstances in which the Court can make a proposal for amendments to the Rules and so it is unclear whether the Court can make such a proposal of its own motion, or whether this would need to arise from litigation. Even if such a proposal was to be made, it is subject to a bureaucratic procedure and approval of any rule changes might therefore be slow. The uncertainties surrounding the implementation of opt-outs in respect of SPCs are therefore likely to persist for some time.

Uncertainty no. 3: if the UPC has jurisdiction over expired SPCs, how far back does that extend?

Assuming, for the sake of argument, that the UPC does have jurisdiction over SPCs which expired before entry into force of the UPCA (according to scenario (ii) above), the question arises as to how long ago those SPCs need to have expired before any actions under those SPCs are time-barred. This is not merely a theoretical question: given the commercial significance of SPCs, there may be a high value attached to asserting SPCs in respect of historical infringements – and, correspondingly, in seeking the retroactive revocation of such SPCs

From a practical point of view, litigation is expected to be less likely the longer ago the SPC expired. However, for SPCs which expired only shortly before the entry into force of the UPCA, the prospect of litigation may be a significant consideration e.g. when determining whether to assert an expired SPC via the UPC in respect of a historical infringement, or whether to attempt to opt an expired SPC out of the UPC's jurisdiction if it is felt to be at risk of a retroactive invalidation (e.g. as a defence to infringement).

There is not a straightforward answer to this question in the legal texts of the UPC. The only statute of limitations provided by the UPCA itself, for either patents or SPCs, is that "actions relating to all forms of financial compensation may not be brought more than five years after the date on which the applicant became aware, or had reasonable grounds to become aware, of the last fact justifying the action" (Article 72 UPCA). This is neither tied explicitly to the expiry date of the patent or SPC; nor does it provide any corresponding limitation period for actions which do not necessarily relate to financial compensation, such as actions for revocation or declaration of non-infringement.

In the absence of a more generally applicable statute of limitations in the UPCA itself or in European law, such as in any of the Regulations relating to SPCs, it appears that provisions of national law need to be applied (Article 24(1)(e) UPCA). Thus, in at least some circumstances, e.g. in respect of actions for revocation of an SPC in a contracting state of the UPCA, it seems that the limitation period will be determined according to the relevant national law, adding a further complication.

There is a lack of harmonisation across Europe with respect to limitation periods under national law for actions involving patents (and, presumably, SPCs). For example, we understand that the most common limitation periods for patent infringement actions in many UPC states are three or five years, and that these periods may be calculated according to different principles in different states. The applicable periods can also vary between different types of action, even within a single state: for example, we understand that French law imposes a five-year limitation period in respect of patent infringement actions which is defined essentially in line with Article 72 UPCA, but that there is no limitation period under French law in respect of revocation actions.

The lack of a uniform statute of limitations clearly affects patents and SPCs within the UPC's jurisdiction more widely. However, in the particular case of SPCs which have expired at the date of entry into force of the UPCA, this lack of harmonisation creates a further layer of uncertainty: not only is it unclear whether the UPC will in principle have jurisdiction over such SPCs, but it is also unclear as to whether, as a practical matter, those SPCs could be asserted or revoked in a UPC action, and if so with respect to which states. Conceivably, at any given timepoint the UPC might have jurisdiction over some, but not all, of a bundle of expired national SPCs.

Summary

The lack of clarity concerning the implementation of the UPC Agreement in connection with SPCs is concerning, as is the apparent lack of any public clarification of the problematic provisions in the UPCA and Rules by those overseeing the development and implementation of the UPC.

In view of the numerous possible interpretations of the law which are set out above, it seems quite possible that the UPC will be asked to decide on the correct interpretation of the provisions of the UPCA and Rules relating to SPCs if a suitable case is brought before it in its early years.

While the risks and uncertainties identified above will become less relevant in the future, it cannot be ignored that these issues will potentially affect all existing and previously granted SPCs when the UPC comes into force. The issues identified above should therefore be taken into account by SPC holders when taking decisions on whether to opt in or out of the UPC during the sunrise period and transitional period.

To discuss any of the issues raised above in more detail, please feel free to contact our experienced life sciences & chemistry team.