

MAlinsight

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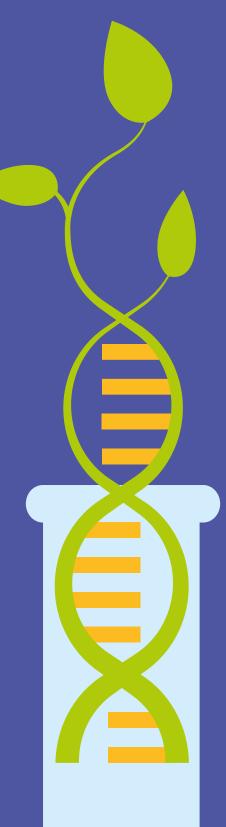
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Plants generated by new genomic techniques

The slow move toward a new regulation for the EU

On 7 February 2024, the European Parliament approved a proposal to **support the cultivation of some plants generated by new genomic techniques** (NGT) in the European Union, **but to ban patents for all plants obtained by such means**.

Under the stewardship of the new Polish presidency, the Council of the European Union, more than a year later, finally succeeded in negotiating with its members on what a resulting law may look like. On 14 March 2025, a qualified majority of the member states approved a new approach that would reinstate the possibility to patent NGT plants that the European Parliament sought to remove.

The NGT proposal accepted by the European Parliament

The proposal accepted by the European Parliament in February 2024 differentiates between two categories of plants obtained by new genomic techniques (NGT), which include gene editing using CRISPR/Cas. These categories are:

- Category NGT 1 plants, defined as NGT plants that could also occur naturally or by conventional breeding, would, provided they meet certain criteria in a verification procedure, be treated like conventional plants and be exempt from the requirements of the genetically modified organism (GMO) legislation. A public online list of all NGT 1 plants is intended.
- Category NGT 2 plants, defined as all other NGT plants, would continue to be subject to the current GMO legislation. That is, they would be subject to risk assessment and authorization prior to market approval, and would have to be traced and labelled as GMOs.

Crucially, the accepted proposal would **exempt NGT 1 plants from the strict requirements of the GMO legislation of the European Union**. Currently, only a single NGT crop, MON810, a Bt expressing maize conferring resistance to the European corn borer, is approved for commercial cultivation in the European Union, while other GMOs may be imported only for food and feed purposes. MON810 was approved in the EU in 1998.

Equally crucially, however, **all patenting would be banned** for NGT plants, plant material, parts thereof, genetic information, and the process features they contain, regardless of which of the two new categories they may belong to.

The European Commission has stated that the accepted proposal not only aims to maintain a high level of protection of health and the environment but also to steer developments towards making a contribution to sustainability goals in a wide range of plant species, especially for the agrifood system, and create an enabling environment for research and innovation, especially for small and medium-sized enterprises (SMEs). In stark contrast thereto, the accepted proposal - via an amendment introduced during the parliamentary process by the Committee on the Environment, Public Health and Food Safety of the EP - would also establish a ban on all patenting for >NGT plants, plant material, parts thereof, genetic information and the process features they contain, regardless of which of the two new categories the NGT plants in question may belong to. The accepted proposal also outlines an according amendment to the Biotech Directive 98/44/EC. A report on the impact of patents on breeders' and farmers' access to plant reproductive material, as well as a legislative proposal to update the EU rules on intellectual property rights accordingly, are due by June 2025 (but may well be delayed). The European Parliament has stated in a press release that the ban on patenting intends to avoid legal uncertainties, increased costs and new dependencies for farmers and breeders.«

Outside criticism of the European Parliament's accepted proposal

The accepted proposal, especially the ban on patenting, has drawn ample criticism. Amongst others, Garlich von Essen, the secretary general of the seed industry association Euroseeds and epi, the Institute of Professional Representatives before the European Patent Office, have pointed out that a complete lack of protection for NGT plants in the EU may prevent European companies from investing in the development of NGT plants, because they would not be able to rely on a period of exclusivity in which to recoup their significant development investments.





The Council of the European Union's struggle to gain approval from the member states

For a proposal accepted by the European Parliament to be implemented as new legislation, the Council of the European Union must further approve the proposal in question. After the acceptance of the NGT proposal by the European Parliament, however, the Council of the EU struggled for over a year to make any headway in negotiating the proposal's adoption.

Facing opposition to a patent ban from multiple member states, Belgium, which held the Presidency of the Council of the EU in the first half of 2024, when the proposal was accepted by the European parliament, proposed to **limit the ban on patenting to NGT 1 plants only**. Despite this suggested amendment softening the patent ban, the Council did not reach a majority vote to move the regulatory package forward.

In the second half of 2024, Hungary, a known sceptic of NGT plants, took over the Council Presidency. The Hungarian Presidency's focus seemed to be on slowing any progress of the regulatory package. Instead of discussing the proposed patenting ban (and not mentioning the Belgian presidency's amendment thereof to NGT 1 plants only), this Presidency instead sought changes to the definition of NGT 1 plants due to apparent concerns about, to name just a few, safety, compliance, and labelling requirements. Another apparent concern of the Hungarian presidency was the burden the intended verification process for NGT 1 plants would put on the member states. Whether this was intended as a delaying tactic or not, the Hungarian Presidency succeeded in, once again, preventing a majority vote.

In January 2025, the Presidency of the Council of the EU passed on to Poland, which sought to regain the steam lost under the Hungarian Presidency. Still in January, the Polish Presidency squarely addressed the issue of the patenting ban, which was the key point that had prevented the formation of a majority, with fresh amendments to the NGT regulatory package. A revised draft taking into account feedback from Member States was published on 7 February 2025 and adopted on 14 March 2025.

The initial amendments of the Polish Presidency

Initially, the new amendments proposed by the Polish Presidency **no longer envisioned a patenting ban** (whether for NGT 1 plants only or for all NGT plants) but instead planned to introduce a verification system for the patenting status of plant reproductive material (PRM) of NGT 1 plants. It appeared that, since this verification system would only have been implemented for plant reproductive material only, e.g., harvested material imported into the EU for food and feed purposes would not have to be so verified. Similarly, the verification system would not have applied to other plants, including NGT 2 plants.

The proposed verification system would have required that plant reproductive material of NGT 1 plants covered by patents, whether owned by the party planning to market the PRM or by a third party, be marked accordingly, likely including in the database already envisioned in the regulatory package. The verification system would also have **differentiated between patents covering basic technologies and patents covering plants and processes resulting in a specific plant trait**.

NGT 1 plant reproductive material that is not covered by any patents could have been, upon request, exempted from the marking requirements and placed on the market without further restrictions. Given that exemption would have required a declaration by the party intending to market the PRM, and given that such a declaration would have had to pertain not only to that party's own patent portfolio, but to third party patents as well, extensive freedom to operate (FTO) analyses would likely have been required before applying for exemption.

On the other hand, NGT 1 PRM either protected by patents or not requested to be exempt despite a lack of patent coverage would not have been generally banned from the marked, but the initially proposed amendments foresaw local restriction options. Any individual member state of the EU that so wished could have **either restricted or completely banned commercial cultivation of the respective NGT 1 plants**.

The revised, adopted proposal

The amended draft, published just over a month after the initial version, and adopted five weeks thereafter, simplified the Polish Presidency's approach further:

Instead of the previously envisioned verification process, the party wishing to obtain NGT 1 status for a plant now would have to provide a written statement identifying both product patents and process patents covering or confirming an absence of patents covering the plant:

>The requester shall submit a written statement (patent information):

- (a) identifying patents for products claiming modifications of biological material resulting in particular traits; or
- (b) identifying patents for processes claiming modifications of biological material resulting in particular traits; or
- (c) confirming the absence of patents referred to in letters (a) and (b).<

In the same declaration, the party could also indicate a willingness to grant licenses:

>The requester may submit a written declaration of a patent holder confirming his willingness to licence the protected subject under fair, reasonable and non-discriminatory conditions, which is applicable within Union territory (licence declaration).>

However, in the adopted proposal, patent information would have to be provided **for any NGT 1 plant material**, **not only for plant reproductive material**. That is, information would apparently have to be provided even when importing material for food and feed purposes. This still appears to include even third party patents and applications.



The labelling requirement also was struck from the proposal, but, as also previously intended, **patent information would have to be recorded in the database of NGT 1 plants** maintained by the European Commission.

The adopted proposal also states that tolerance to herbicides cannot be one of the traits for NGT 1 plants. That is, plants with such traits would remain subject to the authorization, traceability and monitoring requirements for NGT 2 plants.

Perhaps most strikingly, the adopted proposal **no longer includes provisions that would enable individual Member States to restrict or ban the sale of NGT 1 PRM locally except in specific organic farming areas with specific geographical conditions**. The Council thus seems to aim at stimulating innovation in the European Union by recognizing the importance of patents.

The adopted proposal has been met with widespread approval by interested parties. Euroseeds' Garlich von Essen called the adopted proposal *balanced* and *balanced* significant step forward. Plants for the Future stated in a press release that they *baplaud this historic milestone* and the European potato trade association Europatat considers the adopted proposal *balances the forward in advancing agricultural innovation*.

Outlook

Thanks to the Polish Presidency's new approach, the Council of the EU has finally adopted a proposal as of 14 March 2025 and there is a real chance of advancing the NGT regulatory package. On 6 May 2025, the Council of the EU and the European Parliament now need to enter final negotiations (so-called >trilogue negotiations<) to arrive at a final proposal that both institutions can adopt before the new regulation can enter into force.

The proposal as adopted by the Council would not ban patenting of NGT plans, but instead require including information on relevant patents or the absence thereof in a central database. Non-patented NGT 1 plant material would be able to enter the market without the strict GMO legislation requirements currently in force in the EU.

The European Parliament however was in favor of a patent ban for genetically modified plants, their genetic information, and their process characteristics. Similarly, the Parliament wants strict labeling requirements on all NGT 1 plants instead of just seeds. Nevertheless, it is possible that the final law may be more similar to the Council's adopted proposal than to the proposal adopted by the Parliament, as the European elections that occurred in June 2024 have changed the Parliament's composition and, possibly, the inclination of its majority. In the same vein, Swedish MEP Jessica Polfjärd from the center-right European People's Party (EPP), a group broadly supportive of biotech innovation, will lead the trilogue negotiations for the European Parliament's side. The Polish Presidency will negotiate for the Council.

A side-by-side comparison of the EU Commission's (original), EU Council's, and EU Parliament's drafts in trackchanges is available at: https://data.consilium.europa.eu/doc/document/ST-7448-2025-INIT/en/pdf



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>Long-arm< jurisdiction of courts in the EU – how long is the arm?

Competence to hear patent infringement cases in respect of >foreign< patents

The first quarter of 2025 was characterized by landmark decisions of the Unified Patent Court (UPC) and the Court of Justice of the European Union (CJEU) on the so-called >long-arm< jurisdiction of courts of the Member States of the EU (referred to in the following as **EU-MS**) to rule on patent infringement actions, wherein inter alia infringement of a patent with a foreign designation, i.e. of a patent granted or validated in a foreign country, was at issue. Here, **>foreign** relates to any additional country outside the EU-MS of the court seized.

A foreign country may thus be another EU-MS but also a **third country**, which is not an EU-MS and not bound by the Lugano Convention¹ or bilaterial conventions in terms of Article 73 of the Brussels *Ibis* Regulation.

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In this article, we summarize the legal background and briefly discuss potential implications of these recent decisions.

UPC/UP States
 Other EU Member States
 States of the Lugano Convention
 Other EPO Member States

¹ Convention on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, done at Lugano on 30 October 2007, including any subsequent amendments.



1. Legal context

The so-called >Brussels *Ibis* Regulation<² is a well-known and important pillar of European law on international civil proceedings containing, inter alia, a jurisdictional regime. It becomes relevant for any cross-border case in the EU having a link to more than one EU-MS, without being limited to exclusively intra-EU cases.³

The structure of this jurisdictional regime seems quite clear at first glance:

The general rule of jurisdiction (Article 4(1) of the Brussels *Ibis* Regulation) provides that – subject to other provisions of the same Regulation – a defendant domiciled in an EU-MS shall be sued in the courts of that EU-MS. This general jurisdiction also applies to patent infringement proceedings and may even extend to multinational infringement proceedings, thus allowing a patent proprietor to bring claims for infringement of patents in several countries before a single court in an EU-MS and to obtain comprehensive relief from a single forum.

However, according to Article 24(4) of the Brussels Ibis Regulation, which codifies the CJEU case law *GAT v. LUK*⁴, in proceedings concerned with the validity of patents, only the national courts of the EU-MS of the country for which the patent is granted or validated (and now also the UPC for European patents) shall have exclusive jurisdiction. This applies **irrespective of whether an invalidity attack is raised by way of an action or as a defense and regardless of the domicile of the parties**. Further, a European patent (referred to in the following as EP patent) validated in an EU-MS is subject to the same rules on jurisdiction on validity as national patents (Article 24(4) subpara. 2 of the Brussels Ibis Regulation). Consequently, a patent proprietor may bring infringement proceedings in the EU-MS of the defendant's domicile for infringing acts of patents in foreign countries and the court seized has to decline its jurisdiction as soon as the alleged infringer either files a separate revocation action in the respective country or raises an invalidity attack against the foreign patent in the infringement proceedings.

In case of *lis pendens*, i.e. if revocation proceedings regarding the same patent and parties are pending before a court of a third country at the time a court of an EU-MS is seized, Articles 33 and 34 of the Brussels *lbis* Regulation define the conditions under which the court seized may stay, dismiss or even continue the infringement proceedings if jurisdiction is based on Article 4 of the Brussels *lbis* Regulation.

The same jurisdictional regime applies to the UPC: The international competence of the UPC is defined in Article 31 UPCA, which refers to the Brussels *Ibis* Regulation and the Lugano Convention, the latter binding Island, Norway and Switzerland.

Also, the Brussels Ibis Regulation includes provisions relating to the UPC, namely Articles 71a to 71d. According to Article 71a of the Regulation, **the UPC is a >common court** and shall be deemed to be a court of an EU-MS. Consequently, the UPC has jurisdiction where a court of a Contracting Member State of the UPCA (referred to in the following as UPC-CMS) would have jurisdiction under the Brussels Ibis Regulation in a matter governed by the UPCA (Article 71b (1) of the Brussels Ibis Regulation).

² REGULATION (EU) No 1215/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2012, on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast), OJ L 351 20.12.2012, p. 1, recast of 26.02.2015.

³ CJEU of 01.03.2005 - C-281/02 - Owusu, marginal no. 31; see also Kalden, GRUR Patent 2023, 178, 182, marginal no. 48.

⁴ CJEU of 13.07.2006 - C-4/03 - GAT v. LUK.

Despite these fairly clear provisions in the Brussels *lbis* Regulation, a number of open questions remain(ed), inter alia:

- Does a validity attack against a foreign patent prevent a court of an EU-MS from continuing with infringement proceedings?
- What happens if there is no lis pendens situation, but the validity of the foreign patent is only challenged in the framework of the infringement proceedings?
- In case of lis pendens, is a stay of the infringement proceedings regarding this specific foreign patent until the outcome of the validity proceedings a must or an option, and does this stay affect only one or all patents in suit? Alternatively, may the court continue the infringement proceedings and decide on infringement of all patents, thus ignoring ongoing validity proceedings relating to the foreign patent and in particular not commenting on (in)validity aspects?
- Or, can the court consider validity as an incidental question to rule on infringement, with an inter partes effect of the ruling on validity only?
- And finally: Does it make a difference whether the patent is a foreign patent for another EU-MS or a foreign patent for a third country?

Both the UPC and the CJEU have provided answers recently, whereby the UPC had the first serve.

2. Decision UPC_CFI_355/2023 of the Dusseldorf Local Division - Fujifilm v. Kodak

On 28 February 2025, the Dusseldorf Local Division (LD) of the UPC issued a decision dealing inter alia with the long-arm jurisdiction of the UPC regarding third countries (here: the United Kingdom (UK)).

The case: FUJIFILM Corporation (Plaintiff) sued three German entities of Kodak (Defendants) for infringement of EP 3 594 009, in force in Germany and the United Kingdom, before the Dusseldorf LD of the UPC. No opposition was pending at the EPO, nor was any national revocation action pending at the time of the infringement proceedings. The Defendants sought revocation of the patent by means of a UPC counterclaim for revocation for the territory of all UPC-CMS in which the EP patent is in force, which was only Germany (i.e. the DE part). Revocation (on a national basis) was not sought for the UK part of the patent at the time of the decision. Regarding the UK, the Defendants lodged a preliminary objection against the jurisdiction of the court seized.

The Dusseldorf LD stated that it has **international competence** to decide the case with respect to the infringement action for Germany and the UK arising from Article 4(1) in conjunction with Article 71b(1) of the Brussels Ibis Regulation and Article 31 UPCA (see section A.II.1 of the Grounds).

Although a decision in the (at that time pending) CJEU case *BSH Hausgeräte v. Elektrolux (see Chapter 3 below)* was expected only a few weeks later, the Dusseldorf LD was of the opinion that the outcome of that case was not decisive for the *Fujifilm v. Kodak* case (as regards the third question referred to the CJEU concerning jurisdiction for revocation actions for third country-patents) and therefore **no stay** was required. In the Court's view, there was no situation in which the Court had to decide whether it has jurisdiction to revoke the UK part of the EP patent since no (national) revocation action was pending in the UK (see section A.II.2.a) of the Grounds).

>Even if the Court cannot decide on the validity of the UK part of the patent in suit, and certainly cannot revoke that part, the infringement action cannot be successful in such a factual and legal situation<.

Providing detailed and worthwhile reasons, the Court held that it has jurisdiction to decide the infringement action in respect of the UK part of the EP patent (see section A.II.2.b) of the Grounds), thus making use of the UPC's long-arm jurisdiction extending to non-EU-MS. In this context, the Court made also clear that the question of jurisdiction is to be separated from the question of the (national) law to be applied for determining infringement in third countries.

Further, the Court found that the patent in suit is to be revoked in its entirety, within the framework of the UPC counterclaim for revocation (for which it has competence according to Article 32(1) UPCA), which concerns only the DE part of the EP patent. Therefore, the infringement action regarding acts in Germany was without basis and thus to be rejected. During the proceedings, the Defendants argued that the UK part of the EP patent is invalid for the same reasons as the DE part (see section D of the Grounds). Although the Court stated that it had no competence to rule on the validity of the UK part, it concluded that the grounds for invalidity of the DE part also apply to the UK part, irrespective of any differences between the UPC-CMS and the UK potentially leading to another outcome of invalidity assessment regarding the UK part, in particular because the Plaintiff did not comment on such differences potentially leading to another outcome of invalidity assessment regarding the UK part. Thus, the Court found that *>even if the Court cannot decide on the validity of the UK part, the infringement action cannot be successful in such a factual and legal situation*.

Hence, the Dusseldorf LD confirmed jurisdiction regarding infringement of a third country-patent and ruled on infringement of the UK part of the EP patent. Without having jurisdiction regarding validity of the UK part of the EP patent, the Court considered validity aspects as >primary question< for the decision on infringement of the UK part which in the end may be regarded as a >decision< on validity with *inter partes* effect.

The UPC's case management system does not show (as of April 7, 2025) that an appeal has been filed, so the *Fujifilm v. Kodak* case does not appear to lead to a decision of the Court of Appeal of the UPC on long-arm jurisdiction.

3. Judgement of the Grand Chamber of the CJEU in the case C-339/22 - BSH v. Electrolux

Shortly after the Fujifilm v. Kodak decision, the long-awaited ruling of the CJEU on the international jurisdiction of EU courts, particularly in cases relating to third countries, was issued on 25 February 2025 in the case *BSH v. Electrolux*.

The case: BSH Hausgeräte GmbH (Plaintiff), a company incorporated under German law, filed an infringement action concerning infringement **of all the national parts (Germany, Greece, Spain, France, Italy, the Netherlands, Austria, Sweden, the United Kingdom and Turkey)** of the EP patent EP 1 434 512 against Electrolux AB (Defendant), a company incorporated under Swedish law, before the competent Court in **Sweden**. The Plaintiff sought an order requiring the Defendant to cease using the patented invention in all countries in which the EP patent had been validated and for the Defendant to be ordered to pay reasonable remuneration and damages for the allegedly unlawful use of that invention. In the first instance decision, the Swedish Court declared that it did not have jurisdiction to hear the action relating to infringement of patents validated in EU-MS other than the Kingdom of Sweden. It also declared that it did not have jurisdiction to hear the action alleging infringement of the patent validated in Turkey (i.e. the TR part, >the Turkish patent<) on the ground that Article 24(4) of the Brussels Ibis Regulation is the expression of a principle of jurisdiction recognized at international level. Following the appeal of the Plaintiff against this decision, the Swedish Court of Appeal decided to stay the proceedings and to **refer three questions to the CJEU** for a preliminary ruling:

- >>Is Article 24(4) of the Brussels Ibis Regulation to be interpreted as meaning that the expression >proceedings concerned with the registration or validity of patents ... irrespective of whether the issue is raised by way of an action or as a defence implies that a national court, which, pursuant to Article 4(1) of that regulation, has declared that it has jurisdiction to hear a patent infringement dispute, no longer has jurisdiction to consider the issue of infringement if a defence is raised that alleges that the patent at issue is invalid, or is the provision to be interpreted as meaning that the national court only lacks jurisdiction to hear the defence of invalidity?
- Is the answer to Question 1 affected by whether national law contains provisions, ..., which means that, for a defence of invalidity raised in an infringement case to be heard, the defendant must bring a separate action for a declaration of invalidity?
- Is Article 24(4) of the Brussels Ibis Regulation to be interpreted as being applicable to a court of a third State, that is to say, in the present case, as also conferring exclusive jurisdiction on a court in Turkey⁵ in respect of the part of the European patent which has been validated there?

In short, the CJEU's answer to all referred questions is $\mathbf{No}(\mathbf{A})$

Extracts from the Brussels Ibis Regulation

Article 4 (1)

Subject to this Regulation, persons domiciled in a Member State shall, whatever their nationality, be sued in the courts of that Member State.

Article 24 (4)

The following courts of a Member State shall have exclusive jurisdiction, regardless of the domicile of the parties:

(4) in proceedings concerned with the registration or validity of patents, trademarks, designs, or other similar rights required to be deposited or registered, irrespective of whether the issue is raised by way of an action or as a defence, **the** courts of the Member State in which the deposit or registration has been applied for, has taken place or is under the terms of an instrument of the Union or an international convention deemed to have taken place.

Without prejudice to the jurisdiction of the European Patent Office under the Convention on the Grant of European Patents, signed at Munich on 5 October 1973, the courts of each Member State shall have exclusive jurisdiction in proceedings concerned with the registration or validity of any European patent granted for that Member State.

Article 71a

- (1) For the purposes of this Regulation, a court common to several Member States as specified in paragraph 2 (a >common court<) **shall be** deemed to be a court of a Member State when, pursuant to the instrument establishing it, such a common court exercises jurisdiction in matters falling within the scope of this Regulation.
- (2) For the purposes of this Regulation, each of the following courts shall be a common court:
 - (a) the Unified Patent Court established by the Agreement on a Unified Patent Court signed on 19 February 2013 (the ›UPC Agreement(); ...

Article 71b(1) and (2)

The jurisdiction of a common court shall be determined as follows:

- (1) a common court shall have jurisdiction where, under this Regulation, the courts of a Member State party to the instrument establishing the common court would have jurisdiction in a matter governed by that instrument;
- (2) where the defendant is not domiciled in a Member State, and this Regulation does not otherwise confer jurisdiction over him, Chapter II shall apply as appropriate regardless of the defendant's domicile.

Application may be made to a common court for provisional, including protective, measures even if the courts of a third State have jurisdiction as to the substance of the matter; ...

Extract from the UPC Agreement

Article 31 International jurisdiction

The international jurisdiction of the Court shall be established in accordance with Regulation (EU) No 1215/2012 or, where applicable, on the basis of the Convention on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Lugano Convention).

Specifically, the CJEU ruled that Article 24(4) of the Brussels *Ibis* Regulation must be interpreted as

- >>meaning that a court of the Member State of domicile of the defendant which is seised, pursuant to Article 4(1) of that regulation, of an action alleging infringement of a patent granted in another Member State, does still have jurisdiction to hear that action where, in the context of that action, that defendant challenges, as its defence, the validity of that patent, whereas the courts of that other Member State have exclusive jurisdiction to rule on that validity (regarding the first question and – at least implicitly – the second question); and
- > >not applying to a court of a third State and, consequently, as not conferring any jurisdiction, whether exclusive or otherwise, on such a court as regards the assessment of the validity of a patent granted or validated by that State. If a court of a Member State is seised, on the basis of Article 4(1) of that regulation, of an action alleging infringement of a patent granted or validated in a third State in which the question of the validity of that patent is raised, as a defence, that court has jurisdiction, pursuant to Article 4(1), to rule on that defence, its decision in that regard not being such as to affect the existence or content of that patent in that third State or to cause the national register of that State to be amended (regarding the third question).

This very clear decision confirms that a court of an EU-MS which is competent under Article 4(1) of the Brussels Ibis Regulation does not lose jurisdiction over a multinational infringement action concerning acts violating a patent granted for a foreign country only because the defendant raises an invalidity defense concerning that foreign country. However, the CJEU made clear that there is a difference as regards the >territorial context< of that foreign county:

If the foreign country is an EU-MS (or bound by the Lugano Convention or corresponding bilateral conventions in terms of Article 73 of the Brussels *Ibis* Regulation), it follows from Article 24(4) of the Brussels *Ibis* Regulation that the exclusive jurisdiction laid down in this provision concerns only the part of the dispute relating to the validity of the patent in suit. This could mean that infringement proceedings are separate from a revocation action pending with a court of another, i.e. foreign EU-MS. But how to proceed with the infringement proceedings in such a case? Regarding a possible stay, the CJEU states: >If it considers it justified, in particular where it takes the view that there is a reasonable, non-negligible possibility of that patent being declared invalid by the court of that other Member State that has jurisdiction (...) the court seised of the infringement action may, where appropriate, stay the proceedings, which allows it to take account, for the purpose of ruling on the infringement action, of a decision given by the court seised of the action seeking a declaration of invalidity (see marginal no. 51 of the Decision).

It remains to be seen whether a stay due to validity proceedings in another EU-MS to which the infringement proceedings relate may be limited to the part of the infringement proceedings concerning only that EU-MS, meaning that the infringement proceedings are split. If so, validity proceedings may need to be lodged in any foreign EU-MS involved to ensure a stay of the entire infringement proceedings.

In this context, regarding the **applicable substantive law**, the CJEU makes clear that infringement of a foreign patent has to be examined in the light of the patent law of the country for which that patent was granted or validated (marginal no. 40 of the Decision).

If the foreign country is a third country, Article 24(4) of the Brussels *lbis* Regulation is not applicable because the jurisdictional regime of this Regulation is a system of competence internal to the EU (marginal no. 54 et seq. of the Decision). Therefore, a court of the EU seized, on the basis of Article 4(1) of the Brussels *lbis* Regulation, for an infringement action concerning a patent granted or validated in a third country may in general consider both infringement and validity if the latter is raised as a defense in the context of the infringement proceedings. There are, however, two further restrictions:

- In case of lis pendens, the court may be prompted to stay, or even terminate the infringement proceedings, according to Articles 33 and 34 of the Brussels Ibis Regulation.
- The rules and principles of general international law, in particular the principle of non-interference, are of course binding and form part of the EU legal order. Thus, the Brussels Ibis Regulation is to be interpreted in the light of the general rule that vgrant of a national patent is an exercise of national sovereignty: and only the courts of this country may decide on the validity of such a foreign patent. To comply with these restrictions, the CJEU made clear that a decision of the court of an EU-MS on validity of a third country-patent has only inter partes effect (see marginal no. 68-76 of the Decision), meaning that the third country-patent remains valid, but, depending on the details of the individual case, may not be enforced against the defendant in the context of this specific infringement scenario.

4. UPC case law post BSH v. Elektrolux

Procedural Order UPC_CFI_702/2024 of the Paris Local Division - *IMC Créations v. Mult-T-Lock*

The main points of both landmark decisions discussed in Chapters 2 and 3 above have been first applied by the Paris LD of the UPC in its procedural order of 21 March 2025.

The case: IMC Créations (Plaintiff) sued Multi-T-Lock's German and Swiss entities (Defendants) for infringement of EP 4 153 830, validated, inter alia, in Spain (EU-MS, but not UPC-CMS), Switzerland (MS of the Lugano Convention) and the UK (third country). The Defendants lodged a preliminary objection with regard to international jurisdiction and competence of the UPC concerning the ES, CH and UK parts of the patent. The validity of the EP patent was not attacked, neither as a defense nor in separate UPC or national revocation proceedings.

In marginal nos. 20 and 21 of the Decision, the Court comes to the conclusion that, applying the provisions of the Brussels Ibis Regulation as interpreted in BSH v. Electrolux, it is **competent to decide on infringement in all relevant countries**: Concerning Spain (EU-MS) and Switzerland (bound by the Lugano Convention), the UPC is competent to decide on infringement and, if deemed appropriate, may stay the infringement proceedings if national revocation proceedings are pending. As to the UK, not being an EU-MS or bound by the Lugano Convention and thus a third country, the Court is competent to decide on infringement and may also decide on validity with *inter partes* effect. This is - not very surprisingly - in line with the BSH v. Electrolux and *Fujifilm v. Kodak* decisions discussed in Chapters 2 and 3 above, respectively. Interestingly, the Paris LD did not distinguish between the German Defendant and the Swiss Defendant (in respect of which the Court also has competence) and thus declared jurisdiction to decide on infringement of, inter alia, a non-UPC part of an EP patent (namely the CH part) by a non-EU domiciled Defendant (namely the Swiss Defendant). The Paris LD did not even comment on this point.

Final Order UPC_CFI_792/2024 of the Milan Local Division - Dainese v. Alpinestars

On 8 April 2025, the Milan LD of the UPC issued a Final Order⁶ on the Defendant's preliminary objection alleging lack of jurisdiction. With reference to the decisions *BSH v. Elektrolux, Fujifilm v. Kodak* and *IMC Créations v. Mult-T-Lock*, the Court found that it has jurisdiction to adjudicate on infringement issues related to EP patents validated in non-UPC-CMS – in this case Spain – if the Defendant is domiciled in Italy. Thus, and in line with the **three decisions discussed above**, the preliminary objection was dismissed.

Some may regard the CJEU decision as a game changer to international patent litigation.

⁶ LD Paris, ORD_11997/2025 of 21 March 2025 in ACT_61422/2024 UPC_CFI_702/2024.

5. Key Takeaways

>Long-arm (jurisdiction – in the meaning of giving a court a geographically far-reaching jurisdiction beyond the national borders – is available before national courts in the EU, and also before the UPC. For the latter, it is noted that the UPC shall be treated like a national court of an EU-MS.

The three cases discussed above concern EP patents validated, among others, in the EU-MS in which the defendant(s) is(are) domiciled. The >long-arm< of courts of an EU-MS, including the UPC, has been confirmed to extend to (at least) all Contracting Members states of the EPC (referred to as EPC-CMS), no matter whether they are EU-MS or third countries. Hence, >centralized infringement actions< before EU courts now seem meaningful in light of the *BSH v. Electrolux* decision. For the UPC, the >long-arm< meanwhile appears to be established.

The CJEU did not distinguish between an EP patent and national patents in connection with foreign EPC-CMS in the BSH v. Electrolux decision. Consequently, it seems possible under the Brussels Ibis Regulation's jurisdictional regime to sue a defendant domiciled in an EU-MS for infringement of a foreign patent which is not another national part of the same EP patent (the latter of which may, for good reasons, be seen as the same patent). Without such limitations, it appears possible to enforce a patent granted anywhere in the world, i.e. any foreign patent, before a national court of the EU-MS of the defendant's domicile. Therefore, overly enthusiastic patent proprietors and litigators may even contemplate litigating patents granted outside Europe, such as US or CN patents, before a national court of an EU-MS. This would, however, not be possible before the UPC, which is only competent for EP patents and EP patents with unitary effect, according to Article 1 UPCA.

Further, in the cases decided so far, the subject patent of the legal dispute has been, inter alia, a national part of an EP patent validated in the EU-MS of the court seized: In the cases before the Dusseldorf LD and Paris LD, the UPC was clearly competent because of the DE and FR parts of the respective EP patent. In the case underlying the CJEU decision, the competence of the Swedish courts was not questioned at least for the SE part of the EP patent. We are not aware of cases in which the court seized had not at least undisputed competence for the >domicile< EU-MS of the defendant. On this basis, it appears advisable to always seek patent protection in the EU-MS of a competitor's domicile. To ensure identity of the scope of protection offered by a patent in a third country, an EP patent may be preferable over a plurality of individual nationally granted patents. The CJEU decision definitely re-opens European, and potentially even global, cross-border patent litigation. Some may regard the CJEU decision as a **game changer** to international patent litigation:

For **potential defendants domiciled in the EU**, the CJEU decision means a need for increased vigilance, thinking far ahead and, above all, increased financial effort if they want to defend themselves by arguing invalidity of a patent and, if possible, to obtain a stay of infringement proceedings. As a general rule, it may be necessary to initiate separate revocation proceedings for each foreign country, preferably before an infringement action is brought. A >global< injunctive relief infringement action would require a relatively large number of national revocation actions just to secure the possibility of a stay – which is, however, not mandatory but optional, as the CJEU has made clear.

For **future plaintiffs**, too, this could mean increased effort, as the infringement and, if stay plays a role, also the validity of foreign patents will have to be assessed according to the respective national law. It is the plaintiff's task to a familiarized the court seized with foreign national law. Not only for this reason the question arises whether it indeed makes sense to initiate a acentralized infringement cased. A further risk a future plaintiff may be running into is whether or not foreign, in particular non-EU-MS jurisdictions will recognize and enforce such a decision rendered by a foreign (EU-MS) court.

The CJEU decision may also have an impact on **patent prosecution strategies**, in particular for the time after the transitional period of the UPCA, i.e., when (not opted-out) EP patents can no longer be enforced before national courts of a UPC-CMS. National patents may become a more preferable alternative or addition to EP patents, as for national courts it is (at least), in theory, not excluded that their jurisdiction embraces e.g. US or CN patents.

Finally, and thinking beyond the patent box, it should be emphasized that the CJEU decision is not limited to patents but may relate to all types of IP rights.

So - yes: the new CJEU case law is a game changer, and the games - with all their strategic concepts and opportunities for risk management - are open!





Heike Röder-Hitschke

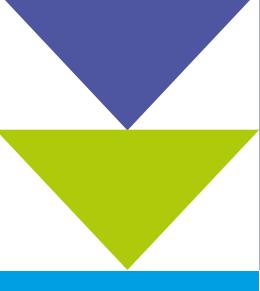
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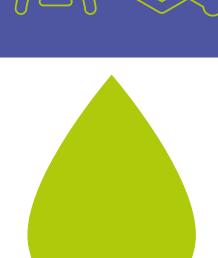
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EUIPO European Union Intellectual Property Office









SPC Supplementary Protection Certificate









The >new< SPC system for medicinal products

Part I - The Grant Procedure

Background

While the proposal for an EU reform on Standard Essential Patents (SEP) has been shelved, the reform of the Supplementary Protection Certificate (SPC) system is still ongoing. It aims at the creation of a more streamlined and unified SPC framework aligned with the unitary patent system.

In April 2023, the European Commission submitted four regulatory proposals for reforming the SPC regime regarding plant protection products and medicinal products. Regarding medicinal products, the Commission issued the following two proposals:

- Proposal for a Regulation on the SPC for medicinal products (COM(2023) 231): This proposal is a recast of EC No 469/2009. Chapters I and II mainly contain the Articles of the current Regulation including some amendments regarding substantive aspects such as 3rd party marketing authorizations (MAs) and several SPCs for one product. Chapter III contains rules defining a centralized grant procedure and the according granting bodies in charge thereof.
- Proposal for a Regulation on the unitary SPC for medicinal products (COM(2023) 222): This proposal contains all regulations defining the procedure regarding unitary SPCs.

In February 2024, the European Parliament approved the two proposals with some amendments. Trilogue negotiations are currently ongoing regarding the design of the system of legal remedies and the designation of the authority responsible for granting unitary SPCs. If successful, these trilogue negotiations will be followed by a second reading and final adoption before the new SPC regulations can enter into force.

The Current SPC Grant Procedure

Currently, the national patent offices (NPOs) are responsible for granting SPC rights based on several types of basic patents and marketing authorizations under regulation (EC) No 469/2009: Presently, a basic patent may be a national patent, a unitary patent, or a national patent validated from a European (EP) patent. The marketing authorization can either be granted centrally by the European Medicines Agency (EMA) or by the national health authorities. Opposition proceedings do not exist for SPCs under regulation (EC) No 469/2009. Although third party observations (TPOs) may be considered by most of the NPOs during the SPC grant proceedings, there are no respective rules manifested in the current SPC regulation.



The New SPC Grant Procedure

Under the new regime as defined by the two proposals, SPC applications relying on an EP patent (unitary patent or a national patent validated from an EP patent) and a centralized marketing authorization granted by the EMA will be examined by the European Union Intellectual Property Office (EUIPO) in Alicante. Application via a national patent office is excluded for such applications based on an EP patent and a centralized marketing authorization.

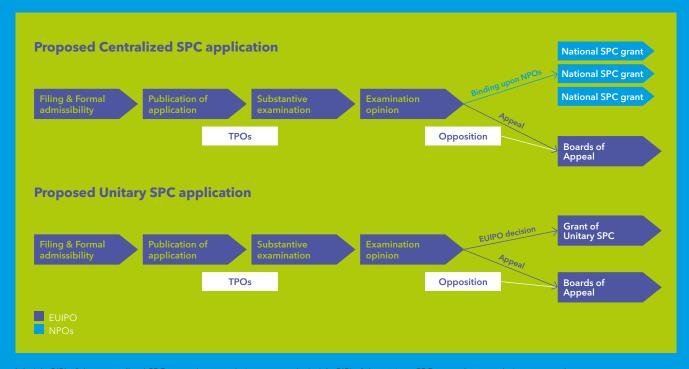
The application must be published within five working days after compliance with formal requirements by the EUIPO.

The EUIPO will then issue a positive or negative examination opinion regarding the grant of the SPC. The EUIPO is required to issue an examination opinion within six months after publication of the SPC application. Where an urgent need for examination can be demonstrated, the SPC applicant may request an expedited examination. In such instances, the EUIPO must issue an examination opinion within four months. The substantive examination process will be carried out by an examination panel consisting of one EUIPO official and two examiners appointed from different national patent offices. At least one of the national examiners must have a minimum of five years of experience in examining patents and SPCs.

TPOs must be submitted within three months of the publication of the application, or within six weeks in expedited procedures. These TPOs will be notified to the applicant.

Within two months after the publication of the examination opinion, a notice of opposition can be filed by third parties, which must include grounds laying out that the conditions for obtaining a certificate or conditions regarding entitlement to the certificate are not fulfilled and supporting evidence. The opposition will be examined by an opposition panel within the EUIPO.

If a positive examination opinion is issued, after the expiry of the appeal or opposition period or after a final decision has been issued, national SPCs are then formally granted by NPOs of the designated Member States for which the SPCs have been requested and/or, if a single unitary SPC was applied for, this unitary SPC is granted by the EUIPO.



Proposed Combined SPC application

¹ Article 3(3) of the scentralized SPC procedure regulation proposals, Article 3(2) of the sunitary SPC procedure regulation proposals

² Article 6(2) of both scentralized SPC procedure regulation proposal and sunitary SPC procedure regulation proposal

See for example epi position paper dated April 2024 (https://patentepi.org/assets/uploads/documents/epi-reports/epi-Position-paper-on-urisdiction-of-uSPC.pdf) and November 2024 (https://patentepi.org/assets/uploads/documents/epi-reports/241114_epi%E2%80%99s%20comments%20on%20the%20Proposals%20 to%20introduce%20a%20more%20centralized%20granting%20process%20for%20SPCs%20in%20the%20EU_EEA.pdf).

Types of SPC Applications Under the New System

Accordingly, applicants will have different filing options under the new system:

- A sunitary SPC application, will be available exclusively for products that have received a centralized marketing authorization from the EMA, are based on a unitary patent, and will be examined and granted by the EUIPO.
- A single >centralized SPC application<, which can be based on an EP patent (bundle patent or unitary patent) and a centralized marketing authorization from the EMA, will result in a bundle of national SPCs in the designated EU member states. The examination will be conducted by the EUIPO and national SPCs will ultimately be granted by national offices.
- The centralized SPC application may include a request for a unitary SPC application. This so-called **combined** application leads to a unitary SPC covering all states where the unitary patent is in effect, along with a bundle of national SPCs in the remaining designated EU member states. Examination is conducted by the EUIPO, and the unitary SPC will be granted by the EUIPO while the national SPCs will the granted by NPOs.
- In the rather uncommon case in which the SPC is based on a national marketing authorization, the old routed would be still available via examination by the respective national patent office. Such an SPC could be based on a national patent or EP patent (including unitary patent in force in the corresponding national country).

Changes to the Substantive Aspects of the SPC System

Although the European Commission initially claimed that the proposed legislation would not alter the substantive aspects of the existing SPC regime, some notable changes have been introduced. Article 3¹ now states that multiple SPCs for the same product may be granted if filed by different patent holders, provided they are not >economically linked‹. A new definition of >economically linked entities in respect of different holders of two or more basic patents protecting the same product has been introduced, stating that companies are considered economically linked if one controls, is controlled by, or is under common control with the other entity. This clarifies that independent companies having agreed on a licensing agreement should not be regarded as economically linked and may each obtain an SPC for the same product based on their respective patents.

Additionally, Article 6(2)² has been introduced into the new regimen, stipulating that an SPC can only be granted if the marketing authorization holder has given explicit consent when the authorization is held by an entity differing from the patent proprietor. This consent has to be filed together with the SPC request. Thereby, so-called >SPC squatting< based on a third party's MA without consent of the third party is explicitly excluded in the future regimen.

No further changes were carried out regarding the substantive aspects. Of note, the recitals of the proposed regulations newly incorporate relevant citations regarding Article 3 from the case law from the Court of Justice of the European Union (CJEU).

Next Steps

Currently, trilogue negotiations, i.e., informal interinstitutional meetings between the Council of the European Union, the European Parliament, and the European Commission are ongoing to align open key points. It remains to be seen whether these negotiations succeed or whether the SPC reform will suffer the same fate as the SEP regulation to be shelved since no agreement could be reached. If an informal agreement is achieved in trilogue, the proposals must then be approved according to the rules of procedure of each of the institutions so that the new SPC regulations can enter into force.

For example, at present there are doubts regarding the suitability of the EUIPO as the examining authority³. At present, the EUIPO primarily deals with trademarks and designs and has no experience in examining patents. Some voices advocate for the European Patent Office (EPO) to take on this role, as it has an established patent register, an efficient language regime, and examiners experienced in patent assessment. Additional concerns have been raised regarding the fragmented system for invalidation proceedings that may result from the current proposal, which will be analyzed in greater detail in the next issue of MAlinsight.



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A > method for< claim - when is the recited purpose limiting?

The tug-of-war between Patent Proprietors and Opponents in EPO Opposition proceedings



There has been a recent surge in the biosimilars market in Germany. According to Horizon Grand View Research's >Germany Biosimilars Market Size & Outlook 2020-2027<, the biosimilars market in Germany is expected to reach a projected revenue of US\$ 3,347.3 million by 2027. A compound annual growth rate of 12.6% is expected from 2021 to 2027. This has also led to a surge of Oppositions against European Patents pertaining to methods of manufacturing pharmaceutical products. Therefore, claims to a method and their correct legal interpretation has become increasingly important for Patent Proprietors, Opponents, and their representatives.

While there is a common understanding that a product for claim reciting a purpose is only limited to the extent that the product is merely suitable for that purpose, it is often a point of debate in EPO Opposition proceedings whether a protocomes to assessment of novelty.

The Opponents usually argue that a prior art document does not have to disclose the purpose to be novelty-destroying when the actual method steps are disclosed in that prior art document. The Patent Proprietors usually respond by asserting that a >method for< claim reciting a purpose is not equivalent to a >product for< claim reciting a purpose and that a higher legal standard needs to be applied. This higher standard for method claims under the EPC, according to Patent Proprietors, allows for reading the defined purpose as a hard limitation on the method claims, such that a prior art document would have to also disclose in order to be novelty-destroying.

We herewith review the legal standard for interpreting a >method for< claim reciting a purpose and provide examples of recent cases.

D

R

>Not limiting!‹

The established legal standard for interpreting >method for< claims under the EPC

Indeed, the Guidelines for Examination at the EPO outline a legal assessment of a higher standard that is to be applied for a method claim as compared to a product claim reciting a purpose, however, only in certain cases (Guidelines for Examination at F.IV.4.13.3). According to the Guidelines, in view of the landmark Decision T 1931/14, there are two types of method claims that often lead to different interpretations:.

- Methods where the stated purpose is a specific application of the method and the recited steps of the method would not inevitably result in that stated purpose. Thus, said stated purpose should be construed as a functional feature and, hence, limiting feature of the claim (such as, e.g., a >method for remelting of the galvanic layer< in which additional steps not implied by or inherent in the recited steps are necessary to achieve remelting, T 848/93), and
- Methods where the stated purpose is an intended technical effect which inevitably arises when carrying out the remaining steps of the claimed method and is thus inherent in those steps. This stated purpose should not be construed as a limiting feature of the claim (such as, e.g., >a method for reducing malodor< is anticipated by a prior-art document describing a method having such suitability >for reducing malodor> although not mentioning the technical effect, T 304/08).

One of the major points of discussion in EPO Opposition proceedings pertaining to method claims reciting a purpose ensues from the Patent Proprietors' stance that, **even though the stated purpose is a technical effect** and not an application, if it does not inevitably result from the recited method steps, **it should be construed a limiting feature** of the claim when assessing novelty of the method claim.

The question to be asked is whether this is the right approach.

Genentech's EP Patent 2 188 302 -Purpose considered a non-limiting technical effect

An example of how Patent Proprietors often seek to use the higher standard for >method for< claims reciting a purpose to their advantage when establishing novelty of the claim can be taken from a recent, heavily publicized EPO Opposition case against European Patent 2 188 302 granted to Genentech, Inc. Granted claim 1 was on a method of manufacturing an antibody and recited: >A method for the prevention of the reduction of a disulfide bond in a polypeptide (...)<.

Initially, ten Oppositions were filed against the grant of EP 2 188 302, with an 11th Opposition from an Intervener in the Opposition proceedings. Oral proceedings in the first instance were initially scheduled for **five days** and were extended by three more days leading to a total of **eight days** of oral proceedings concluding the first instance Opposition proceedings.

The Patent Proprietor argued that the recited technical effect of prevention of disulfide bond reduction **is not inherent or implied in the recited steps and therefore, it is not inevitably achieved when the recited steps** are performed. They argued that, since it is not inevitably achieved, this effect should be considered **a limiting feature** when assessing novelty of the claim. According to them, it is the recitation of the effect that ensures that only such methods in which the recited steps do lead to the recited technical effect are encompassed by the claim. The Patent Proprietor also argued that a >method for< claim reciting a purpose is to be construed such that the purpose is necessarily achieved, and since it is necessarily achieved, that purpose needs to be disclosed in a prior art document for it to be considered novelty-destroying.

All Opponents argued that the feature *ifor the prevention* of the reduction of a disulfide bond in a polypeptide (...)
reflects a technical effect inevitably resulting from the
recited method steps and, therefore, a novelty-destroying
document disclosing these steps need not acknowledge
that prevention of disulfide bond reduction had occurred.

In the first instance Decision, the Opposition Division sided with the Patent Proprietor. They decided that the purpose is a limiting feature of the claim because there are **additional steps that need to be taken that are neither implied nor inherent in the explicitly mentioned method steps** to achieve the recited purpose. They eventually decided that the claim was novel due to the recited purpose and maintained the Patent with minimal amendments.

Seven of the eleven Opponents appealed the Decision of the Opposition Division and one of the main arguments in their Grounds of Appeal was that the purpose was a mere technical effect inevitably arising from the method steps and, thus, should not be considered a limiting feature of the claim when assessing its novelty, in line with the Guidelines.

The Preliminary Opinion of the Board was issued on 12 September 2024. In it, the Board applied the legal standard established in the Guidelines for method for claims reciting a purpose **and preliminarily concluded** that the purpose *for the prevention of the reduction* of a disulfide bond in a polypeptide (...) cannot be considered a limiting feature of the claim and thus, cannot confer novelty on the claim over a prior art document reciting all other method steps. The Board considered that the recited purpose was a technical effect that is a mere verbal description of a mechanism inevitably taking place when carrying out the step(s) defined in the claim or as the mechanistic explanation of an effect inherently arising during the use of certain compounds in a method for antibody production (see point 33 of the Preliminary Opinion of the Board).

The Board reminded the parties in point 36 of its Preliminary Opinion:

>This view is consistent with the general principle of the EPC that patents are granted for contributions to the state of the art which allow new technical applications, but not for the discovery of a previously unknown property of a compound already known to be used in the same process (see Case Law of the Boards of Appeal of the EPO, 10th edition 2022, I. C. 8.1.3.(e)).<

The Board concluded in point 40 of its Preliminary Opinion:

>The board therefore considers the stated purpose of the method >for preventing reduction of a disulfide bond only limiting on the claim as far as the corresponding effect has to be inherently achieved when carrying out the method. For a method of the prior art to anticipate the claimed subject matter it is not necessary that achieving this effect was intended or recognised.<

The Patent Proprietor withdrew all Auxiliary Requests on file and their request for oral proceedings. Also, the Patent Proprietor indicated their understanding that the Patent would be revoked for lack of novelty of claim 1 of the Main Request. The Board cancelled the oral proceedings that were scheduled for 12-14 February 2025.

The Board's Decision was issued on 4 March 2025 as T 2695/22, and the Patent was revoked for added subject matter under Art. 123(2) EPC without touching upon novelty.

Nevertheless, this case shows that, while there are settings in which a >method for< claim reciting a purpose does enjoy a higher standard when it comes to interpreting the purpose as a limiting feature, such a standard can only be applied under certain circumstances, i.e. when the purpose is an application, which tends to be quite rare.

Cambridge Enterprise Limited's EP Patent 3 545 079 - Purpose considered a limiting application

In Opposition proceedings concerning Cambridge Enterprise Limited's EP 3 545 079, the Opposition Division decided that the purpose of a method for feature that defines a specific application is a limitation when assessing the claim's novelty. The method recited, in a wherein clause, that the method is *sfor forward programming of pluripotent stem cells*. The Opposition Division preliminarily sided with the Opponent and opined that this purpose was not a limiting feature of the claim and, therefore, the claim lacked novelty over a prior art document that was focussed on reprogramming specialized cells.

The Patent Proprietor in turn argued that the claim must be interpreted such that the feature *for forward programming of pluripotent stem cells* is the **specific application** of the method that provides an actual technical limitation in view of the Guidelines F.IV.4.13.3 and established Case Law of the Boards of Appeal, T 1931/14.

The Opposition Division changed their preliminary opinion on the day of the oral proceedings and maintained the Patent in amended form. The Decision was issued on 24 October 2024. In points 83 to 88 of the Grounds for the Decision, the Opposition Division applied the legal standard for interpreting *method for* claims established by the Guidelines and concluded that the purpose *for forward programming of pluripotent stem cells* represents a limiting feature of the claim when assessing novelty.

This Decision shows that, though rare, in certain circumstances, when adhering to the legal standard established by the Guidelines F.IV.4.13.3, it is possible to successfully argue that a method claim reciting a purpose is to be considered its limiting feature for the assessment of novelty. There is no pending appeal proceedings and the Opposition Division's decision has become final.

Discussion

While it is somewhat concerning that the Opposition Divisions at the EPO appear to differ in their interpretation and application of the legal standard (e.g. as laid out in the Guidelines) compared to the Boards of Appeal, it nevertheless seems that careful argumentation that adheres to the established legal standard for interpretation of method claims under the EPC may succeed in unifying the resulting decisions.



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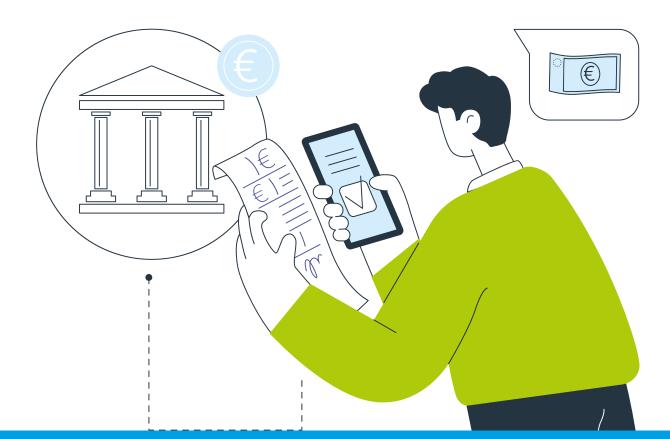
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Court fees and recoverable costs at the UPC

The real costs of litigation before the UPC

I. Introduction

Since the Unified Patent Court (UPC) became operational, one of the most frequently asked questions by clients and practitioners alike has been >What are the costs of UPC proceedings and how do they compare with national litigation?<. While the UPC's court fee structure is set out in the official regulations, many aspects of the actual costs initially remained unclear. In practice, legal teams regularly involved in UPC litigation are increasingly concerned that the total cost of UPC litigation may be **significantly higher than in national patent infringement proceedings** – especially when compared to German practice. The latter is based on remuneration of costs on the basis of the so-called >Rechtsanwaltsvergütungsgesetz< (RVG).



Drawing from the legal framework and our own experience before the UPC, this article aims to shed light on the practical cost implications for parties involved in UPC litigation. Our goal is to provide some initial guidance in this evolving landscape and to help better anticipate the financial exposure associated with patent litigation under the UPC system.

What are the costs of UPC proceedings and how do they compare with national litigation?

II. Court fees: fixed and value-based

UPC court fees, which are generally payable in advance by the claimant, consist of a fixed fee and, where applicable, an additional value-based fee. The fee structure is governed by Rule 370 of the Rules of Procedure (RoP) and the fee schedule adopted by the UPC Administrative Committee.¹

Type of Action	Fixed Fee	Value-Based Fee
Infringement action	EUR 11,000	EUR 2,500 - EUR 325,000 (value between > EUR 500,000 and EUR > 50,000,000)
Declaration of non- infringement	EUR 11,000	Value-based component applies as above
Counterclaim for revocation	EUR 20,000 <i>(flat)</i>	-
Standalone revocation action	EUR 20,000 (flat)	-
Applications for interim measures	EUR 11,000	-
Appeal (ordinary)	EUR 11,000	-

25

Overview of the additional value-based fees:

Value of the action	Additional value-based fee
≤ EUR 500,000	EUR 0
≤ EUR 750,000	EUR 2,500
≤ EUR 1,000,000	EUR 4,000
≤ EUR 1,500,000	EUR 8,000
≤ EUR 2,000,000	EUR 13,000
≤ EUR 3,000,000	EUR 20,000
≤ EUR 4,000,000	EUR 26,000
≤ EUR 5,000,000	EUR 32,000
≤ EUR 6,000,000	EUR 39,000
≤ EUR 7,000,000	EUR 46,000
≤ EUR 8,000,000	EUR 52,000
≤ EUR 9,000,000	EUR 58,000
≤ EUR 10,000,000	EUR 65,000
≤ EUR 15,000,000	EUR 75,000
≤ EUR 20,000,000	EUR 100,000
≤ EUR 25,000,000	EUR 125,000
≤ EUR 30,000,000	EUR 150,000
≤ EUR 50,000,000	EUR 250,000
> EUR 50,000,000	EUR 325,000

III. Recoverable costs and security for costs

As in German proceedings, **the costs of legal representation and other necessary expenses incurred by the successful party generally have to be reimbursed by the unsuccessful party**, provided that such costs are reasonable and proportionate (Art. 69(1) of the Unified Patent Court Agreement (UPCA)). However, **the reimbursement is subject to a ceiling** determined by reference to the value of the proceedings (Rule 152(2) RoP). Rule 370(6) RoP stipulates that the assessment of the value of the proceeding *shall reflect the objective interest pursued by the applicant at the time of bringing the actions*.

The value of the proceeding **>shall reflect** the objective interest pursued by the applicant at the time of bringing the action **•**.

The **ceiling of recoverable** costs per instance ranges from EUR 38,000 (for cases with a value of up to EUR 250,000) to a maximum of EUR 2,000,000 (for cases with a value of over EUR 50,000,000). A detailed table of the applicable ceilings is set out in Section IV below.

Where a party is only partially successful, or in exceptional circumstances, the court may order an equitable apportionment of costs or that each party bear its own costs (Art. 69(2) UPCA). In addition, any party who has caused unnecessary costs, whether to another party or to the court, shall bear those costs (Art. 69(3) UPCA).

Security for costs: Upon a reasoned request by the defendant in an action, the court may order the claimant to provide adequate security for the legal costs and other expenses of the defendant (Art. 69(4) UPCA and Rule 158 RoP).

Further, a **reduction** of the court fees of 40% is possible for small and micro enterprises (SME) under certain conditions (Rule 370(8) RoP). Legal aid is also in principle possible (Rule 375 et seq. RoP).



IV. Ceilings on recoverable costs

Recoverable legal representation costs are capped depending on the value of the proceedings.

The ceilings apply **per instance**, regardless of the number of patents, claims, or parties involved. Where success is only partial, ceilings are adjusted proportionally.

Value of the proceedings	Ceiling for recoverable costs	
≤ EUR 250,000	EUR 38,000	
≤ EUR 500,000	EUR 56,000	
≤ EUR 1,000,000	EUR 112,000	
≤ EUR 2,000,000	EUR 200,000	
≤ EUR 4,000,000	EUR 400,000	
≤ EUR 8,000,000	EUR 600,000	
≤ EUR 16,000,000	EUR 800,000	
≤ EUR 30,000,000	EUR 1,200,000	
≤ EUR 50,000,000	EUR 1,500,000	
> EUR 50,000,000	EUR 2,000,000	

However, these ceilings may be adjusted in certain circumstances, meaning that a party's cost exposure may not be entirely clear at the outset of the proceedings. The court has discretion to raise the ceiling upon a party's request in some specific situations – for instance, where the case is particularly complex. The extent to which the ceiling can be raised depends on the value of the proceedings²:

- Up to 50% increase for cases valued up to EUR 1 million,
- > Up to 25% increase for cases valued between EUR 1 and 50 million,
- > Up to an absolute cap of EUR 5 million for cases valued above EUR 50 million.

Conversely, the court may also lower the ceiling if a party (especially an SME, non-profit organization, public research organization, or individual) can demonstrate that enforcement of full recoverable costs would threaten its economic existence.

Requests to raise or lower the ceiling must be submitted as early as practicable - ideally with the statement of claim or defense - and must include supporting evidence.

² Art. 2(1) of the Scale of ceilings for recoverable costs by the Administrative Committee.

V. UPC vs. German courts: A cost comparison

As an example, for an assumed value of the proceedings (infringement action) of EUR 3 million, the costs for UPC proceedings and German proceedings for infringement proceedings (without revocation proceedings) are compared.

	UPC	Germany
Court Fees	EUR 11,000 fixed fee + EUR 20,000 value based fee (infringement claim) = EUR 30,000	EUR 41,403
Recoverable Costs	Up to EUR 400,000 (based on value of the proceeding of EUR 3.0 million)	Approx. EUR 100,388 (1x patent attorney and 1x attorney at law; including court fees; based on RVG)

This example shows that the recoverable costs before the UPC (maximum of EUR 400,000) are higher than the recoverable costs before German courts (about EUR 100,000). Although court fees before the UPC are lower than before national German courts, the broader scope for recoverable legal costs can result in a higher overall cost risk, which of course also reflects the (in most cases) extended territorial scope of UPC proceedings.

VI. How to claim cost reimbursement

From a practical perspective, the question is how the aforementioned principles are applied in UPC proceedings. In particular, parties must consider how a (separate) cost proceeding is conducted and which expenses are actually regarded as reasonable and therefore recoverable.

According to Rule 150(1) RoP a cost decision may be the subject of separate proceedings following a decision on the merits and, if applicable, a decision for the determination of damages. Where the successful party wishes to seek a cost decision, it must lodge an application for a cost decision within one month of service of the decision (Rule 151 RoP).

Under Rule 152(1) RoP, the successful party (i.e., the applicant in cost proceedings) is entitled to recover the reasonable and proportionate costs of legal representation (including costs of experts, witnesses, interpreters, and translators, see Rules 153 to 155 RoP). According to Rule 151(d) RoP, the application for a cost decision must indicate the costs for which reimbursement is sought, in particular the costs of representation.



VI.1 Detailed breakdown of costs

A detailed specification of the claimed costs, i.e., of which costs arose at what time and for which specific activity, is generally not required by the Rules of Procedure. A broad overview of the cost categories may be sufficient, provided the submission remains plausible and coherent.

VI.2 No general requirement to submit cost evidence

Pursuant to Rule 156(1) RoP, the judge-rapporteur may request written evidence of any claimed costs, but such a request is discretionary. In principle, the cost decision can be made without written substantiation.

That said, the judge-rapporteur will typically request supporting documents if the cost submission appears implausible or lacks transparency. There is no general obligation to itemize and document legal fees, patent attorney fees, or translation expenses in detail.

VI.3 Objections from the other party

The more granular a cost submission is, the more likely it is that the other side will use it to challenge the necessity or proportionality of individual cost items. This can lead to lengthy disputes - a situation largely unfamiliar in German cost reimbursement practice. In the authors' view, such scrutiny may also be difficult to reconcile with the professional code of conduct of lawyers. Therefore, while it is advisable to substantiate costs sufficiently, one may consider avoiding excessive detail that may invite counterarguments (e.g., regarding the number of hours spent drafting a submission).

While it is advisable to substantiate costs sufficiently, one may consider avoiding excessive detail that may invite counterarguments.

Often, disputes often arise on how many representatives are considered appropriate. Under Art. 48(3) UPCA, a party may be represented both by a lawyer and, in addition, by a patent attorney. Neither the UPCA nor the Rules of Procedure impose a numerical limit on the number of legal representatives. Since recoverable costs must be reasonable and proportionate (Art. 69(1) UPCA) and within the applicable ceiling, there is no need for a hard cap on the number of lawyers or patent attorneys.

The Local Division Munich appears to follow a pragmatic approach: In a recent case, the judge-rapporteur considered the number of representatives for the applicants in light of

- the number of representatives appointed by the respondent,
- the number of judges deemed necessary to decide the matter under the UPC's procedural rules, and
- > the case's complexity.



In a moderately complex preliminary injunction case involving one applicant and two respondents, the participation of one lawyer and two patent attorneys representing both respondents jointly was found to be reasonable - especially since separate legal teams for each respondent would also have been permissible.

VI.4 Interim award of costs

In appropriate cases, the UPC also allows for interim award of costs. Pursuant to Rule 150(2) RoP (or Rule 211(1) lit. (d) RoP with regard to applications for provisional measures), the court may, upon a party's request, in its decision on the merits (Rule 119 RoP) or in a decision awarding damages, order that certain costs be reimbursed even before the final decision on costs is rendered. This may be **particularly relevant in proceedings for provisional measures or other urgent matters,** where one party incurs substantial costs that would otherwise not be reimbursed for quite some time.

Such interim cost awards are at the discretion of the court and require that the court is satisfied that the claim for reimbursement is well-founded and that there are equitable grounds justifying an early cost award. This tool can be strategically valuable, especially where the financial burden of interim proceedings is significant or has a deterrent effect on further enforcement.

VI.5 Interim award of damages

According to Rule 119 RoP, the court may award provisional damages to the successful party. Such damages shall at least cover the preliminary costs incurred by the successful party in the proceedings for damages and compensation. It should be noted that the value of the claim in damages proceedings is not necessarily the same as in the corresponding infringement actions. Rather, the value of the proceedings is determined by calculating the damages to which the claimant is entitled pursuant to Rule 131(2) lit. (e) RoP. For this, it should be possible to estimate the relevant costs on the basis of the value of the claim assumed for the damages proceedings in accordance with the court's scale of court fees and a reasonable estimate of legal costs.

VII. Conclusion and practical takeaways

Understanding how court fees and cost reimbursement operate under the UPC framework is essential for strategic and financial case planning.

Our experience with UPC litigation confirms that estimating the actual costs remains challenging, especially when compared to the much more predictable cost risks in national German litigation. The ceilings for recoverable

costs under the UPC Rules of Procedure are significantly higher than the typical cost exposure for comparable cases before German courts. However, infringement actions before the UPC usually cover several countries and may also include a central revocation action or a counterclaim for revocation, which increases the scope and complexity of the proceedings. In order to make a meaningful comparison of costs, additional factors such as geographical scope, procedural efficiency and enforcement value need to be taken into account. Nevertheless, the initial concern that UPC proceedings could prove more expensive and burdensome than national litigation appears to have been confirmed within the first 22 months of the UPC - although this may also be due, at least in part, to the current lack of settled case law, particularly from the Court of Appeal, on the many procedural and substantive legal issues arising under the new system.

Given the limited number of decisions to date, many important issues - in particular the amount and appropriateness of costs - remain to be resolved by the Local Divisions and the Court of Appeal. Until guidance from the Court of Appeal becomes available, parties are advised to proceed with caution.

Recommendations

- Assess litigation cost risks early and carefully
- Substantiate the value of the proceedings clearly in pleadings
- Consider the implications of cost ceilings especially in high-value and multi-defendant cases
- Where justified, consider early applications to adjust cost ceilings
- Consider finding an amicable agreement on cost reimbursement with opposing party





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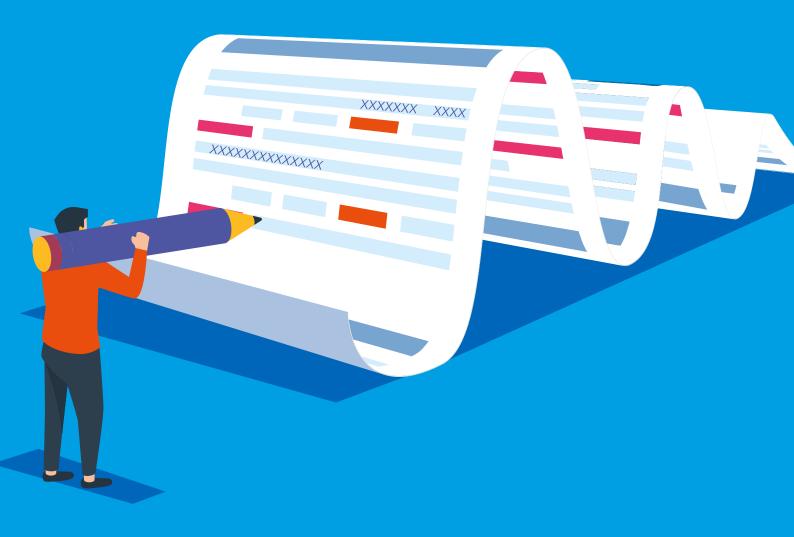
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Actually adapting the description to amended claims?

How to deal with T 56/21 in practice





Background

There is an ongoing discussion on whether and to what extent the description needs to be adapted to allowable claims amended relative to original claims in European (EP) examination proceedings. For example, embodiments described in the specification and falling under the original claims may no longer fall under the granted claims due to the amendment. This may entail an inconsistency between the claims and what is disclosed as the invention in the description. It is EP practice (within the framework of the *>adaptation of the description*<) to remove this inconsistency by amending, i.e. adapting, the description. However, for various reasons, it may be desired to avoid an (extensive) adaption of the description to amended claims.

In earlier decisions such as T 757/01, the Board of Appeal (BoA) referred to Article 84 EPC stipulating an adaption of the description to the wording of the amended claims, without giving reasons for this interpretation of Article 84 EPC, however.

Some discussion has come up with the BoA decision T 56/21, according to which the BoA in examination of a patent application could not identify a legal basis for requiring that the description be adapted to match allowable claims of more limited subject-matter, either in Article 84 EPC or in Rules 42, 43 and 48 EPC. As a consequence, the question arises whether decision T 56/21 can successfully support the view that adapting the description is not necessary based on the BoA's findings in T 56/21.

BoA's Findings in T 56/21

In the case underlying T 56/21, the description contained a passage entitled >SPECIFIC EMBODIMENTS<, which contained claim-like clauses. The Examining Division refused the application on this basis with reference to Article 84 EPC, the Guidelines for Examination and Rule 48(1) (c) EPC.

Based on a discussion of several earlier decisions relating to the adaptation of the description, in decision T 56/21 the BoA came to the following conclusions (see in particular margin no. 99 of T 56/21): Article 69 EPC concerns the enforcement of a patent after grant and, hence, the extent of protection conferred by the claims is determined in view of allegedly infringing subject-matter (see margin no. 15, also G 1/98). Hence, Article 69 EPC and its Protocol are concerned with the extent of protection (>demarcation of what is protected<, see margin no. 14 of T 56/21) in the context of national (or UPC) proceedings of a European patent following such examination, and are



not concerned with the assessment of patentability in examination before the EPO. Article 69 EPC and its Protocol are hence not applicable to examination proceedings before the EPO.

Only when it comes to amendments after grant, under Article 123(3) EPC, the extent of protection before and after the amendment is assessed by the EPO (see e.g. margin nos. 32 and 90 of T 56/21).

- Article 84 EPC pertains to the examination of subjectmatter intended for grant of a patent and, hence, the subject-matter claimed delimited and characterized in view of the prior art relevant to the examination of patentability (see margin no. 15). Article 84 EPC and Rule 43 EPC are not a corollary of Article 69 EPC even though claims are the main determinant of the extent of protection. Consequently, the requirements of Article 84 EPC and Rule 43 EPC are to be assessed separately and independently of any considerations of extent of protection (under Article 69 EPC) when examining a patent application.
- > Article 84 EPC and Rule 43 EPC set forth requirements for the claims. They do not provide a legal basis for mandatory adaptation of the description to claims of more limited subject matter. Specifically, due to the fact that Article 84 EPC sets out requirements to be met by the claims and not by the description, Article 84 EPC on its own does not provide a legal basis for a mandatory adaptation of the description to the more limited subject-matter claimed (margin no. 76).

Within the limits of Article 123 EPC, an applicant may, however, amend the description on its own volition.

Rule 48 EPC is concerned with the publication of an application and the avoidance of expressions which are contrary to public morality or public order, or certain disparaging or irrelevant statements. Rule 48 EPC (in particular Rule 48(1)(c) EPC) does not provide a ground for refusal based on the inclusion of merely >irrelevant or unnecessary< matter in the description intended for grant and even less based on >discrepancies< between the subject-matter claimed and disclosed in the description.

Discussion and Outlook

In our experience, most of the Examining Divisions consider decision T 56/21 as a singular decision. Consequently, it appears that most of the Examining Divisions do not and are not willing to follow this decision. Rather, we presume that Examining Divisions may follow such a decision only if confirmed by the Enlarged Board of Appeal (EBA) or if it became advised practice as outlined in the Guidelines for Examination. At present, the decision has not (yet) found its way into the Guidelines for Examination and will probably only do so if and when there are subsequent decisions and, in the event of divergence, a referral to the EBA. The BoA in T 56/21, however, did not see any reason to refer the case to the EBA (see margin nos. 100 to 104).

Denying a requirement for adapting the description is likely to result in more EP patents without a properly adapted description. If the unamended description entails contradictions, this is likely to lead to issues under Article 69 EPC in subsequent proceedings (EP opposition proceedings, national or UPC infringement or revocation proceedings). In particular in infringement proceedings, where courts generally tend to interpret granted claims with the aim not to contradict the overall teaching of the patent (i.e. the description of the granted patent), issues may arise more frequently. Notably, the BoA does acknowledge the importance of a clear definition of the subject-matter in the claims for post-grant proceedings (see margin no. 34 in T 56/21). Apparently, the BoA sees a > solution (in that clarity of the claims should be key in examination, such that such clear definition of the subject-matter claimed inherently enables the extent of protection to be determined under Article 69 EPC in case of infringement (see margin no. 33).

In summary, there is likely little reason to change the current EP practice of adapting the description upon claim amendments in view of T 56/21. Rather, EP proceedings are often pragmatically based on a cost-benefit analysis, as on the one hand unnecessary adaptations of the description can take a lot of time (and generate costs), and on the other hand a rejection of non-critical adaptations of the description, e.g., proposed by the Examiner, also generates delays (and costs) for a further submission.



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