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Unitary Patent Protection, Unified Patent Court, Supplementary Protection Certificate and Brexit

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New development in terms of Unitary Patent Protection (UPP) system in Europe is anticipated by the end of the year 2017. This article reviews the advantage of UPP over European Patent system (EPS). In addition, the upcoming Unified Patent Court (UPC) system allows parties to litigate in a single forum which would be time saving and cost effective. In this article we have tried to briefly summarize the structure of UPC. There are certain areas like Supplementary Protection Certificate (SPCs) relating to pharmaceutical products which may be significantly impacted by UPP and UPC. We have tried to weigh the implications of the new system on SPC and also provide some possible solutions. Lastly, Britain's exit from European Union, popularly referred to as Brexit, may pose some challenges to the UPC and UPP and might adversely affect the fundamental purpose of a single patent system in Europe.

Keywords: UPC Agreement, SPC, Unified Patent Court, Brexit, Treaty on European Union

Unitary Patent Protection

The Council of the European Union (EU) and the European Parliament agreed on two regulations in December 2012, which laid the foundation for Unitary Patent Protection (UPP) system in Europe. Later in February 2013, twenty five EU Member States signed the Agreement on a Unified Patent Court (UPC). This committed the Contracting Member States to establish a Court common to them with exclusive jurisdiction for future European patents with unitary effect (Unitary Patent Protection, UPP) as well as for European patents validated in one or several of the contracting states.[1]

The aim of the UPP and UPC is to offer businesses an alternative to the existing European patent system and support a cost effective route to patent protection and dispute settlement. It will still be possible to use the national route for those preferring to seek protection in individual EU Member States and to validate a European patent in one or several Member States. It will also be possible to combine the new system with the old one and have a European Patent with unitary effect and in addition validate the patent as a classical European Patent in other Contracting States. Consequently there will be three routes to patent protection in Europe in the future. The Unitary Patent Protection (UPP) will make it possible to get unitary effect for a European patent in 25 EU Member States by one request.

The UPP builds on the European Patent Convention (EPC). There are no changes in the pre-grant phase. The applicant applies for a European patent at the European Patent Office (EPO). The EPO handles the application in accordance with the EPC and, if all relevant criteria are met, eventually grants a European patent. The flow chart for the grant of a traditional European patent from the stage of filing to grant is depicted in Figure 1.[2]

Unitary Patent Effect

The classical European patents, where the patentee needs to validate the patent in each Member State where protection is required. Different validation requirements apply in the Member States. In several Member States the patent holder must file a translation of the European patent into the official language of the state where protection is requested. Further, the patentee needs to pay a publication fee to the national patent office and within prescribed periods of time

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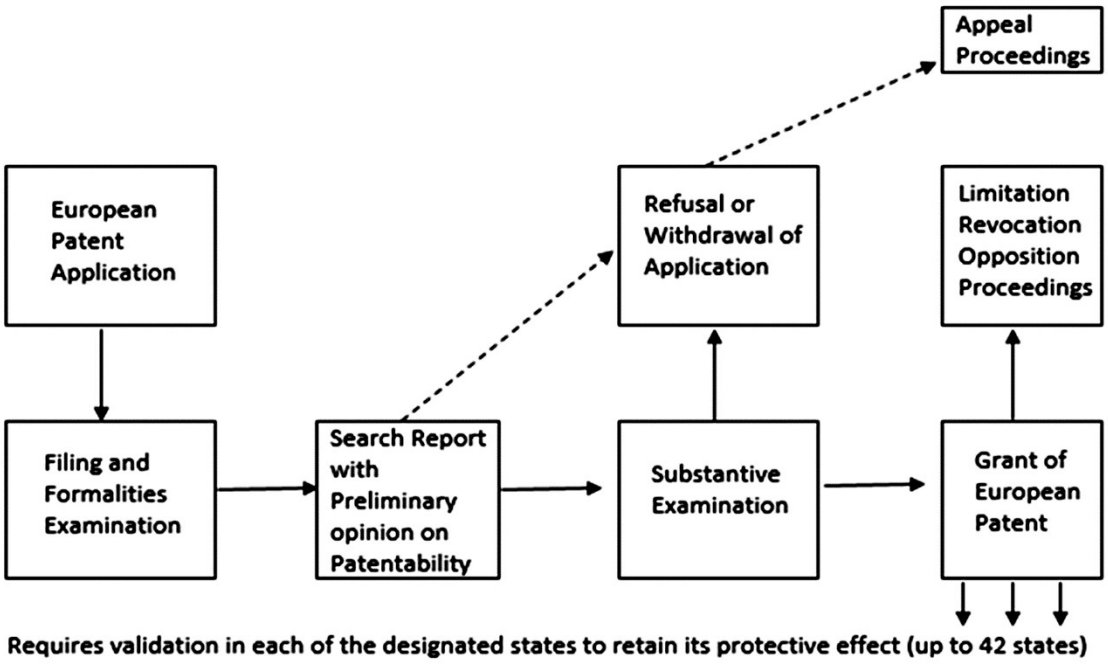

Fig. 1 — Centralised granting procedure for European Patents

comply with various formal requirements relating, in particular, to the number of copies to be filed and the use of specific forms. Once the patent is validated the patent holder must pay renewal fees in every Member State where the patent is valid.

The above shortcomings of the classical European patent will be overcome by the patentee with filing request for unitary effect patent after the grant of traditional European patent. If the formal requirements are met the European patent shall then benefit from unitary effect (uniform protection and equal effect) in all the participating Member States. Consequently, by the means of one single request, the proprietor of a European patent will be able to get patent protection in 25 Member States of the European Union.

Conditions to Grant of Unitary Patent Effect

In order to gain Unitary Patent Protection the European patent must have been granted with the same set of claims for all the participating Member States. All 25 Member States need to be designated. Consequently, withdrawal of designations and limitation of claims for certain of the participating Member States need to be avoided since it would prevent unitary effect. In addition, the request for unitary effect shall be filed at the EPO in the language of proceedings within one month from the publication of the mention of the grant in the European Patent Bulletin.[1]

Translation Requirement:

As from the date of application of the UPP regulations there will be a transitional period of six months or years to a maximum of twelve years during which the patent holder will need to file a translation of the patent specification into one additional language. If the patent is granted in German or French, the translation shall be into English. If the patent is granted in English, the translation shall be into any other official language of the EU at the discretion of the patentee. These translations are for information purposes only and do not have any legal effect. After the transitional period no translations will be required.

The unitary effect of a European patent will cover the territories of those Contracting Member States that have ratified the UPC Agreement at the date of the registration of the unitary effect of the individual patent. The geographical extension of the unitary effect for an individual European patent will remain fixed and will not be extended to those Contracting Member States that ratify the Agreement after the registration. However, once all the Contracting Member States have ratified the UPC Agreement, European patents registered thereafter will enjoy unitary effect in all participating Member States.

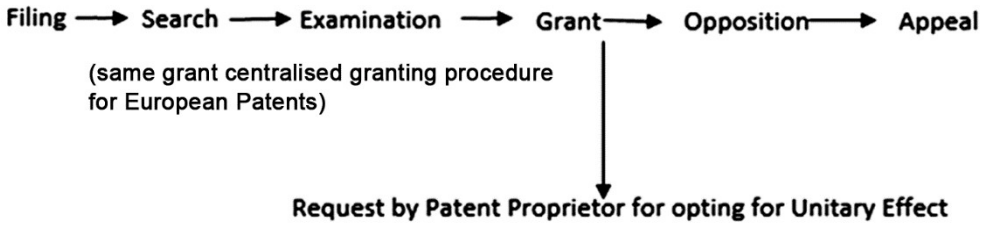

Fig. 2 — Untary Patent Granting Procedure

Advantages of UPP over Classical European Patent System[1-4]

Validation and Translation Cost

The patentee of a European patent with unitary effect can choose to validate the patent as a classical European patent also in the non-participating states. Once all the participating Member States have acceded to the UPC Agreement it will be possible to gain patent protection in the entire EU *via* one request and a maximum of three additional national validations. In addition, it will be possible to validate the same patent in the ten Contracting States of the European Patent Organization that are not EU Member States. This is to be compared with the current European system where the patent, in order to gain the same level of protection, would have to go through individual validation processes in 38 Member States with the need to provide translations, publication fees and comply with various formal requirements.

Compensation for Translation Costs

According to regulation (EU) No 1260/2012 a compensation scheme will be available making it possible to receive reimbursement for all translation costs up to a ceiling for patent applications filed at the EPO in one of the official languages of the Union that is not an official language of the EPO. The compensation scheme will be available only for SMEs, natural persons, non-profit organizations, Universities and public research organizations having their residence or principal place of business within a Member State.

Renewal Fees

The proprietor of a European patent with unitary effect will pay only one annual renewal fee. It shall be paid to the European Patent Office. The level of the renewal fees will be decided by the Select Committee established under the European Patent Convention by the participating Member States. The Select Committee will have to follow the principles contained in the regulation (EU) 1257/2012. The renewal fees shall be sufficient to cover all costs associated with the grant of the European patent and the administration of the unitary patent protection and ensure a balanced budget of the EPO. The level of the renewal fees shall be set, taking into account, the situation of specific entities such as small and medium-sized enterprises, with the aim of facilitating innovation and fostering the competitiveness of European businesses. The level of the renewal fees shall also reflect the size of the market covered by the patent, the renewal rate of current European patents and the number of requests for unitary effect. The fee level shall be similar to the level of the national renewal fees for an average European patent taking effect in the participating Member States at the time the level of the renewal fees is first set.

Unified Patent Court (UPC)

The UPC Agreement aims to establish a unified patent jurisdiction covering all the Contracting Member States that have ratified the Agreement. The UPC will be a common court among all the Contracting Member States and thus be part of their judicial system. The UPC will consist of a Court of First Instance, a Court of Appeal and a Registry. Accession to the UPC Agreement is open to any Member State of the European Union. The Agreement is not open to states outside of the European Union.[5]

UPC Jurisdiction

The UPC will, as a general rule, have exclusive jurisdiction in respect of civil litigation on matters relating to classical European patents, European patents with unitary effect, Supplementary Protection Certificates (SPCs) issued for a product covered by such a patent and European patent applications. The UPC's rulings will have effect in the territory of those Contracting Member States having ratified the UPC

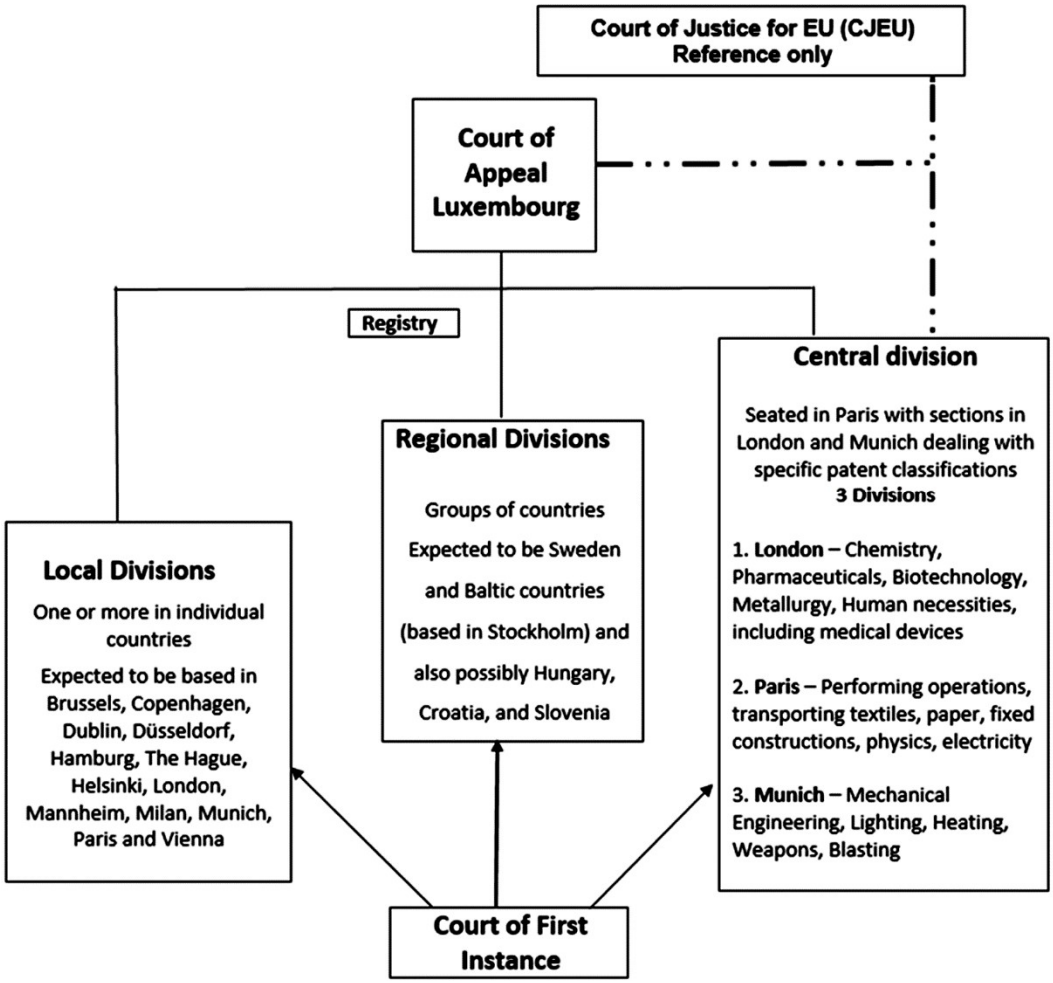

Fig. 3 — Structure of Unified Patent Court System[6]

Agreement. The UPC will not have any competence with regard to national patents or SPCs granted for a national patent. The UPC will also have exclusive competence with respect to actions concerning decisions of the European Patent Office in carrying out the tasks of administering the UPP set out in the UPP regulations.

The UPC Court of First Instance (UPC-CFI)

The UPC-CFI will be one court with several divisions. All the panels will have a multinational composition and will operate under the same Rules of Procedure. The decisions of the UPC-CFI can be appealed in the UPC Court of Appeal. The UPC-CFI will have a central division as well as local and regional divisions. The central division will be seated in Paris which will take care of cases related to Electronics, software, textile and physics. The Central division will have sections in London and Munich dealing with cases concerning specific patent classifications. The London division will be dealt with Human necessities, chemistry and metallurgy. The Munich division will be dealt with Mechanical engineering, lighting, heating, weapons and blasting. Every Contracting Member State may request the UPC to set up, as part of the UPC-CFI, up to four local divisions or a regional division together with one or more other Contracting Member States.

Working of Divisions of UPC

The actions for or relating to infringement, provisional and protective measures, and injunctions, damages or compensation derived from provisional protection and/or prior use shall be brought before the local/regional division where the infringement has occurred, or where the defendant has residence or place of business. In such a case the plaintiff has the choice between the division of the place of infringement and the division of the residence or place of business of the infringer.

If the alleged infringement has occurred in the territories of several local or regional divisions of the UPC-CFI, the plaintiff will also have the possibility to choose between different divisions relating to the place of infringement. If the defendant has no residence or place of business in one of the Contracting Member States, actions shall be brought before the local/regional division where the infringement has occurred or before the central division. If the concerned Contracting Member State has no local/regional division actions shall be brought before the central division.

The actions for cases related to revocation or non-infringement shall be brought before the central division unless an action for infringement between the same parties referring to the same patent already has been brought before a local or regional division, wherein these actions may only be brought before the same local/regional division.

The actions concerning decisions of the EPO, when carrying out administrative tasks regarding the UPP such as the administration of requests for unitary effect, the Register for the UPP, the collection and administration of renewal fees or the compliance with the transitional translation requirements for the UPP, shall always be brought before the central division.

Different Scenarios

If an infringement action is initiated before a local or regional division of the CFI and a counterclaim for revocation of the patent is brought before the local or regional division concerned, the UPC Agreement foresees different scenarios which are:

a) The local or regional division concerned may decide to proceed both with the infringement action and the counterclaim for revocation together.
b) The local or regional division may alternatively decide to refer the counterclaim for revocation for decision to the central division and, depending on the circumstances of the case, either suspend or proceed with the infringement action (bifurcation); orwith the agreement of the parties, the local or regional division concerned may also decide to refer both the infringement action and the counterclaim for revocation to the central division, where they will be dealt with together.

Language of Proceedings

In the CFI the main rule will be that the language of proceedings is the official language or one of the official languages of the Contracting Member State hosting the local division or the official language(s) designated by the Contracting Member States sharing a regional division. The language of proceedings in the central division will be the language in which the patent was granted (language of the patent). However there are exceptions makingit possible for Contracting Member States to designate one or more of the official languages of the EPO, i.e. English, German or French, in addition to or instead of the official language of the Member State(s) as the language of proceedings of their local or regional division. It will also be possible under certain conditions to change the language of proceedings of the local or regional division, to the language of the patent.

The Court of Appeal

The UPC Court of Appeal will have its seat in Luxembourg. The Registry will be set up at the seat of the Court of Appeal. All the panels of the Court of Appeal will have a multinational composition and will operate under the Rules of Procedure of the UPC. The language of proceedings before the Court of Appeal will be the language of proceedings before the CFI.

Role of the Court of Justice of the European Union

The UPC will be a court common to the Contracting Member States. It will therefore, as any national court, be obliged to refer requests for preliminary rulings on the interpretation and application of EU law to the European Court of Justice in accordance with Article 267 of the Treaty on the Functioning of the European Union.[5-6]

Transitional Period – Opt-out Scheme and Choice of Forum

In the UPC Agreement a transitional period is prescribed. It only applies for classical European patents and not for European Patents with unitary effect. The transitional period is seven years but may be prolonged up to a further seven years on the basis of a broad consultation with the users of the patent system and an opinion of the Court.

During the transitional period, actions for infringement or for revocation concerning classical European patents or for SPC issued for a product protected by such a patent may still be brought before national courts unless an action has already been brought before the UPC.

In addition, during the transitional period, a proprietor of – or an applicant for – a European patent

granted or applied for prior to the end of the transitional period or a SPC issued for a product protected by such a patent will also have the possibility to opt out the patent/application/SPC, from the jurisdiction of the UPC unless an action has already been brought before the UPC. To this end they shall notify their opt-out to the Registry. The opt-out shall take effect upon its entry into the register. It will be possible to withdraw such an opt-out at any time. There will be no possibility to opt out European patents with unitary effect.

Structure of the UPC

The Court will be presided over by both legally qualified judges and technically qualified judges. The judges must be nationals of a Contracting Member State, have the highest standards of competence, have proven experience in the field of patent litigation and good command of at least one official language of the EPO. Legally qualified judges shall possess the qualifications required for appointment to judicial offices in their respective Contracting Member State. Technically qualified judges shall have a university degree and proven expertise in a field of technology as well as proven knowledge of civil law and procedure relevant to patent litigation.

Mediation, Arbitration and Training

A patent mediation and arbitration center with seats in Ljubljana and Lisbon and a training framework for judges with facilities in Budapest shall be established.

Court Fees

The court fees will consist of a fixed fee, and above a predetermined ceiling, a value-based fee. The court fees will be finally decided by the Contracting Member States in the Administrative Committee of the UPC. They will however be prepared by the Preparatory Committee established by the Signatory States of the UPC Agreement.

Benefits of the UPC – Why Not To Opt Out

The proprietor of a classical European patent will be able to choose to opt out the patent from the jurisdiction of the UPC. When making this choice the patent holder will need to weigh the advantages of litigating before the UPC against possible disadvantages. The main benefits of the UPC would be:

a. a unified jurisprudence resulting in increased predictability and the avoidance of parallel litigation
b. judgments (injunctions, damages) with effect in 25 Member States of the EU, and
c. The expectation of speedier procedures than in many of the individual Member States.

Choice between Different Divisions of the UPC-CFI[4-6]

In the case of infringement actions it will, on some occasions, be possible for the plaintiff to choose between different divisions of the UPC-CFI depending on the place of infringement or the domicile of the defendant. The choice is expected to depend mainly on the convenience of the venue and on the language of proceedings of the divisions. In terms of efficiency, speed, quality of judgments and interpretation of law, no major differences are expected. All the panels will operate under the same Rules of Procedure and the decisions of the UPC-CFI will be reviewed under appeal by the UPC Court of Appeal. The UPC Court of appeal will be a warrant for a uniform jurisprudence.

The implementation of the new system takes place under the auspices of two committees. The Select Committee is responsible for preparing for the Unitary Patent Protection and the Preparatory Committee is responsible for the establishment of the Unified Patent Court. Since the application of the UPP regulations is dependent on the entry into force of the UPC Agreement the two strands are closely related. The UPC Agreement will enter into force when it has been ratified by 13 Signatory States. The three most patent intensive Member States, i.e. Germany, France and the United Kingdom must be among the states that have ratified the Agreement. The territorial effects will expand as the ratification processes in the individual Contracting Member States are concluded.

The Select Committee is established under the European Patent Convention. It consists of all the EU Member States participating in the enhanced cooperation. The European Commission, Business Europe, the European Patent Institute and other EPC Member States that are not participating in the enhanced cooperation have received the status of observers. The Select Committee has among other things been given the task to govern and supervise the activities of the EPO relating to the UPP. An important task during the preparatory phase will be to fix the level of the renewal fees for European patents with unitary effect.

The Preparatory Committee is established by the Signatory States of the UPC Agreement. Poland, the European Commission and the EPO have observer

status. Its objective is to prepare for the establishment of the UPC in order for it to be operational once the UPC Agreement enters into force. The Preparatory Committee has identified five major work streams; Legal Framework, Financial Aspects, Human Resources/Training, IT and Facilities. Each work stream has been assigned to a specific working group, which have been given the task of preparing proposals to the Committee where all decisions are taken. The Preparatory Committee has established a roadmap outlining all the different tasks of the Committee.

Up to date information about the time plan and the expected time of entering into force of the new system is published on the websites of the two committees.

The UPP or a Traditional European Patent[3]

The UPP and the UPC add other options to the patent system in Europe. It doesn't replace the already existing ones. The new patent package will consequently provide users with new choices. A choice between a traditional European patent and UPP will need to be made taking into consideration the preferences of the individual patent holder on the different relevant aspects.

The costs for a traditional European patent (costs for validation and the cost of renewal fees in each Member State where protection is required, including related transactional costs) need to be compared with the costs for UPP (no validation costs except the cost for one translation during the transitional period, a single renewal fee).

It will be for the patent holder to consider if there is a need for broad geographical coverage or if protection in a few Member States is enough. Consideration should be made as to whether there is a need for protection at the external borders of the EU against imports from third countries via the EU customs regulation. It is difficult to prevent further distribution of a certain product once it has entered the Single Market.

In addition the patent holder needs to consider if the patent should be subject to the exclusive jurisdiction of the UPC or if it is better to use national courts with a more limited geographical jurisdiction. The exclusive jurisdiction is mandatory for UPP and initially optional for the classical European Patent (transitional period of seven years and opt-out for patent holder). National patents will remain in the jurisdiction of national courts.

Supplementary Protection Certificate (SPC) For Unitary Patents[7]

SPCs were introduced to compensate for the loss of effective patent term caused by the delay in marketing authorization (MA) for a pharmaceutical product. The system currently allows for the grant by national industrial patent offices of SPCs for national patents and for EP patents designated for that country.[8]

Currently, the proposed UPP system does not have provision for SPC. Hence some difficulties may be encountered while developing SPC framework for unitary patents.

It is a prerequisite for an SPC that Marketing Authorization (MA) has been granted in the jurisdiction where the SPC is sought (Article 3(b) of the SPC Regulation). The new question raised by the possibility of a "Unitary SPC" is to what extent the territory covered by the granted MAs needs to match the territory covered by a "Unitary SPC" in order to satisfy Article 3(b)?Although Centralized procedure allows grant of a single MA covering the EU, there is no link between the basis for obtaining an MA via the Centralized procedure (as opposed to the national, Decentralized, or Mutual Recognition procedures) on one hand, and the basis for seeking a Unitary Patent (as opposed to a national or European patent) on the other.[9-10]

One option to this problem would be allowance for "Unitary SPC" to be granted based on any EU MA, regardless of the procedure used to obtain the MA. However, this could represent a significant relaxation of the current requirements if it allow grant of a "Unitary SPC" (that inherently covered all UPP States) where the authorization to place the product on the market did not extend to all UPP States (e.g. where there are national MAs for some, but not all, UP States).

Second option "Unitary SPC" would only be available where either an MA had been obtained via the Centralized procedure (and had not been suspended or revoked in any jurisdiction), or MAs had otherwise been obtained in all UPP States. However, this requirement is very onerous, and would provide a disincentive for pharmaceutical companies to seek Unitary Patents. There would also be issues arising due to the difference in timing of Member States giving effect to central decisions to approve products.

The alternative would be to allow the Unitary Patent to be used as the basis for seeking national SPCs under the current system. The definition of "basic patent" in the SPC Regulation would encompass a Unitary

Patent:"(c) 'basic patent' means a patent which protects a product as such, a process to obtain a product or an application of aproduct, and which is designated by its holder for the purpose of the procedure for grant of a certificate". There is nothing in this definition to exclude a Unitary Patent counting as a "basic patent". In fact, setting up a system of national SPCs based upon Unitary Patents would simply require a few tweaks to the existing SPC Regulation. The advantages of this approach include:(a) it allows for and works with the various procedures for grant of MA; and(b) it builds on the existing system, and so should not require significant negotiation or implementation.

Article 9(1) of the SPC Regulation provides that: "The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose."[10-12]

Unitary Patents will, however, be granted by the EPO rather than by the industrial property office of a Member State. The SPC for a Unitary Patent could either be granted by the EPO, or by the national patent office. In principle, if SPCs are to be granted on a national basis, it would be preferable that examination and grant be carried out by national patent offices. This would avoid any change to existing procedures, provided that an SPC application could designate a Unitary Patent as the basic patent.

However, Article 9(1) does not currently cover this position because there is no "competent industrial property office of the Member State which granted the basic patent"; Unitary Patents will be granted by the EPO. Similarly, although Article 9(1) allows "the Member State [to] designate another authority for the purpose", there is not as such a Member State associated with the grant of the Unitary Patent by the EPO (although arguably all Member States could together designate another authority).

Therefore, to deal with this problem, an amendment to this wording would be required with respect to applications for a national SPC for a Unitary Patent. For example: "In the case of an application for a certificate where the basic patent is a patent granted pursuant to [the UP Regulation], the application shall be lodged with the competent industrial property office of the Member State in which the certificate is sought and in which the authorization referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose."

As with SPCs, it would be a major disincentive for pharmaceutical companies to seek a Unitary Patent if it would not provide abases for a pediatric SPC extension. The proposals in this note regarding SPCs should extend to pediatric SPC extensions.

EU Regulation shall only amend an existing EU Regulation. For example, the Pediatric Regulation has already included amendment to the SPC Regulation. Therefore, the proposed UP Regulation could include provisions amending the SPC Regulation to extend its application to SPCs where the basic patent was a Unitary Patent.

Issues regarding SPCs are very closely tied to the underlying patent. For this reason, it would be sensible for litigation relating to the SPC to take place in the same forum as litigation relating to the Unitary Patent. This forum could be the proposed Unified Patent Court "UPC". This position is already covered by the draft Agreement on a UPC which defines "Supplementary Protection Certificate" as an SPC under the SPC Regulation or SPC Plant Protection Regulation 1610/96, and states that the Agreement covers SPCs issued for a European patent or a Unitary Patent. The UPC has exclusive competence in respect of actions for actual or threatened infringements of SPCs and related defenses, including counterclaims concerning licenses. The draft Rules of Procedure for the UPC appear to extend the general jurisdiction of the UPC to SPCs by stating that references in the Rules to "patent" and "proprietor" shall, when appropriate, include SPCs.[13]

The industries represented by European Crop Protection (ECPA), European Federation of Pharmaceutical Industries and Associations (EFPIA) and European Animal Health Industry (IFAH-Europe) support the concept of Unitary SPCs being granted on the basis of European Patents with unitary effect.[14]

ECPA, EFPIA and IFAH-Europe propose that unitary SPCs on the basis of European Patents with unitary effect shall be granted by a virtual body composed of SPC experts from national patent offices. Such a body would be able to rely on the existing expertise at national level instead of trying to build a new agency. A virtual body would also overcome issues such as forum shopping or differing national practices that might occur with mutual recognition of decisions by experienced personnel from examining national patent offices. Unitary SPCs would, thus, be

granted by this body, combining expertise and best practices from all offices without the political sensitivity of a mutual recognition system.

As a virtual body, considerations such as the location and associated costs of a new agency may be reduced. It is recognized that there might be a need for a small number of administrative staff and it is believed that these needs would be relatively low. By making the body virtual, the administrative burden is minimized and reduced to considerations of how to optimize the virtual coordination. The details of how such a body would process applications would need to be developed with input from the national offices.

It would be acceptable for appropriate filing and renewal fees to be set to finance this body. A precedent might be taken from the fees for the Unitary Patent, once agreed. At present applicants face filing and renewal fees, in each country where an SPC is filed. It is hoped that the official fees associated with a unitary SPC would be a significant saving over national filings.

A unitary SPC will also benefit European industry in reducing internal time and resources needed for the SPC filings on each product. Set up via an EU instrument, such as a dedicated Regulation, building on the existing enhanced cooperation process used for the Unitary Patent, decisions from this virtual body would be challengeable within a court system such as the Unified Patent Court, which could make any references needed to the CJEU.

Practically, this new body could be a stand-alone institution or attached to an already existing EU agency or body. It could be administratively embedded within an existing EU agency, with the task and responsibilities for granting unitary SPCs entrusted to the virtual body. From a substantive perspective, guidelines would ideally be agreed by this virtual body so that SPCs can be granted relying on consistent principles which are the best practices of current examining national patent offices. These substantive guidelines should however remain flexible and easily adaptable in response to legislative changes, and CJEU decisions. The details of how such a body would process applications would need to be agreed with experts from national patent offices, but building on existing systems e.g. EMA's CHMP or NRG.

ECPA, EFPIA and IFAH-Europe suggest the following working principles:

1. SPC applications received by the virtual body could be allocated to a division of three Examiners: a "principal rapporteur" from a national patent office and two co-rapporteurs from different patent offices should be appointed.
2. The rapporteur would be responsible for considering the application and proposing an Opinion / recommendation on the fulfillment of the conditions laid down in Regulations 469/2009 (as amended) or 1610/96 as well as calculating the term of the SPC.
3. The two co-rapporteurs could then have a limited time period to concur or to object to the recommendation made by the rapporteur.

a) Absent any objection to the application from either the rapporteur or the co-rapporteur, the SPC would proceed to grant. The Applicant would be notified accordingly. Otherwise, an office action would be issued.

b) In case of objections from the co-rapporteurs to the rapporteur's proposal, a dialogue mechanism should be initiated between the rapporteur and the two co-rapporteurs so as to reach a consensus or a majority decision.

4. If the 3-rapporteur examining division eventually objects to the application, an office action should be issued, setting a term for the applicant to overcome the objections, in writing. Where this is not sufficient to overcome the objection, the full body should discuss how to address the issue identified and make a decision, by consensus, and where not possible, by absolute majority. Further, office actions can be produced as necessary with a right to an oral hearing before a refusal.
5. If a refusal is issued, appeal should go to a court having the ability to make references to CJEU, the court preferably having expertise in intellectual property such as the Unified Patent Court.
6. It would be appropriate for SPC applications to be made in the language of the Unitary Patent. The translation arrangements applicable to the European Patent with Unitary Effect as per Article 3 Regulation No. 1260/2012 should also apply to unitary SPCs.
7. The right to act before the virtual body should belong to any person having the right to file SPCs before a national patent office.

The European Union has initiated two major studies in the area of SPC for pharmaceutical products. The first study will provide an economic evaluation of the incentives and rewards for pharmaceutical innovation in Europe and its functioning within the internal market. The study will in particular analyze the effects of SPCs

for pharmaceutical uses (human and veterinary) and plant protection, data protection and market exclusivity for medicinal products for human use. Evidence on the overall impact on availability and accessibility of pharmaceutical care for patients and the pressure on health systems across the European Union will be examined. The evidence and analysis provided by this study will support the policymaking in that areas.[15]

This second study will be used by the Commission for an overall evaluation of the SPC system in the EU and to inform the decision on whether to come forward with a new SPC title at European level or to revise the existing SPC legislation. The contracted study shall evaluate whether a new European SPC title, with the current or broader scope within the field of pharmaceutical and plant protection products, with improved provisions, is required to meet the requirements of current and expected innovative market developments in the EU. With this primary purpose, the study shall evaluate the current SPC framework in terms of its legal efficiency in meeting its stated objectives given the development of directly affected and related product markets. It shall also suggest whether the existing SPC rules need to be recalibrated given identified limitations. The results could serve as a basis for an impact assessment for a future proposal by the Commission to recalibrate the existing EU SPC rules.[16]

Impact of Brexit[17-18]

On 23 June 2016, people of Britain voted to leave the European Union (EU), popularly referred to as "Brexit". This development may have some impact on the UPP, UPC and SPCs but it will be still long way to go as until the UK formally leaves the EU (by a process involving negotiations as stipulated in Article 50 of the Treaty on European Union (TEU)), it remains an EU Member State. The UK's negotiations to leave the EU are likely to take considerably longer than the period of two years stipulated in Article 50 TEU; and the various options for securing patent protection in the UK (e.g. *via* the PCT and/or the EPO) will continue as before, and will be unaffected by the UK's departure from the EU.

In addition to an impact upon the proposed UPP, the impact of Brexit upon SPCs in the UK is a certainty. The UK will need to amend its national law in connection with SPCs and other "IP / regulatory" rights.

SPCs in the UK are governed by EU legislation (Regulations 469/2009 and 1610/96). Further, the grant of SPCs relies upon Marketing Authorizations (MAs) that are rights granted under (or in accordance with) EU legislation. Thus, prior to leaving the EU, UK laws will need to be amended, amongst other things, to provide a new legal basis for SPCs in the UK; a new legal basis for providing regulatory data protection (and Orphan Marketing Exclusivity) in the UK for products authorized by the way of existing "centralized" MAs; and a system for "re-registering" existing SPCs (and "centralized" MAs) under UK law.

On 2 August 2016, UK Intellectual Property Office releases a brief statement on the impact of "Brexit" in which UK office noted that "The referendum result has no impact on UK businesses' ability to apply to the European Patent Office for patent protection. It will remain possible to obtain patents from the EPO which apply in the UK. Existing European patents covering the UK are also unaffected. British exit from the EU will not affect the current European patent system as governed by the European Patent Convention (EPC).

The UK remains a Contracting Member State of the Unified Patent Court at present. We will continue to attend and participate in UPC meetings in that capacity. There will be no immediate changes." Whilst nothing is guaranteed, it is almost unthinkable that these points will not be adequately addressed prior to the UK leaving the EU. Thus, the holders of SPCs or "centralized" MAs may hope that it would be possible to maintain their rights in the UK.

However, on November 28, 2016 the UK government surprised the world by announcing it would proceed with preparations to ratify the UPC agreement. Even though it is not sure the UK can stay in the system once it leaves the EU.

Unified Patent Court to Open in December 2017

The UPC Preparatory Committee posted the news that the UPC is expected to open in December 2017. Since Article 89 of the UPC Agreement provides for the opening of the court on the first day of a month, the target opening date is presumed to be 01 December, 2017. With UK ratification expected in April, and Germany expected to be able to confirm its intention to do likewise, the UPC "Provisional Application Phase" can begin in May 2017. This phase, the result of a Protocol to the UPC signed on October 1, 2015, allows various parts of the UPC Agreement to come into force early. The Provisional Application Phase

Table — 1 UPC ratification details till May 2017[2]

Country	Date of ratification
Austria	6 August 2013
Belgium	6 June 2014
Bulgaria	3 June 2016
Denmark	20 June 2014
France	14 March 2014
Italy	10 February 2017
Luxembourg	22 May 2015
Malta	9 December 2014
Netherlands	14 September 2016
Portugal	28 August 2015
Sweden	5 June 2014
Finland	19 January 2016
United Kingdom, Greece, Hungary, Slovenia, Slovakia, Estonia, Latvia, Ireland, Lithuania, Cyprus, Czech Republic, Germany	Not ratified yet

will mean the hand-over of preparations from the Preparatory Committee to UPC committees which can, for example, interview and recruit judges and other personnel.

The Provisional Application Phase will also include a "sunrise period" for accepting opt-outs for existing European patents and applications. This “sunrise period” will, however, not start until about September 2017, allowing further time for the IT system to be refined before this online system is available to users, but still allowing users three months to file opt-outs prior to the system going live. With the UPC possibly operational, December 1, 2017 will also see that the EPO may be able to issue Unitary Patents for newly granting European patents. Hence, before the system goes live, users must address their policies not only for opting out (or not) their existing patent portfolio, but also their future patenting policy.[19]

References

1. European Patent Office, Select Committee, http://www.epo.org/about-us/organisation/select-committee.html (accessed on 2 May 2017).
2. Frohlinger M, The Unitary Patent: Opportunity or Challenge? Patenting Invention and preparing for the Unitary Patent Package Ljubljana, 5 May 2016.
3. EU Unitary Patent and Unified Patent Court; Presentation by Frank D Peterreins and John B. Pegram.
4. Vormann T & Hagedorn Marc-Ruben, The New European Unitary Patent System, 24 May 2016.
5. Unified Patent Court, The preparatory committee, http://www.unified-patent-court.org/(accessed on 3 May 2017).
6. The Unitary Patent One Single Patent covering 25 EU Members; Presentation by Rodolohe Bauer *et al*., Patent Examiners, EPO, October 2013.
7. SPCS &The Proposed Unitary Patent, Katie McConnell, of Counsel Hogan Lovells International LLP, http://www.theunitarypatent.com/spcs-and-the-proposed-unitary-patent (accessed on 29 April 2017).
8. Joshi O, Roy A & Janodia M, Supplementary protection certificate provisions for pharmaceuticals and biotechnological products in Europe: An era after Medeva and Georgetown decisions, *Journal of Intellectual Property Rights*, 19 (2014) 378-386.
9. Matthew R & Julia B, The effect of opt-out on SPCs, Taylor Wessing, https://www.taylorwessing.com/synapse/spc_upc_optout_effect.html. (accessed on 30 April 2017).
10. SPCs and the UPC: Current Status, Laura Reynolds, of Bristows UPC, http://www.bristowsupc.com/commentary/spcs-and-the-upc/ (accessed on 2 May 2017).
11. Lunze A & Melon E Kluwer, Patent Blog [Internet] Initiatives to include SPCs in the Unitary Patent system: Anja Lunze & Elise Melon. 2015 November, http://kluwerpatentblog.com/2015/11/21/initiatives-to-include-spcs-in-unitary-patent-system/ (accessed on 2 May 2017).
12. Unified Patent Court: Supplementary Protection Certificates (SPCs), Jan-Diederik Lindemans&Christian Dekoninck, of Crowell & Moring LLP, https://www.crowell.com/NewsEvents/AlertsNewsletters/all/Unified-Patent-Court-Supplementary-Protection-Certificates-SPCs (accessed on 3 May 2017).
13. The impact of the UPC on life science companies, Bert Oosting, Andreasvon Falck, Stanislas Roux-Vaillard, Stephen Bennett and Daniel Brook in UPC Lifesciences. MANAGINGIP.COM, 2015 April, http://www.theunitarypatent.com/_uploads/news/50-54%20Feature%20UPC.PDF (accessed on 2 May 2017).
14. Proposal for a Unitary SPC, http://www.efpia.eu/uploads/ECPA-EFPIA IFAH_Joint_Position_for_a_Unitary_SPC.pdf (accessed on 3 May 2017).
15. Study on the Economic Impact of Supplementary Protection Certificates (SPCs), Pharmaceutical Incentives and Rewards in Europe. Tender Number 590/Pp/Gro/Sme/16/F/121, December 22, 2016, https://etendering.ted.europa.eu/cft/cft-display.html?cftId=2025#caDetails(accessed on January 2017).
16. The European Commission's Directorate-General For Internal Market, Industry, Entrepreneurship And SMEs Plans To Contract A Legal Study On The EU System Of Supplementary Protection Certificates (SPC). Tender Number - 559/Pp/Gro/

Ima/15/15153, June 09, 2016, https://etendering.ted.europa.eu/cft/cft-display.html?cftId=1533 (accessed on 10 July 2017).

17. Facts on the future of intellectual property laws following the decision that the UK will leave the EU, IP and BREXIT: The facts. August 2, 2016, https://www.gov.uk/government/news/ip-and-brexit-the-facts (accessed on 16 August 2017).
18. Cook T, BREXIT and intellectual property protection in the UK and the EU, *Journal of Intellectual Property Rights*, 21 (2016), 355-361.
19. Kluwer Patent Blog [Internet]Unified Patent Court will become operational in 2017 December, http://kluwerpatentblog.com/2017/01/16/unified-patent-court-will-become-operational-in-december-2017/ (accessed on 2 February 2017).
20. Agreement, European Council Council of the European Union, http://www.consilium.europa.eu/en/documents-publications/agreements-conventions/agreement/?aid=2013001 (accessed on 6 April 2017).