

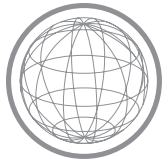
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Major Change to European Patent System in 2023 to Impact Patent Owners' Portfolios

A major change to the European patent system is expected in 2023. Currently, patent owners: 1) validate European patents in individual States, 2) pay renewal fees, and 3) enforce the patent independently in each individual State where the patent was validated. This will change in view of the new Unitary Patent System (UPS) that is expected to come into force, at its earliest, in Q2 2023. The UPS will allow patent owners to: 1) obtain patent protection in participating European Union (EU) Member States by submitting a single request and 2) introduce a multijurisdictional court to deal with patent infringement and validity proceedings in up to 24 EU Member States. For a transitional period, patent owners may be able to opt out of this new system.

For your convenience, we have provided an overview of the UPS below.

Unitary Patent and Unified Patent Court

Overview: The Unitary Patent System (UPS) will introduce both Unitary Patents (UPs) and the Unified Patent Court (UPC) to

participating EU Member States. The UP will make it possible to obtain unitary patent protection in up to 24 EU Member States by submitting a single request to the European Patent Office (EPO), making the procedure simpler and more cost effective. In the current system, patent applicants must validate their European patents in each European Patent Convention (EPC) country. When the UPC comes into force, the UPC will deal with the infringement and validity of UPs and will have non-exclusive jurisdiction over European patents that have not been opted out, putting an end to costly parallel litigation (in each Member State) and enhancing legal certainty following the transitional period.

Timing: The UPS is expected to come into force, at its earliest, in Q2 2023—on the first day of the fourth month after Germany deposits its ratification of the UPC agreement. As an example, if Germany deposits its instrument of ratification on February 20, 2023, the UPS will enter into force on April 1, 2023.

Participating EU Member States: To join the UPS, a State must be an EU Member State. Thus far, 24 EU Member States have agreed to join the UPS and at least 17 EU Member States will join when the UPS goes live (currently 16 EU Member States have ratified, Germany will be number 17).

For EPC countries not participating and/or not eligible to participate in the UPS, as they are currently, European patents will need to be

validated, maintained, and enforced in each such country.

Transitional Period: During the first seven years (extendable on review after five years) of the UPS, it will be possible to litigate European patents in a national court instead of the UPC. If the patent owner opts out of the UPC, litigation is limited to national courts. On the other hand, if the patent owner does not opt out of the UPC, there is a possibility that actions for the patent could be started in either UPC or national courts. Once the UPS comes into force, patent owners can 1) do nothing and automatically fall under the jurisdiction of the UPC or 2) opt out.

Opting Out: Once Germany deposits its instrument of ratification, there will be a three-month “sunrise” period before the UPS becomes operational. During this sunrise period, patent/application owners will be able to register an opt out of the UPC (which will have immediate effect when the UPS becomes operational). As the UPC is a novel entity with some uncertainty, it is anticipated that many patent/application owners will opt out during the sunrise period to maintain the status quo. Currently, there are no official fees for opting out.

However, opting out is not as simple as checking a box on a form. Importantly, opting out can be challenged. As such, opting out should be considered early such that the appropriate documents can be obtained and submitted to the UPC registry prior to the UPS coming into force. If challenged and found invalid, the opting out will have no effect and the patent will be subject to the jurisdiction of the UPC.

For pending patent applications, to opt out during this sunrise period, the patent application must be published.

Withdrawal of an Opt-Out:

Withdrawal of an opt-out can be done at any time (unless the patent is subject to a proceeding in a national court), however, it will not be possible to opt out for a second time after an opt-out withdrawal.

Coverage: Patents granted under the UPS will not provide coverage in EU countries that have not ratified the UPC agreement at the time of request for UP or non-EU EPC countries (e.g., UK, Switzerland, and Turkey) (coverage is fixed and will not extend to Member States that ratify later).

For current European patents/applications, UPS is an option only if all 25 participating EU Member States were designated at filing (even

if at the time of UP request not all Member States have ratified). For example, UP is not an option if your patent application was filed before March 1, 2007, because Malta could not have been designated at that time. Additionally, the claims must also be the same in all 25 EU Member States, including Poland, which originally intended to participate but has not signed the UPC Agreement.

The UPC will eventually have jurisdiction over all patents granted by the EPO (both UP and traditional European patents) in the UP Member States. The earliest date for this total jurisdiction will be seven years after the UPC comes into force. After this time, the only

way to avoid the UPC will be to file separate patent applications at the national patent offices.

Requesting UP: Upon patent grant, patent application owners will have one month to request UP protection. The request for a UP requires a full translation of the patent specification to be lodged with the EPO. If the patent was prosecuted in French or German, a full English translation must be filed. If the patent was prosecuted in English, then the translation can be filed in any official EU language, including for example, Spanish or Polish. For countries not participating in the UPS, the regular three-month period to validate in these countries applies.

European Member States That Have Ratified	
Austria	Lithuania
Belgium	Luxembourg
Bulgaria	Malta
Denmark	The Netherlands
Finland	Portugal
France	Sweden
Italy	Slovenia
Latvia	Estonia

European Member States That Intend to Ratify	
Germany	Slovakia
Greece	Romania
Ireland	
European Member States That Have Not Ratified but Intend to Participate	
Cyprus	Hungary
Czech Republic	

EPC Countries Not Participating and/or Not Eligible to Participate		
United Kingdom	Switzerland	North Macedonia
Croatia	Norway	Albania
Spain	Iceland	Serbia
Poland	Liechtenstein	San Marino
Turkey	Monaco	Montenegro

Reasons Not to Opt Out of UPC/Obtain Unitary Patents	Reasons to Opt Out of UPC/ Obtain Non- Unitary Patents
Injunction against third parties possible across participating Member States following a single proceeding	UPC allows for invalidation of your patent across participating States following a single proceeding
Unitary patents will cover at least 17 countries (UP does not cover EPC countries that are not participating or that are not members of the EU—an applicant will still need to validate in these countries)	Cannot selectively allow a unitary patent in a Member State to lapse during the lifetime of the patent to reduce renewal costs (all or none)
Obtaining a unitary patent potentially reduces renewal fees if applicant typically validates in four-plus Member States	Not possible to opt out of the UPC once the patent is subject to a UPC proceeding
Double patenting— where European patent and national patent overlaps, this may provide a strategic advantage where both rights can exist in parallel— (for example, in Germany)	Can opt out of UPC and can withdraw the opt-out once (provided there has been no national proceedings)
Obtaining a unitary patent provides an opportunity for potential cost savings of at least 50 percent depending on where applicant typically validates European patents (in view of translation and validation costs)	Unknowns are associated with the UPC— potentially less risky to opt out of the UPC and maintain status quo

Also note that patent application owners may delay European patent grant, such that the patent is granted when the UPS becomes operational.

The UPS will change the European patent landscape and provide an opportunity to strategically position individual cases within a given patent portfolio. If you are considering opting out of the UPC, begin strategic discussions early such that appropriate action can be taken during the sunrise period.

Dr. Derrick Rowe is Of Counsel in the Washington, D.C. office of Wilson Sonsini Goodrich & Rosati. His practice centers around patent prosecution and counseling as he seeks to protect the intellectual property rights of clients domestically and internationally within the life sciences, biotechnology, molecular biology, pharmaceutical, diagnostic, and medical device fields. Derrick has extensive experience within private practice and as an in-house counsel at a large pharmaceutical company where he provided patent,

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