ARTICLE

RECASTING THE EXISTING EU SPC REGULATIONS AND INTRODUCING A UNITARY SPC: RECENT PROGRESS AND FUTURE STEPS

Patent Law | 22/04/24 | François Pochart Océane Millon de La Verteville Geoffrey Grandjean David Zygas

PROPRIÉTÉ INTELLECTUELLE

In April 2023, one year after the call for contributions we announced in a flash[1], the European Commission presented a draft reform of the Supplementary Protection Certificates (SPCs)[2] . Concerning SPCs for medicinal products, this project consists of two proposals, one providing for the creation of a unitary SPC (*Unitary SPC Proposal*)[3] and the other for the recasting of Regulation (EC) No 469/2009 and No 2019/933 concerning the supplementary protection certificate for medicinal products (*Recast Proposal*)[4]. Twin regulatory proposals have been made concerning SPCs for plant varieties.

Our analysis here focuses solely on the proposals concerning SPCs for medicinal products.

Presented in plenary session by the German Social Democrat Tiemo Wölken, and discussed beforehand in the Committee on Legal Affairs (JURI), these proposals were adopted by the European Parliament on February 28 by a very large majority[5] , with a few minor amendments.

The gestation period for the unitary CCP, the future little brother of the fledgling unitary patent, is well underway.

With the European elections just a few weeks away, and the Council of the European Union yet to make its position on this reform project public, what are the issues surrounding these two proposals?

EUIPO to become examining body for national and unitary SPC applications

The proposals provide that the European Union Intellectual Property Office (*EUIPO*) will examine the SPC applications based on basic patents[6] relating to medicinal products which have obtained a valid marketing authorization (*MA*) from the European Medicines Agency (*EMA*)[7] .

At the end of its examination, the EUIPO will issue a reasoned examination opinion[8] .

The grant of national SPCs will remain the responsibility of the national offices of the member states, but they will be bound by the examination opinion of the EUIPO[9]. In the case of unitary SPCs, the EUIPO itself will grand the SPC directly[10].

In response to concerns about the EUIPO's lack of expertise in patents, SPCs and, more generally, medicinal products [11], the Parliament stipulated in the recitals of both proposals that the examiners in charge of the examination (one EUIPO examiner and two examiners from national offices) will have *"relevant expertise and sufficient experience in the assessment of supplementary protection certificates"**[12].* This requirement is reiterated in the articles concerning the 'Examination panels' in both proposals. However, the criteria used in these articles to assess whether the expertise/experience is *"relevant"* and *"sufficient"* appears to have been set rather low, as these articles merely stipulate that the Office must ensure *"in particular, that at least one examiner has a minimum of five years of experience in the examination of patents and supplementary protection certificates"*[13]. In other words, a panel made up of one examiner with 5 years' experience in patents and SPCs and two examiners with less than 5 years' experience could be considered sufficiently experienced as a whole...

As the French Patent & Trademark Attorneys Institute (CNCPI) pointed out in its comments to the Commission[14], it is "*vital to ensure a high-quality examination*", as *"the economic stakes attached to each certificate application are very high*". Unfortunately, it is to be feared that the Parliament's amendments will not be sufficient to ensure this high quality... It is to be hoped that the Council will raise the standards.

Third-party comments, opposition and appeals against EUIPO decisions

During the examination phase before the EUIPO, third parties will be able to submit observations[15]. This possibility for third parties to submit observations before the SPC is granted was strongly criticized by the German Federal Council (Bundesrat) before the Parliament[16] .

Opposition will be possible within two months of publication of the EUIPO examination opinion[17] .

EUIPO decisions will be subject to appeal to the EUIPO Boards of Appeal and subsequently to the General Court of the European Union and possibly ultimately before the Court of Justice as for the EU trademark and design proceedings.

Consideration of CJEU case law on SPCs

In the explanatory memorandum to the Recast Proposal, the Commission stated*: "It was noted that there were no relevant recitals in Regulation (EC) No 469/2009 that could assist in interpretation of Article 3. Accordingly, certain recitals concern the conditions in Article 3 for the grant of SPCs, and incorporate the case law of the Court of Justice. The aim is to ensure consistency. In particular the judgements in cases C-121/17 and C-673/18 interpret Article 3(a) and 3(d) of Regulation (EC)No 469/2009, respectively, and should be considered settled case law. This is also the case for judgement C-471/14, whereby the date of the first marketing authorisation in the Union, within the meaning of Article 13, is the date on which notification of the decision granting the authorisation was given to the addressee of the decision".*

The explanatory memorandum to the Unitary CCP Proposal contains a similar indication.

The incorporation of CJEU case law into the legislation is indicative of a fundamental trend, pushing the Commission to provide extensive detail in its proposals.

Going one step further, Parliament has amended several recitals to bring them even more into line with CJEU case law.

Thus, in recital 16 of the Unitary PCC Proposal and recital 8 of the Recast Proposal, the Parliament very precisely endorsed the case law of the CJEU on the notion of "*product protected by a basic patent in force*"[18] (amendments in bold):

> *"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* ***in light of*** *the description* ***and drawings*** *of the patent****, on the basis of that person's general knowledge in the relevant field and of the prior art at the*** *filing date* ***or priority date of the basic patent****. 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* ***active ingredient*** *is specifically identifiable in the light of all the information disclosed by that patent****, on the basis of the prior art at the filing date or priority date of the basic patent****."*

The Parliament also took into consideration a comment from the German Federal Council (*Bundesrat*)[19], which criticized the imprecise wording of recital 9 concerning the issue of a new SPC for a product composed of a combination of active substances if one of these substances had already been the subject of an SPC. According to the Bundesrat, the wording proposed by the Commission could lead to a contradiction with the case law of the CJEU, in particular in its *Actavis v. Sanofi* ruling[20]. Following examination by the Parliament, recital 9 of the Recast Proposal and recital 17 of the Unitary SPC Proposal now read as follows (amendments in bold):

> *To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any ~~therapeutically equivalent~~ derivative such as salts, esters, ethers, isomers, mixtures of isomers, complexes or biosimilars, should not have already been the subject of a prior certificate, ~~either alone or in combination with one or more additional active ingredients~~, whether for the same therapeutic indication or for a different one.*

By codifying the current state of CJEU case law, the legislator appears to aim at stabilizing the legal landscape and preventing further reversals on these established points. Indeed, since the series of Yissum-Neurim-Santen rulings, we know that the CJEU can make 180-degree reversals...

Next steps

Since the European elections will be held from June 6 to 9, the current European Parliament has set its priorities for finalizing certain legislative proposals before the transfer of its mandate to the newly-elected Parliament. Generally speaking, a change of Parliament means that it cannot be taken for granted that all dossiers will be taken up by the new Parliament.

With regard to the proposals analysed here, on which the current Parliament has taken a position, the legislative process should continue after the elections, even if the next Parliament is governed by a different coalition. In any case, this is the announcement made by the current Parliament, which, in its press release of February 28, 2024, states that: "*The dossier will be followed up by the new Parliament after the European elections on June 6-9*"[21] .

In addition, the current Parliament has announced that it is ready to start discussions with the Council within the framework of trilogues, once the latter has also finalized its position. Trilogues are inter-institutional negotiations between representatives of the three institutions (European Parliament, Council of the European Union, European Commission) with a view to reaching a provisional agreement on a legislative proposal.

To our knowledge, no information on the Council's position on these two proposals has yet been made public. The Council is currently examining them in its working group on intellectual property[22] .

Once a provisional agreement has been reached in the trilogues, the proposals will return to the Parliament and the Council for formal approval. The final version will then be published in the Official Journal of the European Union.

It can be deduced from these various factors that the European elections should not prevent the legislative process relating to these proposals from following its course, but that the current draft of the proposals is undoubtedly bound to evolve before their publication in the Official Journal of the European Union.

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[1] https://www.august-debouzy.com/fr/blog/1809-le-systeme-des-ccp-un-systeme-imparfait-a-reformer-telle-est-la-question-posee-par-la-commission-europeenne

[2] https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/supplementary-protection-certificates-pharmaceutical-and-plant-protection-products_en.

[3] Report on the proposal for a regulation of the European Parliament and of the Council concerning the supplementary unitary protection certificate for medicinal products and amending Regulations (EU) 2017/1001, (EC) No 1901/2006 and (EU) No 608/2013. All the parliamentary proceedings and the proposals adopted by the European Parliament are available at: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0097_FR.html

[4] Report on the proposal for a regulation of the European Parliament and of the Council on the SPC for medicinal products (recast). All the parliamentary proceedings and the text adopted by the European Parliament are available at: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0099_FR.html

[5] Unitary CCP proposal: 518 votes in favor, 29 against, 70 abstentions; Recast proposal: 526 votes in favor, 23 against, 70 abstentions.

Details of the votes can be found at the following link: https://www.europarl.europa.eu/doceo/document/PV-9-2024-02-28-VOT_FR.html

[6] The basic patent is defined as "*a unitary patent which protects a product as such, a process for obtaining a product or an application of a product, and which is designated by its holder for the purposes of the procedure for obtaining a unitary certificate*" (Article 2 of both reports).

[7] Article 3 of the Consolidated Proposal.

[8] Article 24 of the Recast Proposal and Article 13 of the Unitary CCP Proposal.

[9] Article 32 of the Consolidated Proposal.

[10] Article 18 of the Unitary CCP Proposal.

[11] See in particular the comments of the European Patent Institute (epi) available here: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13353-Arzneimittel-und-Pflanzenschutzmittel-einheitliches-Verfahren-fur-die-Erteilung-von-erganzenden-Schutzzertifikaten/F3436412_en

[12] Amendment 7 to Recital 30 of the Recast Proposal and Amendment 11 to Recital 26 of the Unitary CCP Proposal.

[13] Amendment 45 modifying article 28 of the Recast Proposal and Amendment 48 modifying article 17 of the Unitary CCP Proposal.

[14] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13353-Medicinal-plant-protection-products-single-procedure-for-the-granting-of-SPCs/F3436418_en

[15] Article 25 of the Recast Proposal and Article 14 of the Unitary CCP Proposal.

[16] Comments from the German Bundesrat, point 5 (https://www.europarl.europa.eu/RegData/docs_autres_institutions/parlements_nationaux/com/2023/0231/DE_BUNDESRAT_CONT1-COM(2023)0231_DE.pdf and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_14208_2023_INIT) (in German).

[17] Article 26 of the Recast Proposal and Article 15 of the Unitary CCP Proposal.

[18] CJEU, Gr. Ch., July 25, 2018, *Teva UK Ltd. v. Gilead Sciences Inc*, Case C-121/17 and especially CJEU, 4e ch., April 30, 2020, *Royalty Pharma Collection Trust v. DPMA*, case C-650/17.

[19] Comments from the German Bundesrat, point 5 (https://www.europarl.europa.eu/RegData/docs_autres_institutions/parlements_nationaux/com/2023/0231/DE_BUNDESRAT_CONT1-COM(2023)0231_DE.pdf and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_14208_2023_INIT) (in German).

[20] CJEU, 3e ch., Dec. 12, 2013, Actavis v. Sanofi, case C-443/12.

[21] *The file will be followed up by the new Parliament after the European elections on 6-9* June (https://www.europarl.europa.eu/news/fr/press-room/20240223IPR18090/meps-approve-protection-for-innovative-medicinal-and-plant-protection-products).

[22] Council of the European Union, *List of working papers (WK) distributed to the Working Party on Intellectual Property in the Q3 2023:* https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_14208_2023_INIT