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The Proposal for a Regulation on the “unitary SPC” published earlier today: the Long and Winding Road to Luxembourg

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When the European Commission earlier today published the legislative proposals aimed at introducing a unitary SPC to be examined by a central examination procedure, one of the Beatle’s most beautiful songs immediately sprang to mind: *The Long and Winding Road.*

In particular, the European Commission has published several legislative proposals, four of which are relevant for the point discussed in this blog: (i) Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate (“SPC”) for medicinal products (recast); (ii) Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast); (iii) Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013; and (iv) Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products.

In short, one of the main objectives of these regulations is to create a “unitary SPC” for medicinal products and another for plant protection products. Another objective is to introduce a single examination procedure which will be entrusted to the EUIPO. An applicant will be able to file a “combined” centralized SPC application before the EUIPO requesting the grant of both a unitary SPC (for those Member States where the basic patent has unitary effect) and, at the same time, national SPCs (for the other Member States). After examining the application, the central examination authority will issue an opinion as to whether or not the application fulfils the criteria required by the regulation. The applicant will be able to file an appeal before the EUIPO’s Boards of Appeal, and subsequently the General Court in Luxembourg and, finally, assuming that the general admissibility conditions are fulfilled, before the CJEU. Third parties will be able to file an opposition within two months against positive opinions of the central examination authority. In view of the examination opinion, as amended following an opposition, the EUIPO will then decide to either grant or reject the SPC. If there has been an appeal before the Boards of Appeal, the grant or refusal to grant will be subject to the outcome of that appeal. After the grant, third parties will be able to bring actions for a declaration of invalidity before the EUIPO. Again, the decisions could be then appealed before the Boards of Appeal, the General Court and, if the general admissibility criteria are fulfilled, before the CJEU.

Also, the proposed regulations envisage an amendment of the UPC Agreement pursuant to article

87(2) of the Unified Patent Court Agreement ("UPCA") to include the new "unitary SPC" within the competences of the UPC. According to article 87(2), the Administrative Committee may amend the UPCA "to bring it into line with an international treaty elating to patents or Union law." In fact, one of the main reasons for including article 87(2) in Regulation (EU) 1257/2012 was the foreseeable future introduction of a "unitary SPC."

Most interestingly, the regulations contain new recitals seeking to clarify the conditions laid down in article 3 for the grant of an SPC and, in particular, seeking to incorporate the case law of the CJEU to "ensure consistency" in the application of the regulations.

The publication of these regulations will no doubt prompt a slew of comments in the coming days discussing the nitty-gritty of the proposed unitary SPC and the centralized examination procedure and remedies envisaged by the regulations. In this blog we would like to raise a more general comment, which is that the publication of these proposals may well mark the kick-off of a new curve in the long and winding road to Luxembourg. For the purpose of this blog, Luxembourg does not mean the UPC's Court of Appeal but the General Court and the CJEU.

As UPC aficionados warming up for the *de facto* start of the UPC are well aware, the architects of the UPC did their very best to try to keep those moving in European patents with unitary effect, and even classical patents, as far as possible from the long and winding road to Luxembourg. As is well known, the best example was the last minute removal of articles 6–8 from the text of Regulation (EU) 1257/2012, a move that voices from the Max Planck Institute for Intellectual Property and Competition Law labeled "a rash and futile exercise." But as the Beatles put it in The Long and Winding Road, "Anyway, you'll never know, the many ways I've tried, and still they lead me back to the long and winding road." This will certainly be the case for substantive patent law on scope of protection. This is because one of the requirements for the granting of an SPC is of course that the product (whatever it may be) be protected by a basic patent.

In this regard, in its judgment of 12 December 2013 (case C-493/12, *Eli Lilly v Human Genome Sciences*), the CJEU made the following observations:

> "*30. In that regard, it should be noted that, under European law as it applied at the material time in the main proceedings, provisions concerning patents had not been made the subject of any kind of harmonisation at European Union level or of any approximation of laws (see Medeva, paragraph 22 and the case-law cited), although, since that time, Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ 2012 L 361, p. 1) and the Agreement on a Unified Patent Court (OJ 2013 C 175, p. 1), which may be applicable in the future, pursuant to Article 3(b) of that agreement, to SPCs granted on the basis of Regulation No 469/2009, have been adopted.*
>
> *31.Since no harmonised European Union patent rules are applicable in the main proceedings, the extent of the protection conferred by a basic patent can be determined only in the light of the non?European Union rules governing patents (Medeva, paragraph 23 and the case-law cited).*"

Building from the foregoing observations, in paragraph 40, it added that:

> *"40. With regard to the requirements laid down by the EPC, it should, however, be noted that the Court does not have jurisdiction to interpret the provisions of that Convention,*

> *since, unlike the Member States, the European Union has not acceded to the Convention. The Court cannot, therefore, provide further guidance to the referring court concerning the manner in which it is determine the extent of the claims of a patent issued by the EPO."*

However, as readers will have observed, in the last sentence of paragraph 40 the CJEU opened the door to the possibility that the Regulation (EU), the UPCA and the future evolution of SPC law may move the debate on the competence to determine the "extent of protection" into a new realm.

In fact, in more recent cases, the CJEU has already taken more nuanced stances, as, according to the legal test it has crafted, it is simply not possible to determine whether or not the product "is protected" by the basic patent without first interpreting the law that defines the extent of protection (i.e. article 69 EPC and its Protocol of Interpretation). For this reason, in its judgment of 25 July 2018 (case C-121/17 *Teva UK Ltd and others v Gilead Sciences*), it was inevitable that article 69 EPC and the protocol would slip into the judgment:

> "*46. It follows from the above that the subject matter of the protection conferred by an SPC must be restricted to the technical specifications of the invention covered by the basic patent, such as claimed in that patent.*
>
> *47. With regard to the implementation of that rule, it must in the first place be stated that, in accordance with a principle shared by the patent laws of the Member States and reflected in Article 1 of the Protocol on the Interpretation of Article 69 of the EPC, the claims of a patent are to be interpreted from the perspective of a person skilled in the art and, therefore, the issue whether the product which is the subject of the SPC necessarily falls under the invention covered by that patent must be assessed from that perspective.*
>
> *48. To that end, it is necessary to ascertain whether a person skilled in the art can understand without any doubt, on the basis of their general knowledge and in the light of the description and drawings of the invention in the basic patent, that the product to which the claims of the basic patent relate is a specification required for the solution of the technical problem disclosed by that patent."*

Again, readers will have noticed that, in these paragraphs, the CJEU did exactly what in paragraph 40 of *Eli Lilly v Human Genome Sciences* it said it was not competent to do. As mentioned, it is simply not possible to examine the requirements laid down in article 3 of the Regulation without determining the "scope" or "extent" of protection first.

The proposals that the European Commission has published this morning have moved the substantive patent law on scope of protection even closer to Luxembourg. This is because, as mentioned, the proposed regulations include recitals seeking to clarify issues such as when the product is protected by the basic patent. For example, recital (16) reads as follows:

> *"(16) One of the conditions for the grant of a certificate should be that the product is protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art by the description of the patent on its filing date. This should not necessarily require that the active ingredient of the product be explicitly identified in the claims. Or, in the event of a combination product, this should not necessarily require that each of its active ingredients be explicitly identified in the claims provided that each of them is specifically identifiable in the light of all the information disclosed by that patent."*

Going back to the song from which this entry takes its title, the case law of the CJEU has undoubtedly “left a pool of tears.” If the text of the regulations pass muster, those tears will be here to stay, for they form part of the recitals of an EU regulation that will make new inroads into the long and winding road that leads to Luxembourg.

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