"THE IP STATE OF THE UNION"
EUCOF REPORT Q2/2023 – Q4/2023

1. Patents: The Unified Patent Court (UPC) and the Unitary Patent (UP)

1.1. The UPC and the UP

For a comprehensive review of the history and the preparatory actions (Preparatory Committee, Select Committee, other legislative measures, etc.): see EXCO/CA18/EUC/301 and EXCO/FR22/EUC/301.

Up to now (3 March 2024), 17 EU Member States have finally ratified the UPC-Agreement[1]: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Slovenia, and Sweden.

The UPC has exclusive jurisdiction on (classical) European patents (EPs), European patents with unitary effect (Unitary patent, UPs), SPCs issued for a product covered by such a patent and European patent applications as specified in Article 32 of the UPC Agreement. The UPC has, inter alia, jurisdiction on actions for actual or threatened infringements and related defences, actions for declaration of non-infringement, actions for provisional and protective measures and injunctions, actions for revocation and counterclaims for revocation. The UPC also has exclusive jurisdiction in respect of actions concerning decisions of the European Patent Office in carrying out the tasks set out in Regulation (EU) 1257/2012 on Unitary Patent Protection[2]. National courts will remain competent for actions which do not come within the exclusive jurisdiction of the UPC.

During the transitional period of seven years after the date of entry into force of the UPC Agreement actions relating to (classical) EPs (not UPs) may alternatively be brought before national courts or other competent national authorities as provided for in Art. 83(1) of the UPC Agreement ("Opt-out" for EPs).

The new UP is based on the EP granted by the European Patent Office (EPO) under the rules of the European Patent Convention (EPC), so nothing changes in the pre-grant phase for the UP. After a EP is granted, the patent proprietor can request "unitary effect", thereby getting a EP with unitary effect (i.e. the UP) that provides uniform patent protection in the 17 EU Member States mentioned above. UPs remove the need for complex and costly national validation procedures for these 17 EU Member States.

Accordingly, the EPO is in charge of the technical operation of the UP and acts as a one-stop-shop, allowing for a simple registration of a UP. No fees are due for the filing and examination of the request for unitary effect or for registration of a UP. No post-grant translations will be required after a six-year transitional period. During this period, a translation will be required for information only and will not have any legal effect. UPs are not subject to the currently fragmented renewal fee system (which is still in place of the 22 EPO Member States which are not (yet) part of the UP/UPC system): there is only one procedure and one deadline, all payments are made in EUR to the EPO. The renewal fees for UPs have been set at a very competitive level[3]. UPs confer truly uniform protection since the substantive patent law –

[1] https://www.unified-patent-court.org/sites/default/files/upc-agreement.pdf
[2] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:361:0001:0008:en:PDF
[3] https://www.epo.org/en/applying/european/unitary/unitary-patent/cost

particularly the rights conferred by the UP and any limitations of these rights and the remedies available in cases of infringement – has been harmonised in the UPC Agreement.

The UP/UPC system is open for all EU Member States but not for non-EU Member States. This means that of the 39 EPC Member States only the 27 EU Member States can become Member States to the UPC Agreement. Accordingly, Croatia, Cyprus, the Czech Republic, Greece, Hungary, Ireland, Poland, Romania, Slovakia and Spain have access to the UPC/UP system; the 12 non-EU EPC Member States Albania, Iceland, Liechtenstein, Monaco, Montenegro, North Macedonia, Norway, Serbia Switzerland, Türkiye, and the United Kingdom cannot join the UP/UPC system unless they join the EU.

1.2. The UPC/UP system started on 1 June 2023 for currently 17 (of the 27) EU Member States.

From 1 June 2023 onwards, it was possible to file actions with the UPC in the **Central Division** in Paris (France) and in Munich (Germany) (a further Central Division is planned to be located in Milan (Italy)) (in all Central Division locations, English, German or French is used as the language of proceedings ("LoP"), with the **Regional Division** for Sweden, Estonia, Latvia and Lithuania in Stockholm (Sweden; LoP: English) with place of hearings in Tallinn (Estonia), Riga (Latvia) and Vilnius (Lithuania), and with **Local Divisions** in Vienna (Austria; Lop: German and English), Brussels (Belgium; LoP: Dutch, English, French, German), Copenhagen (Denmark; LoP: Danish, English), Paris (France; LoP: French, English), Helsinki (Finland; LoP: English, Finnish, Swedish), Düsseldorf/Hamburg/Mannheim/Munich (all: Germany; LoP: German, English), Milan (Italy; LoP: Italian, English), The Hague (Netherlands; LoP: Dutch and English), Lisbon (Portugal; LoP: Portuguese and English), Ljubljana (Slovenia; LoP: Slovenian and English).

The UPC is represented by Judge Klaus Grabinski (DE), the President of the Court of Appeal who acts as chairperson of the Presidium. The President is elected by all judges of the Court of Appeal for a term of three years by secret ballot. The President may be re-elected twice. The President directs the judicial activities and the administration of the Court of Appeal and chairs the Court of Appeal sitting as a full court.

The UPC is administered by the Administrative Committee (AC). The AC, amongst other things, adopts the secondary legislation of the Court, such as the Rules of Procedure of the Court[4], the Financial Regulations, and the court fees[5]; and appoints the judges[6][7].

The AC comprises as members representatives from each state in which the Agreement on a Unified Patent Court (UPCA) is in force as well as observers, including the European Commission[8].

Each state that is a member of the AC has one vote. The AC generally adopts its decisions by a majority of three quarters of the states represented and voting. The Chairperson of the AC

[4] https://unified-patent-court.org/en/court/legal-documents?field_legal_doc_type_target_id=26&field_doc_keywords_target_id
[5] https://unified-patent-court.org/en/court/legal-documents?field_legal_doc_type_target_id=201&field_doc_keywords_target_id=
[6] https://unified-patent-court.org/en/news/unified-patent-court-judicial-appointments-and-presidium-elections
[7] https://unified-patent-court.org/en/news/unified-patent-court-appoints-21-technically-qualified-judges
[8] https://unified-patent-court.org/en/organisation/administrative-committee

is currently Mr Johannes Karcher (DE) and the Deputy Chairperson is Mr Paul van Beukering (NL).

The Administrative Committee has its own Rules of Procedure.

Up to date (3 March 2024), the UPC already issued 136 orders or decisions[9]. Remarkably, in 78 of these cases, the language of proceedings was German, in 47 English, 8 in Italian, in 2 Dutch and 1 in French. Already 14 of these 136 decisions/orders were handed down by the Court of Appeal.

1.4. The UPs are administered by the EPO

The EPO is the administrative authority granting the UPs based on the two relevant EU Regulations 1257/2012 and 1260/2012 of 17 December 2012 for the UPs[10]. For this purpose, the EPO has adopted several secondary legislations to enable proper working of this system, including the "Rules relating to Unitary Patent Protection" [11], which provide for the establishment of a UP Division at the EPO and lay down the procedures to be carried out by the EPO, and the "Rules relating to Fees for Unitary Patent Protection[12]", which set out the fees to be paid to the EPO by proprietors of a UP and the methods of paying them.

The EPO has established a "dashboard" which shows in a very actual manner the status and evolution of the requests for unitary effect; the location of patent proprietors; the technology fields (IPC) to which their patents relate; as well as the language in which their European patents were published and subsequently translated[13].

Up to date (3 March 2024), 20 919 UPs were registered at the EPO which translates in an "uptake rate"[14] (2023/2024) of 18,0 %).

2. Patents, European patent attorneys and the EPO: Change of practice at the EPO, new e:EQE

A significant change in practice at the EPO has become effective in November 2023 "to support digital transformation". By decision of 13 October 2022[15], the Administrative Council of the European Patent Organisation adopted a set of legal changes to the Implementing Regulations to the (EPC) that are intended to support the ongoing digital transformation in the patent grant procedure at the European Patent Office (EPO) and strengthen alignment with the Patent Cooperation Treaty (PCT). The changes to EPC Rules 46, 49, 50, 57, 65, and 82 (i.a. defining the form of the documents to be filed with the EPO, including the figures) have become effective on 1 February 2023; the changes to EPC Rules 126, 127 and 131 (i.a. the "10 days Rule") have become effective from 1 November 2023 onwards.

[9] https://unified-patent-court.org/en/decisions-and-orders
[10] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:361:0001:0008:en:PDF and https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:361:0089:0092:en:PDF
[11] https://www.epo.org/law-practice/legal-texts/official-journal/2022/04/a41.html
[12] https://www.epo.org/law-practice/legal-texts/official-journal/2022/04/a42.html
[13] https://www.epo.org/en/about-us/statistics/statistics-centre#/unitary-patent
[14] the percentage of UP requests received with respect to EPs
[15] https://www.epo.org/en/legal/official-journal/2022/11/a101.html

On 13 and 14 December 2023 the Administrative Council of the European Patent Organisation officially embraced the new Regulation on the European Qualifying Examination (REE), taking effect on 1 January 2025[16].

The duration of the exam remains the same as today's EQE (about 20h in total), but five new modules are introduced[17].

- Module F "tests declarative knowledge in procedural patent law and claim analysis".
- Module 1 "assesses whether candidates can carry out tasks relating to the analysis and assessment of information and evaluate and act on instructions from a client".
- Module 2 "examines whether candidates are capable of applying procedural and substantive patent law of the EPC and the PCT. It assesses whether candidates are familiar with all procedures established by the EPC and the PCT and with the procedural law".
- Module 3 "establishes whether candidates possess the required skills to analyse, execute and create patent documentation and submissions. It consists of three parts, addressing the drafting of claims, the response to Office actions and opposition".
- Module 4 "assesses candidates' competence to advise the client and provide an answer in the form of a legal opinion responding to an enquiry".

To take the five modules, candidates are required to have performed the professional activities for one year in the case of Module F, for two years in the cases of Module 1 and 2, and for three years in the cases of Modules 3 and 4.

The following transitional measures have been implemented as well as a roll-out date of application:

- In 2025, the new Module F will be launched, and no pre-examination will be held.
- In 2026 the present main exam papers (A, B, C and D) will be held for the last time, alongside new modules M1 and M2.
- In 2027 the fully-fledged new EQE modules will be in place.

Furthermore, a detailed system of equivalence between the present papers and future modules and the corresponding results is established.

The implementing provision of the REE will be decided by the Supervisory Board in Q1 2024.

3. Patents: The EU "Patent Package" (see also EXCO/UK23/EUC/301)

On 28 April 2023, the EU Commission proposed legislation for the following projects:

1. Supplementary Protection Certificates (SPCs) (proposals for four EU-Regulations)
2. Standard Essential Patents (SEPs) (proposal for a EU-Regulations)
3. Compulsory Licenses for Crisis Management (proposal for a EU-Regulations)
4. Revised EU Pharma Legislation

[16] https://link.epo.org/elearning/REE_2025
[17] https://www.epo.org/en/learning/professional-hub/european-qualifying-examination-eqe

3.1. Supplementary Protection Certificates (SPCs) (proposals for four EU-Regulations)

This package contains proposals for amending the existing two EU Regulations for SPCs for medicinal products and plant protection products as well as two proposals for corresponding "Unitary" SPCs for these two product classes.

Here, the EU Commission seems to have followed many of our proposals we provided in our FICPI Position paper on SPCs for UPs, including our Congress Resolution of 2015[18], namely

- that a **centralised procedure** should be established based on a **centralised market authorization** (for medicinal products; there is no centralised marketing authorization for plant protection products yet established in the EU);
- that the SPC legislation should move back to the "patent world" rather than "drifting away" to the "pharma world" (as done by the CJEU jurisdiction (e.g. by the "Medewa" based case law (C-322/10: "active ingredients which are not **specified** in the wording of the claims of the basic patent"))), especially with respect whether the SPC product falls under the claims of the basic patent and with respect to combinations, etc.;
- that the owner of the market authorization (who made major investment into this product) should not simply be bypassed (as by the "Smithkline" based CJEU case law, C-181/95);
- that the question of more than one SPC for more than one owner of a basic patent is clarified and be made more appropriate (again, "correcting" the CJEU case law C-482/07 ("AHP Manufacturing")).

The present proposals include the following issues:

(a) EUIPO as the new EU SPC Office

Although FICPI has also identified the EUIPO as one of the possible bodies to establish the centralised SPC procedure, we have also referred to the downsides of this solution (see item 5 of our Position paper of 2016: "EUIPO currently does not deal with patents"; "A problem with EUIPO becoming the UP-SPC Office might arise from the appeal routes available: the “default appeal” path to the General Court does not seem to be appropriate, mainly owing to representation issues and lack of specialization. However, a “UPC route” could be opened up by enabling appeals to the UPC against actions concerning decisions of the EUIPO as the UP-SPC Office.").

The present proposals suggest that the procedures can be carried out in any official EU language, i.e. not only the three languages of the EPO or the five of EUIPO, but all (currently 24) EU languages. This is suggested to be established and facilitated with standardised forms and "verified machine translations" (without defining of what is meant by that). The proposals are based on an understanding that all (legal) questions to be dealt with (a comprehensive procedure for the "centralised SPCs is defined in the Regulations) are straightforward (and therefore easily to be automatically translated)

In practice, however, it is clear that 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 product and services of a trademark).

[18] EXCO/1 CH16/CET/1503

(b) Representation of Centralised SPC applications

An important issue for us as representatives before the EUIPO is the right to represent in further appeal proceedings before the EU General Court in proceedings against decisions of the Board of Appeals of the EUIPO.

SPC issues are technically and legally complex (and will also be complex in view of the clarifications suggested in the present proposals) and should therefore be represented and decided by competent representatives and competent decision bodies.

Therefore, we need to establish the right for (continued) representation of qualified patent attorneys at the General Court in such SPC issues (i.e. the right to represent without the need to include an attorney at law at this stage of proceedings). We have already tried to establish such rights for trademark and design matters and the establishment of a specialised senate or court at the level of the General Court (see FICPI Position Paper and Resolution of 2013[19]) but were - for the time being - not successful. However, from a technical point of view, SPC matters require a thorough qualification and understanding to represent clients and a discrimination of qualified patent attorneys compared to attorneys at law is therefore against all rationality.

(c) some wordings

Recital 8 (of the amended SPC Regulation for medicinal products; and the corresponding recitals in the other proposals) defines 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". To overcome the Medewa CJEU case law, it its explicitly defined that "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" which seems to define a "truly Patent world claim scope" interpretation of the claim which includes equivalents. This seems to be further supported by the fact that as "therapeutically equivalent derivative" of the medicinal product derivatives "such as salts, esters, ethers, isomers, mixtures of isomers, complexes or biosimilars" are explicitly referred to in the recitals.

However, Recital 16 (of the amended SPC Regulation for medicinal products; and the corresponding recitals in the other proposals) then stipulates that the "protection granted should furthermore be **strictly** confined to the product which obtained authorisation to be placed on the Union market as a medicinal product" which seems to (in contrast) exclude equivalent forms. A constructive suggestion may be to delete the term "strictly".

Recital 12 (of the amended SPC Regulation for medicinal products; and the corresponding recitals in the other proposals) defines that "Furthermore, no certificate should be granted to the proprietor of a basic patent in respect of a product which is the subject of an authorisation held by a third party, without that party's consent." which addresses the "Smithkline" based CJEU case law, C-181/95. However,

[19] EXCO/CO13/EUC/305

the course of SPC proceedings, it does not seem to be required to prove such a "Consent of the Market Authorisation Holder".

The "Centralised Procedure" Articles 20-53 (of the amended SPC Regulation for medicinal products; and the corresponding articles in the other proposals) need to be carefully examined (by the CET of FICPI). The timing of proceedings for third parties (opposition within 2 months after publication of the examination opinion; Art. 26 "Opposition") seems to be challenging; appeal proceedings follow the EPO regimen (2 months: notice of appeal; 4 Months: grounds of appeal).

Further critical issues are also:

- that oral proceedings in first instance shall not be public (including opposition; Art. 44)
- that taking evidence and oral proceedings (Art. 44 and 45) may be challenging if they can be performed in any EU language (Art. 41)
- that Restitutio is performed by the (very strict) practice of the EUIPO, established on trade marks which usually do not cause detrimental consequences because trade marks may also be re-filed (Art. 49, and not by the more appropriate practice by the EPO)
- that there is a cost appointment (the losing party has to pay; the maximum costs to be specified by adopted "implementing acts"; Art. 51) and enforcement might expect the same challenges as seen in the current EUIPO practice in trademarks and design opposition cases.

3.2. Standard Essential Patents (SEPs) (proposal for an EU-Regulation)

Many standards are based on patented technologies. Specifically, the mobile telecommunications industry is driven by a heavy reliance on standardisation, which is made up of a great number of innovations protected by patents. 2G (GSM), 3G (UMTS), 4G (LTE), 5G and WiFi networks rely on thousands of patented technologies to work, as well as “connected cars” and other Internet of Things (IoT) products. Such communication standards are also key for the development of the hyper-connected society, for example in the field of the Internet of Things in sectors such as consumer electronics, the automotive industry and the electricity grid industry. Organisations engaged in standard setting have developed rules and practices to ensure the efficient licensing of patents that are essential for their standards ('standard-essential patents'). A smooth licensing environment is essential to the success of a standard. It helps to achieve broad and rapid diffusion of innovation and to give patent holders an adequate return on investment in research and development (R&D). It also gives all users of the standard fair access at a reasonable cost.

However, increasing litigation on these patents and first high-ranked court decisions (such as the decision C-170/13 (“Huawei vs. ZTE”) of the CJEU[20]) showed that further practical, administrative and legal steps are necessary to adapt this field of technology to the patent system.

In its 2020 intellectual property (IP) action plan (“Making the most of the EU’s innovative potential - An intellectual property action plan to support the EU’s recovery and resilience”[21])

[20] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A62013CJ0170
[21] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52020DC0760

the EU Commission proposed ways to improve transparency and predictability in the licensing of SEPs.

The Commission already provided some guidance in a Communication of 2017 ("Setting out the EU approach to SEPs"[22]), continued friction in the uptake of SEP-protected standards was observed (including a huge number of court proceedings).

The Commission aimed at improving transparency and predictability in the steadily turning more complicated matter of SEP licensing by encouraging industry-led initiatives in the most affected sectors, combined, if necessary, with reforms, including regulatory if and where needed, aiming to clarify and improve the SEPs framework and offer effective transparency tools. Therefore, the Commission monitors the SEP licensing markets with a particular focus on Internet of Things (IoT) technologies. In this context, an expert group of 15 members was set up in July 2018[23] to deepen expertise on industry licensing practices, sound IP valuation and FRAND (fair, reasonable, and non-discriminatory) determination. The members of the expert group were in particular invited to (1) "look at licensing and valuation practices, and techniques that are currently applied and/or immediately available to address the identified challenges, with a particular focus on IoT"; and (2) "generate ideas looking forward to the future framework for SEPs licensing and valuation, taking into account the particular needs of small and medium-sized enterprises (SMEs). A first report of the SEP expert group was issued in 2021 ("Contribution to the Debate on SEPs"[24]).

Based on this actualised input, the EU Commission then initiated a second public consultation (after the first one of October 2014 to February 2015) which closed in May 2022 (also FICPI provided input[25]).

As a next step, the Commission now provided a draft EU Regulation as a specific legal measure (and not – as also discussed earlier – a EU Directive for harmonising certain issued between the EU Member States).

The present proposal for a Regulation has the aim of "promoting transparency and predictability in licensing of standard essential patents (SEPs)", thereby "improving the licensing of SEPs, by addressing the causes of inefficient licensing such as insufficient transparency with regard to SEPs, fair, reasonable and non-discriminatory (FRAND) terms and conditions and licensing in the value chain, and limited use of dispute resolution procedures for resolving FRAND disputes" (Recitals 1 and 2; Articles 1 and 2). It should "add the flesh to the bones" outlined in the Huawei vs. ZTE decision of the CJEU (C-170/13)

A "competence centre" will be established by the EUIPO, including "an electronic register and an electronic database containing detailed information on SEPs in force in one or more Member States, including essentiality check results, opinions, reports, available case-law from jurisdictions across the globe, rules relating to SEPs in third countries, and results of studies specific to SEPs" (Recitals 12 and 13, Articles 3-13). These entries may be amended by SEP holders and "essentiality checks" may be conducted randomly by independent "evaluators

[22] https://ec.europa.eu/docsroom/documents/26583
[23] https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?do=groupDetail.groupDetail&groupID=3600&news=1
[24] file:///C:/Users/alge/AppData/Local/Temp/SEPs%20Expert%20Group%20-%20Executive%20Summary.pdf
[25] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13109-Intellectual-property-new-framework-for-standard-essential-patents/F3257371_en

selected according to objective criteria to be determined by the Commission" (Recitals 18-29; Articles 14-25).

The proposal also includes a "FRAND determination" defined by an appointed "conciliator" from the "conciliation centre" (Recitals 31-44; Articles 26-58; procedural rules and fees: Articles 59 to 65) as a mandatory step before a SEP holder would be able to initiate patent infringement proceedings or an implementer could request a determination or assessment of FRAND terms and conditions concerning a SEP before a competent court of a Member State.

3.3. Compulsory Licenses for Crisis Management (proposal for an EU-Regulation)

This proposal should give the EU Commission the power to grant compulsory licenses to patents, patent applications, utility models and SPCs covering "crisis-related products" in times of crisis so that the "Union has access to crisis-relevant products" (Art. 1, 2, 3).

The EU Commission plans to establish this “last resort” or “Plan B” in times of an EU-wide crisis “to provide an alternative to the “TRIPs waiver” (see below).

The procedure to obtain such a compulsory license is not clearly outlined in the present proposal, it is only defined that an "Advisory body" is created which the EU Commission can consult (and then follow or not) and the EU Commission may grant such compulsory license (if it "finds that the requirements for a Union compulsory license are met" (Art. 7 (7)). It is not even defined in the present draft of what is meant by “crisis” or how the “crisis” can be defined.

The rights of the licensor seem to be very restricted in the planned regime, only a review by the CJEU is defined to the "fines" or "payments" the Commission has imposed (Art. 21) without any details as to who may act or initiate such review and under which circumstances. Of course, challenging the decision of the Commission to grant such a compulsory license may be performed at the General Court (Art. 256 (1) in connection with Art. 263 TFEU).

In the course of the discussions around the “TRIPs-Waiver” in the course of the COVID-19 crisis where India and South Africa requested at the WTO level to waive the obligations of WTO/TRIPs members to implement or apply Sections 1 (copyright and related rights), 4 (industrial designs), 5 (patents) and 7 (protection of undisclosed information) of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement for an undefined number of years in relation to prevention, containment or treatment of COVID-19[26].

After lengthy discussions within WTO (and by many groups in the public), on 22 June 2022 the WTO adopted a “Ministerial Decision on the TRIPs Agreement”[27] as a “compromise approach”, giving WTO/TRIPs Member States which are “developing countries” (“eligible Member”) the right to limit the rights provided for under Article 28.1 of TRIPs (“rights conferred” by a patent) by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines, including [patents drawn to] ingredients and processes necessary for the manufacture of a COVID-19 vaccine, without the consent of the right holder to the extent necessary to address the COVID-19 pandemic. This limitation has to be in accordance with the provisions of Article 31 of TRIPs (“other use without the

[26] file:///C:/Users/alge/AppData/Local/Temp/W669.pdf
[27] https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True

authorization of the right holder") dealing with compulsory licenses, but the "compromise approach", enables an eligible Member to authorize such an "unauthorized use" through more flexible instruments as currently foreseen in Art. 31 TRIPs, namely also with "executive orders, emergency decrees, government use authorizations, and judicial or administrative orders [or by other means], whether or not a Member has a compulsory license regime in place". Moreover, no authorization from the right holder as set out in Article 31(b) TRIPs has to be obtained. The Ministerial Decision also contains certain soft clauses, such as that eligible Members "shall undertake all reasonable efforts to prevent the re-exportation of the products manufactured" under this exceptional authorization; or that the eligible Member in "determination of adequate remuneration under Article 31(h) [TRIPs] may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines in order to support manufacturers in eligible Members to produce and supply these vaccines at affordable prices for eligible Members".

In the course of this TRIPs-Waiver discussions, the Council of the EU announced already in June 2021 to look forward to "further deliberations on possible IP tools and options for better co-ordination to cope with cross-border crisis situations", also to "support affordable and equitable access to COVID-19 medicinal products, diagnostics, vaccines and treatments, in order to provide for a robust, rapid and universal response to the pandemic", i.a. by using "the flexibilities provided for in Articles 31 and 31bis of the TRIPS Agreement"[28]. On 11 November 2021, also the European Parliament made a decision wherein the Commission was asked "to analyse and explore possible options for ensuring effectiveness and better coordination of compulsory licensing in the EU"[29].

Accordingly, the EU Commission started a "Call for Evidence" for an "Impact Assessment" with the objective "to create a compulsory licensing system in the EU that would be less fragmented and better-suited for EU-wide crises"[30]. Legislative changes which may be connected with this project are the creation of an EU coordination mechanism for compulsory licensing in times of crisis with or without harmonising national compulsory licensing law and establishing an "EU-level compulsory licence" for use in a crisis, to be applied in some or all Member States, depending on the circumstances. These options could apply to all crises, including health crises, and may exist in parallel to national regimes for purely national purposes. A public consultation was established by the EU Commission[31] to collect views from all stakeholders to gather "the different grounds and procedures for issuing compulsory licensing in a crisis and should discover bottlenecks and the impact on stakeholders". This public consultation closed on 29 September 2022 and provided the soil for the present proposal.

[28] https://www.consilium.europa.eu/media/50529/st-9932-2021-init.pdf
[29] https://www.europarl.europa.eu/doceo/document/TA-9-2021-0453_EN.html
[30] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13357-Intellectual-property-revised-framework-for-compulsory-licensing-of-patents_en
[31] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13357-Intellectual-property-revised-framework-for-compulsory-licensing-of-patents/public-consultation_de

3.4. Revised EU Pharma Legislation

Despite some cross-referencing to the new SPC Regulations, the main "patent aspect" of this proposal [32] seems to reside in appropriately respecting patent and SPC protection but immediately paving the way for generics and biosimilars as soon such patent/SPC protection is not present anymore (see e.g. Recitals 59 and 120 and Articles 2 (11), 4, 25, and 42 of the proposed new wording in the EU "Human Medicines" Regulation [33]).

4. Patent ban in the EU for plants produced by "New Genomic Techniques" (NGTs)?

On 5 July 2023, the EU Commission published a proposal for a EU regulation "on plants obtained by certain new genomic techniques and their food and feed" (COM(2023) 411 final[34]) wherein new rules on plants obtained through "New Genomic Techniques" (NGTs) are suggested. The proposal foresees two categories of NGT plant, each with their own regulations: Category 1 NGT plants (NGT-1) are considered equivalent to "conventional" plants (as those obtained by conventional mutation techniques, such as gamma-radiation and mutagenic chemicals) and will be subject to fewer regulations, while Category 2 NGT plants (NGT-2) must comply with current Genetically Modified Organism (GMO) legislation [35]. Category 1 NGT plants will be subject to mandatory labelling for seeds, and must be listed on a public online database. Moreover, Category 1 NGT plants must differ by no more than 20 genetic modifications from the parent plant in order to benefit from exemption. The amended proposal notes that such plants "could also occur naturally or be produced by conventional breeding techniques".

There have been calls for a review on this since 2018, when the legal status of NGT-modified plants was first addressed by the European Court of Justice (C-528/16 of 25 July 2018, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt[36]). The scientific community has widely advocated for the EU Parliament to embrace NGT plants. 37 Nobel laureates signed an open letter to the Members of European Parliament (MEPs) to "reject the darkness of anti-science fearmongering", advising on the "immense promise for sustainable agriculture, enhanced food security and innovative medical solutions" offered by NGT plants.

On 7 February 2024, the EU Parliament approved the EU Commission's proposals with a series of modifications and amendments [37]. Crucially, the European Parliament suggests to introduce a full ban on patents for both NGT-1 and NGT-2 plants, as well as plant material, parts thereof, genetic information and process features. This ban should be introduced by way of amending the "Biotech-Patenting-Directive" [38],[39]. The EU Parliament justified this amendment citing concerns over legal ambiguities, heightened expenses, and the potential creation of new dependencies for farmers and breeders. The EU Parliament has additionally

[32] https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en
[33] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0193
[34] https://eur-lex.europa.eu/resource.html?uri=cellar:c88fe9ac-1c06-11ee-806b-01aa75ed71a1.0001.02/DOC_1&format=PDF
[35] Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC
[36] https://curia.europa.eu/juris/document/document.jsf?docid=204387&doclang=EN
[37] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0067_EN.pdf
[38] Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions
[39] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044

called for a report by June 2025, assessing the effects of patents on breeders' and farmers' access to diverse plant seeds.

This ban is now under heavy discussion in- and outside the EU. It is evident that such ban does not align with the EPC, nor the EPO's case law.

On an economic point of view, it was argued that Members of the EU Parliament (MEPs) "have failed to comprehend the full extent of consequences that could arise from implementing such a ban". Whereas consumer groups and agricultural stakeholders welcome the proposal, industry and science raised relevant arguments against such an almost purely politically reasoned patent ban. It was argued that such a ban is a very negative sign for future developments in general causing a significant reduction in investment in one of the key future technologies and a consequential stagnation in innovation in the EU. But also for EU agriculture, the impact of such a ban is highly likely to be negative on agricultural economies by limiting farmers' access to cutting-edge technologies; reducing their ability to compete in global markets; decreasing agricultural productivity and impacted food security, flowing from reduced research into NGT-plants with desirable traits; and increasing pesticide and herbicide usage, resulting from fewer options of NGT plants engineered to be resistant to pests or tolerant to herbicides.

The EU Parliament will now start negotiations with EU Member States (the EU Council) on the final law.

Daniel Alge,
President of the European Union Members Commission of FICPI (EUCOF)
3 March 2024

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