

What's an *opt-out* like you doing on a patent like this?

Noemí Daviu, Bernabé Zea

Rarely has a choice between two options given rise to so much controversy as whether or not to *opt-out* of a European patent document or associated Supplementary Protection Certificates (SPCs). Possibly this is because, on many occasions, there is no one option that is clearly more correct than the other.

In this sense, it is paradoxical that the pharmaceutical industry, which is the business sector that has advocated the hardest for the implementation of the unitary patent, has now clearly positioned itself in favour of applying for *opt-outs* for its granted patents, leaving them momentarily outside the system.

In this article we first discuss the complexity of the system for requesting *opt-outs*, and finally we discuss essential aspects for defining an appropriate strategy for their use.

The *opt-out* removes the jurisdiction of the *Unified Patent Court* (UPC), thus eliminating the main risk for a patent or SPC holder: that a single invalidity action can simultaneously kill all validations of a European patent in the UPC countries. During the *sunrise period*, which started on 1 March, patentees can register *opt-outs* in advance.

It is important to know that if an *opt-out* is registered for a pending application, it will continue to apply for the life of the validations once the corresponding European patent is granted. The same applies to SPCs granted on the basis of a patent for which an *opt-out* has been requested.

The exclusion of the competence of the UPC is not compatible with the request for unitary effect. By definition, unitary patents will always fall under the competence of the UPC. Thus, if an *opt-out* has been registered for a patent application, once granted it is still possible to request unitary effect, but, in such a case, the *opt-out* will be considered withdrawn.

Opt-out requests are registered in the UPC provided that the formal requirements are met, i.e. the UPC does not validate whether the request has been properly made in accordance with the substantive requirements set out in the UPC rules of procedure.

This is relevant as *opt-out* requests can be challenged. In fact, the registration of an *opt-out in itself* does not prevent third parties from bringing revocation actions before the UPC against patents for which an *opt-out* has been registered. Thus, when this happens, the defendant will have one month to file a preliminary objection and assert the *opt-out*. If the owner does not enforce their *opt-out*, or finally in the course of this preliminary action it is concluded that the *opt-out* has not been properly performed, then the UPC will be deemed to have jurisdiction over the action filed.

The UPC rules of procedure provide for the possibility to correct *opt-out* requests if errors are detected after they have been registered. However, these errors will most likely not be detected before *opt-outs* are challenged, since at no time will there be an external check of the information included in the *opt-out*.

The rules of procedure set out the basic requirements that must be met in order to carry out a valid *opt-out*. These include the following two:

- All the actual owners of the patent, patent application or SPCs, irrespective of whether they are those on record at the EPO or at the national offices, must agree to make the request.
- The *opt-out* request must be made in relation to all states in which the patent has been granted or which have been designated in the patent application.

Far from being clear, these requirements raise many questions of interpretation, especially in the case of granted patents. In fact, throughout the life of a patent, changes of address, changes of names, changes of owners and even the disappearance of some owners are common. These changes can greatly complicate the *opt-out* request. Unfortunately, the rules of procedure do not provide more detail on how to proceed in each of the specific cases that occur in actual practice.

The issue of ownership seems to be relevant only at the time of the *opt-out* request, or at least the rules of procedure do not contemplate that this information must be kept up to date throughout the life of the patent while the *opt-out* is in force.

Where there is an interest in excluding competition from the UPC, one of the important strategic considerations to take into account is the timing of the *opt-out*.

The UPC Agreement provides that an *opt-out* may be registered as long as no court action has been filed prior to this request at the UPC against the patent application, patent or SPCs for which the *opt-out* is registered. It is for this reason that, if a one wishes to exclude the competence of the UPC for a granted patent, it is safest to make the *opt-out* request during this pre-registration period.

Once the pre-registration period is over, it is always safer to file the *opt-out* before the patent is granted.

On the other hand, the more time has elapsed since the filing of the patent application, the more likely it is that there have been changes in ownership that must be taken into account for the correct application of the *opt-out*.

In the absence of any real risk of an invalidity action against the UPC prior to the grant of the patent, it seems logical to wait until the moment of granting to decide whether to opt for the unitary patent, whose only jurisdiction would be the UPC; or to use the traditional validations, and possibly then ask for an *opt-out* to limit the *forum-shopping* options of third parties.

However, in cases where it is clear from the outset that there is no interest in the unitary patent, and that an *opt-out* is desired, it may make more sense to request the *opt-out* at the beginning of the application's prosecution, to avoid possible complications due to changes in ownership.

The request of the *opt-out* together in parallel with the filing of the patent application could be ideal in these cases, since there would be complete certainty of the identity of the patentees and there could even be a cost saving by joining the two administrative acts (filing of the patent application and the *opt-out*).

Unfortunately, according to the rules of procedure, the *opt-out* can only be registered for published patent applications, which means that in the case of a priority European patent application, the *opt-out* cannot be requested until 18 months after filing and, in the case of Euro-PCTs, until 2-3 months after entering the European regional phase, which is when the European office assigns a publication number to the application.

A change in the rules of procedure would be welcome to facilitate the work of patent practitioners and provide greater certainty for patent applicants.

Despite the significant complications related to the requirements and deadlines for applying for *opt-outs*, these fall far short of the difficulty of defining an adequate strategy as there are multiple variables to take into account.

Without wishing to be exhaustive, the following section discusses the three most important considerations to take into account when deciding when to use the unitary pathway and when to *opt-out*.

1. Economic:

Even the economic considerations associated with the use of the unitary patent are not easy to establish for certain specific cases. It is true that from a number of countries where protection is desired, the unitary route is cheaper, but it is also less flexible. For example, it does not allow some countries to be abandoned in order to reduce maintenance fees.

Thus, in conclusion, the unitary route is clearly preferable when protection in many countries is desired and there is no doubt that there will be no interest in abandoning some countries in the future, in order to limit maintenance costs. Conversely, where protection in one or two countries may be sufficient for commercial interests, the classical route of validations seems the most appropriate.

2. Strength of the patent:

In the case of a legal dispute, the greater the conviction that the position is strong, the greater the interest there is in the court being able to properly appreciate the argumentation that has been developed. In principle, the UPC will be a highly specialised court with highly competent judges. Thus, it seems to some extent logical that strong patents will remain under its jurisdiction, while weaker patents will avoid its jurisdiction by requesting *opt-outs*.

3. The business model:

Possibly universities and public research centres should be the least concerned about the jurisdiction of the UPC. The chances of a third party initiating an action to revoke their patents are practically nil, as it would be much more attractive for them to negotiate a licence of the patent than to face the high costs of an invalidity action and the risk of not getting it revoked. Therefore, an *opt-out* of the patents to be licensed does not seem particularly relevant.

However, when a patent has been licensed to a *start-up*, whose investment is focused on the development of the invention, they should reduce the risk of a centralised revocation of the patent, as the patent is a critical asset for the company. And the possibility that other companies in the same sector may decide to act against it in order to eliminate competitors is a real risk. Therefore, closing off possibilities, such as the jurisdiction of the UPC, that make it easier for third parties to attack the patent, seems the most appropriate decision.

Conclusion

The unitary patent and the *opt-out* are new options that, if used appropriately, can improve the IP strategy of IP owners. However, which decision to take in relation to these aspects is not simple, nor can it be automated, but must be assessed on a case-by-case basis, and even at different points in time, in order to make the best possible decisions.

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