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COVER NOTE

From:	European Economic and Social Committee
To:	General Secretariat of the Council
Subject:	Opinion of the European Economic and Social Committee on the Patent Package: a) Proposal for a regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products [COM(2023) 221 final – 2023/0126 (COD)] b) Proposal for a regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 [COM(2023) 222 final – 2023/0127 (COD)] c) Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) [COM(2023) 223 final – 2023/0128 (COD)] d) Proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 [COM(2023) 224 final – 2023/0129 (COD)] e) Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) [COM(2023) 231 final – 2023/0130 (COD)] f) Proposal for a regulation of the European Parliament and of the Council on standard essential patents and amending Regulation (EU)2017/1001 [COM(2023) 232 final – 2023/0133 (COD)]

Delegations will find attached the opinion of the European Economic and Social Committee on the above-mentioned proposals.

Encl.: INT 1035 Patent package.

European Economic and Social Committee

OPINION

European Economic and Social Committee

Patent package

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a) Proposal for a regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products
[COM(2023) 221 final – 2023/0126 (COD)]

b) 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
[COM(2023) 222 final – 2023/0127 (COD)]

c) Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast)
[COM(2023) 223 final – 2023/0128 (COD)]

d) Proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006
[COM(2023) 224 final – 2023/0129 (COD)]

e) Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast)
[COM(2023) 231 final – 2023/0130 (COD)]

f) Proposal for a regulation of the European Parliament and of the Council on standard essential patents and amending Regulation (EU)2017/1001
[COM(2023) 232 final – 2023/0133 (COD)]

INT/1035

Rapporteur: **Rudolf KOLBE**

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Referral	a) Council of the European Union, 06/09/2023 European Commission, 02/06/2023 b) Council of the European Union, 06/09/2023 European Commission, 02/06/2023 c) European Parliament, 11/09/2023 Council of the European Union, 07/09/2023 d) European Parliament, 12/06/2023 Council of the European Union, 12/06/2023 e) European Parliament, 11/09/2023 Council of the European Union, 07/09/2023 f) European Parliament, 15/06/2023 Council of the European Union, 21/06/2023
Legal basis	a) Article 304 of the Treaty on the Functioning of the European Union b) Article 304 of the Treaty on the Functioning of the European Union c) Article 114(1) of the Treaty on the Functioning of the European Union d) Article 114 and 207 of the Treaty on the Functioning of the European Union e) Article 114(1) of the Treaty on the Functioning of the European Union f) Article 114 of the Treaty on the Functioning of the European Union
Section responsible	Single Market, Production and Consumption
Adopted in section	04/09/2023
Adopted at plenary	20/09/2023
Plenary session No	581
Outcome of vote (for/against/abstentions)	220/0/1

1. Conclusions and recommendations

1.1 The European Economic and Social Committee (EESC) welcomes the European Commission's plans to take action on supplementary protection certificates (SPCs), and specifically the plan to create a novel centralised SPC, not only for "traditional" European patents but also for European patents with unitary effect (unitary patents, UPs). These are key for establishing a more harmonised patent system within the EU. The present proposals for a centralised process for obtaining SPCs, as well as the proposals for improving the already existing SPC Regulations for Medicinal Products (MPs) and Plant Protection Products (PPPs), are highly welcome. There are details still to be clarified in the proposals (see item 3 below), however the overall concept has been well received.

1.2 The proposal for a centralised Standard Essential Patents (SEPs) system has the potential to effectively promote transparency and predictability in SEPs. However, creating appropriate processes and administration for establishing the essentiality and the FRAND terms and conditions for a given SEP will be a major challenge for this project due to its technical and legal complexity. The EESC therefore requests that the Commission further investigate the project (based on Option 4), and consider further involving experts and competent authorities, including the Unified Patent Court (UPC) (see item 5 below).

1.3 The new SPC proposals and an appropriate and transparent approach for SEPs will be significantly advantageous for innovative SMEs in the EU. These proposals may form part of an improved EU Intellectual Property (IP) system allowing competitive investments into innovative EU SMEs, including enabling EU start-up companies to bring their innovative ideas to the market, both to the Single Market and those beyond.

1.4 The COVID-19 crisis and the way it was successfully handled by the EU has shown that making crisis-relevant products (such as COVID-19 vaccines) available did not interfere with the patents for these products and technologies. It is relevant and paramount that the patent system provide a system for Compulsory Licensing (CL) which is transparent and fair to all stakeholders (the rights holders, the potential licensees and the public), and safeguards fundamental rights (see also items 2.5 and 4 below). The present proposal does not fulfil these criteria: it neither complies with the European Convention on Human Rights (ECHR), nor with the minimum standards required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs-Agreement)[1]. The present proposal for CL for crisis management (CLCM) neither establishes a fair and transparent trial system[2] where the patent owner has full party status[3], nor provides specific legal remedies[4]. This is not appropriate for such an act of expropriation.

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1 Processes must guarantee a fair trial, including the right to an effective remedy (Articles 6 and 13 ECHR; Articles 42 and 59 TRIPs).

2 Article 7(7) of the present proposal for Compulsory Licensing.

3 The patent owner only has "an opportunity to comment" Article 7(3) of the present proposal for Compulsory Licensing.

4 Article 21 of the present proposal for CL defines only a review by the CJEU to the "fines" or "payments" without any details as to who may act or initiate such a review, and under which circumstances.

1.5 The EESC recommends that establishing CLCMs for European and unity patents be dealt with by a court that is also technically competent, such as the UPC, on the basis of a transparent legal and procedural framework, which should be elaborated on the basis of Articles 5(A)(2) and (4) of the Paris Convention, Article 31 TRIPs, and with the guidance of national case law. Compulsory licensing of national patents and national utility models should be performed by the national authorities and courts already established for requests for CLCMs, guided by an appropriate EU directive on CLCMs corresponding to the law and practise for the proceedings before the UPC.

2. General comments

2.1 Unitary patents and the UPC should be more integrated in the present proposals. The UPC judges, and especially the technically qualified judges, are the most suitable people to deal with the complex technical and legal issues concerned in all three projects. These judges are highly knowledgeable on patent practices and the relevant fields of technology (either concerning MP- and PPP-related patents for SPCs and CLCMs, or concerning IT-related patents for SEPs). In fact, the UPC already has exclusive competence to decide on the validity of SPCs and SEPs. The UPC also has the exclusive competence for any "related defences" of a defendant in patent infringement cases, including counterclaims concerning licenses[5], which includes FRAND-based licenses. Therefore, issuing CLCMs could be integrated into the UPC competences. Moreover, the UPC could serve as a competent appeal body for appeals against decisions on SPCs (and this may be established in a straightforward manner straight away for SPCs for UPs) or SEPs taken by the European Union Intellectual Property Office (EUIPO) in first instance proceedings. Such appeals may be introduced in a similar way to appeal proceedings in questions related to Article 32(1)(i) of the UPC Agreement[6] already available. The UPC (as the "crown of patent jurisdiction") should be involved and fully integrated into the present projects; this also protects against establishing a bifurcated system between the EUIPO and the UPC.

2.2 EUIPO is the central hub for registering EU trademarks (EUTMs) and community designs, and related questions of intellectual property protection[7]. The EUIPO is – up to now – not involved in major patent matters. Nevertheless, the present proposals suggest establishing the administrative processes required for each of the three projects at the EUIPO. The projects concerned (SPCs, SEPs and CLCMs) may involve complex technical and legal issues, such as:

a) whether a product (for which an SPC is requested) is protected by a basic patent in force (Article 3(1)(a) of the SPC proposals; an issue which has come up in a significant number of cases before the CJEU);
b) whether a patent is an SEP (Article 20 of the SEP proposal, including the essentiality checks of Title V: "at least one patent claim shall correspond with at least one requirement or recommendation to the standard, identified by standard name, version (and/or release) and sub-clause");

5 Article 32(1)(a) of the UPC Agreement.

6 "Actions concerning decisions of the European Patent Office in carrying out the tasks referred to in Article 9 of RE (EU) No 1257/2012".

7 By the European Observatory.

c) the FRAND determination (Title VI of the SEP proposal); or
d) whether an expropriation of the right holder by a CLCM is justified, "strictly limited to the relevant activities of crisis-relevant products in the Union"; and the licence fee for the CLCM is "adequate" (Articles 4 and 5 of the present proposal for CLCMs).

Such issues are usually dealt with in national proceedings by administrative authorities and in courts, where technically and legally qualified judges, officers and representatives are involved.

2.3 While this involvement of specialised personnel may be put in practice through the creation of "examination panels" as suggested in Article 17 of the SPC proposals, because SPC experts of established national patent offices are eligible to participate, the planned "competence centre" to be established at the EUIPO for performing essentiality checks and FRAND determination does not yet provide – in the proposed form – the instruments and personnel required for the planned tasks, because the requirements for qualified evaluators and conciliators have not been satisfactorily defined.

2.4 The language systems proposed for the present projects are challenging. Processes involving patents, especially those that involve assessing the scope of protection of a given patent (such as essentiality checks (for SEPs) and for determining whether a product falls under a basic patent (for SPCs)), are far from trivial, and the complexity rises with any requirement for translations. While computer-generated translations are already highly beneficial in the patent field (Recital (11) to (13) of EU Regulation No 1260/2012 of 17 December 2012), exchanging procedural statements in the course of examination proceedings or in the course of proceedings involving more than a single party (as in opposition proceedings) requires a clear and transparent language regime. In the patent field, the three-language system of the European Patent Office (EPO) – German, English and French – has already proved its merits. Since all unitary patents are granted in one of these three languages, the EPO languages or "English only" may also be a suitable system for all three projects. Users of the system for whom an otherwise practical language system entails an additional burden, such as SMEs at a disadvantage because of the language system, may be eligible for appropriate compensation.

2.5 The COVID-19 crisis proved the importance of innovative EU companies (such as BioNTech, the developer of a successful mRNA COVID-19 vaccine) having accessibility to a strong patent system which allowed, among other things, proper financing in the early stages of development of their innovative concepts (such as developing the mRNA technology for vaccines). Without such IP-based securities and an appropriate financial investment environment, the means and developments which led to the fast and successful provision of the crisis-relevant products could not have taken place.

3. Specific comments on the SPC proposals

3.1 The present SPC proposals may be suitable for overcoming problematic jurisdiction, such as:

a. "Medeva-based" case law (C- 322/10: "active ingredients which are not specified in the wording of the claims of the basic patent" cannot be "products" eligible for SPC protection);

b. "Smithkline-based" CJEU case law (C-181/95: that the owner of the market authorisation (who made major investments into this product) can simply be bypassed); or
c. the question under which circumstances more than one SPC can be granted for the same "product" (CJEU case law based on C- 482/07 ("AHP Manufacturing")).

This makes the system more predictable, which is especially advantageous for innovative SMEs.

3.2 However, to ascertain the intentions in the Recitals, the following proposals are made. To overcome the "Medeva-based" case law (C- 322/10), the relevant stipulation concerning the extent of protection (both of European and unity patents), namely Article 69 of the EPC (Extent of protection), should be included in the definition of a "basic patent" in Article 2 of the draft regulations:
"'basic patent' means a patent which protects – according to the extent of protection as defined in Article 69 EPC, including the Protocol on the Interpretation of Article 69 EPC – a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate".
Consequently, the term "strictly" in Recital (16) and (18) of the revised existing SPC regulations should be deleted.

3.3 In the Recitals of the present proposals, the "Smithkline-based" CJEU case law (C-181/95) is addressed (no SPC is granted without the consent of the holder of the market authorisation). However, no stipulations are included in the regulation proposals to safeguard the rights of the market authorisation holder. Therefore, stipulations have to be included to consider these rights, e.g. as an issue in examination proceedings or at least as a reason for opposition (this reason should then be limited to the market authorisation holder or their successor in title).

3.4 The present SPC proposals aim to provide for "all EU languages" for centralised SPC applications. While this may be feasible for the application request (except if a declaration concerning Article 3(1)(a)[8] is voluntarily made), this language regimen is not suitable for the process as a whole. In practice, after filing the initial request in SPC proceedings, legal arguments (which are often technically intertwined) may be complex (and far more difficult to be automatically translated into all EU languages as a list of products and services of a EUTM or a community design). This holds specifically true in view of the possibility for third parties to observe, take evidence, or oppose proceedings against granting an SPC. In addition, the legal definition and implications of what is a "verified machine translation" should also be included in the proposals.

3.5 Finding legally and technically qualified members to perform the processes planned for the present SPC proposals is a major challenge for the present SPC proposals. An even bigger challenge is to establish appropriate appeal proceedings before the EUIPO and before the General Court. The current EUIPO Boards of Appeal (BoA) hold the highest competence for dealing with EUTM and community design matters. They do not have any competence in patents or SPCs. It is therefore necessary for fair and appropriate appeal proceedings to establish the possibility to launch appeals after the EUIPO first instances for SPC matters, to be overseen

8 As to why and how the product is protected by the basic patent.

by a body with high competence in both fields (patents and SPC), such as the UPC (see items 2.1 and 2.2 above).

3.6 SPCs are normally represented by qualified national or European patent attorneys, because SPC matters require a thorough qualification and understanding of both the legal and technical (chemical/biological) details of any given SPC case. Accordingly, the right to fully represent SPC clients in the proceedings for obtaining centralised SPC protection without unnecessary further costs has to be safeguarded. While this is not problematic in proceedings before the EUIPO, including the BoA of the EUIPO (or the UPC), the right of continued representation by qualified patent attorneys before the General Court in proceedings against decisions of the BoA of the EUIPO[9] and in further proceedings before the CJEU has to be included in the present SPC proposals. While qualified patent attorneys have always had and still have the right to represent their SPC cases before the CJEU (as representatives in referrals to the CJEU under Article 267 TFEU), this right should explicitly also be available for the General Court. Excluding patent attorneys from being able to represent in the EU courts (and the need to hire an attorney-at-law for this late step) would lead to a highly inequitable result and to high additional costs under which innovative SMEs would considerably suffer. Moreover, together with the UPC, a specific high-standard patent attorney qualification was created (the European Patent Litigation Certificate, enabling holders to represent clients before the UPC and in referrals of the UPC to the CJEU under SPC under Article 267 TFEU). Accordingly, these holders as representatives must have full access to all possible instances of proceedings under the present proposals.

4. Specific comments to the proposal for compulsory licensing for crisis management

4.1 As already mentioned above (item 1.4), the COVID-19 crisis has shown that patent protection does not hinder the fast introduction of vaccine products. The possibility to do so was, however, based on many years of previous developments of the various vaccine platforms, including traditional vaccine platforms, but also innovative platforms, such a mRNA-based vaccines. The provision of strong and efficient patents and an efficient and balanced environment for enforcing patents was and is key to any innovation process and will be key to all the future developments needed to address and overcome future challenges, such as climate change, future pandemics, etc. with new technologies.

4.2 The patent system has established balances for limiting patent protection, if needed. The traditional instrument for providing such a balance was the system of CLs[10] established internationally by the revision of the Paris Convention at The Hague in 1925[11], to alleviate the previously planned instrument against non-use of a patented invention: forfeiture. Forfeiture of the patent was, from then on, only possible if granting CLs would not have been "sufficient to prevent the said abuses" (i.e. non-working of patented inventions).

9 Article 28(6) of the present proposals for a centralised SPC, and Article 29(6) of the revised existing SPC regulations.

10 Based on an initial proposal made by Ratkowsky as early as 1870: "Zur Reform des Patentrechts. Vermittelnde Vorschläge" (1870), Vienna.

11 Introducing current paragraphs (2) to (4) of Article 5A into the Paris Convention.

4.3 All states party to the Paris Convention have therefore introduced appropriate and balanced systems for establishing CLs[12]. Since granting CLCMs severely goes against the "right to own", it is an act of expropriation. The proceedings concerning CLCMs must therefore involve the parties concerned (at least the patentee, as the potential licensor of the CLCM, and the requester of the CLCM, as the potential licensee of the CLCM).

4.4 It is therefore relevant and paramount that the patent system provide a system for CLs which is transparent, quick and fair to all stakeholders. This requires competence of the first instance and the appeal instance(s) in both technical and legal interpretation of patents. The UPC has, based on its Rules of Procedure, established a patent litigation system which aims to provide such competent decisions of first instance within one year, which is also an acceptable timeframe for CLCM processes.

4.5 The EESC therefore recommends that establishing CLCMs for European and unity patents be dealt with by the UPC or a court with comparable technical and specific legal competence on the basis of a transparent legal and procedural framework, which should be elaborated on the basis of Articles 5(A)(4) of the Paris Convention[13], Article 31 TRIPs, and with the guidance of national case law. Established national authorities and courts should grant CLs for national patents and national utility models, guided by an appropriate EU directive corresponding to the law and practise for the proceedings before the UPC.

5. Specific comments on the SEP proposal

5.1 As already noted under item 1.2 above, determining if a patent is an SEP or not is not a trivial task. According to the present proposal, this task (which often requires hundreds of hours of work in court proceedings) is carried out through a discussion between an evaluator at EUIPO and SEP proprietors. Any alleged infringer not part of the evaluation will be able to challenge these results in the court. Also, if an evaluator does not agree with the proprietor, there needs to be a possibility for an appeal to challenge such EUIPO decision. Also here (see items 2.1 and 3.5 above) the UPC is to be established as a competent appeal body.

5.2 The present proposal does not suggest how many resources are needed per evaluation, as they are paid by users of the system. This is an additional job that will be a burden for SEP proprietors, as they will be required to do an additional evaluation for patents that may never be used in detail in licensing negotiations or in litigation. Also here, the question must be asked as to where the EUIPO will find the professionals for this activity.

5.3 The EESC takes note of Title VIII of the SEP proposal providing for training, advice and support for micro, small and medium-sized enterprises, as well as specific FRAND terms for such enterprises, and highly welcomes them.

Brussels, 20 September 2023.

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12 Including the requirements as defined in Art. 30 and 31 of TRIPs.

13 Subject to certain modifications concerning absolute time limits in Art. 5(A)(4) PC.

Oliver Röpke
The president of the European Economic and Social Committee