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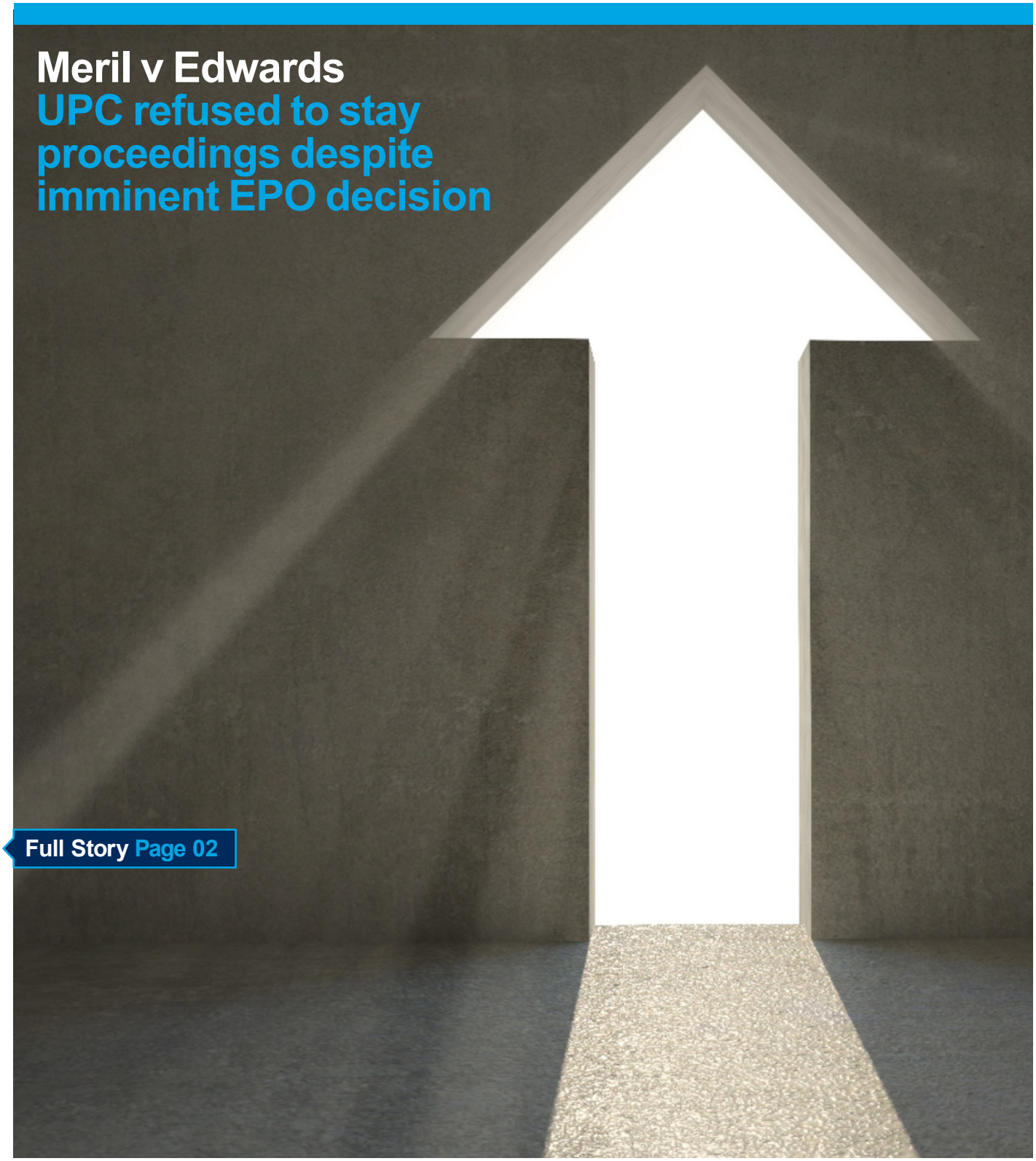
In this issue:



Meril v Edwards
UPC refused to stay proceedings despite imminent EPO decision

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Editorial

As the UPC continues to generate new caselaw, the interaction between the UPC and the EPO is becoming pronounced. In this issue we touch on two aspects. The first relates to the timing of parallel related proceedings whereas the second is an acknowledgement by the Enlarged Board of Appeal as to practice before the UPC when considering the referral regarding claim interpretation (G1/24). Springtime brings change and we report on the annual update to the EPO and the likely changes by the EU in Regulations governing SPC practice. Of note in this area has been the UK Court maintaining the CJEU approach to combination SPCs.

Neil Nachshen, Editor

Events

SPC Case Law & Strategic Insights
Webinar, 1pm (BST) 10 June 2025
Garreth Duncan presents the latest developments in SPC case law.

BIO International Convention
Boston, USA, 16-19 June 2025
Antony Latham, Jennifer O'Farrell and Tom Pagdin will be attending BIO 2025.

Space & Communications Week
London, UK, 17-18 June 2025
David Al-Khalili and Sean McCann will be attending the International Satcomms Conference, the Quantum Engineering & Technology Conference, and the 6G Future Network Conference.

UPC Case Law, Observations & Analysis
Webinar, 1pm (BST) 18 June 2025
Our latest UPC webinar is hosted by Anthony Albutt, Rachel Bateman and Tom Pagdin.

Global Conference & Expo on Optics, Photonics & Lasers
London, UK, 11-13 August 2025
Cathrine McGowan will be attending.

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Unified Patent Court

Meril v Edwards
UPC refused to stay proceedings despite imminent EPO decision

In a series of orders in Meril v Edwards, the Unified Patent Court (UPC) Court of Appeal has provided further clarification for stays of infringement proceedings, when opposition proceedings are running in parallel before the European Patent Office (EPO).

UPC stays of proceedings

Decisions in parallel UPC infringement and EPO opposition proceedings may conflict, for example, where the EPO revokes a patent that has formed the basis of a UPC infringement action.

> To prevent such conflicts, Article 33(10) of the Agreement on a UPC (UPCA), and Rule 295 of the Rules of Procedure of the UPC (RoP), allow a UPC court to stay its proceedings provided a rapid decision is expected from the EPO.

In Meril v Edwards, the UPC Court of Appeal made clear that such EPO decisions include those issued by opposition divisions.

Case background

At first instance, Edwards brought a UPC infringement action against Meril on the basis of a European patent, and Meril counterclaimed for revocation. The oral hearing was scheduled for 16 January 2025.

Meril opposed the same patent before the EPO. The EPO opposition division accelerated the opposition proceedings, and issued a non-binding preliminary opinion that the grounds of opposition prejudice the maintenance of the patent as granted. Oral proceedings were scheduled for 17 January 2025, one day after the UPC oral hearing.

Meril also requested the UPC Court of First Instance to stay the infringement proceedings, pending a decision from the EPO opposition division.

However, the Court of First Instance **rejected** Meril's request, on the basis that the EPO opposition division's decision is likely to be appealed, meaning a **final** EPO decision cannot be expected rapidly.

In contrast, the UPC aims to allow a final oral hearing to take place within one year, therefore the UPC is expected to issue its decision before a final decision is issued by the EPO.

Appeal

Meril appealed against this decision.

The UPC Court of Appeal acknowledged that the relevant provisions (Article 33(10) UPCA and Rule 295(1) RoP) do not require a **final** EPO decision to be expected rapidly: a rapidly expected decision from the opposition division is sufficient, even if it is likely to be appealed.

Accordingly, the Court of Appeal found that the Court of First Instance was wrong to refuse to grant the stay on the basis that the EPO opposition division's decision is not final.

However, the Court of Appeal recognised that the court is not **required** to stay proceedings if a rapid (final or non-final) EPO decision is expected. Article 33(10) UPCA and Rule 295(1) RoP state that the Court "**may**" stay proceedings. Therefore, whether to stay proceedings is at the discretion of the court.

The Court of Appeal emphasised that in deciding whether to stay proceedings or not, the court should consider the balance of interests of the parties, and the specific circumstances of the case. Such circumstances include the stage of the opposition proceedings (factoring in non-final decisions and the potential for appeal, versus final decisions), the stage of infringement proceedings, and the likelihood of revocation in the EPO opposition proceedings.

The Court of Appeal also suggested some alternative ways for the court to prevent conflicting decisions, which avoid staying proceedings during the written proceedings:

Case details at a glance

Decision level: Court of First Instance, Nordic Baltic Regional Division
Case: UPC_CFI_380/2023
Order: ORD_16663/2024
Parties: Meril Life Sciences PVT Limited & Ors v Edwards Lifesciences Corporation
Date: 20 August 2024
Decision: dycip.com/ord-16663-2024

Decision level: Court of Appeal, Luxembourg
Case: UPC_CoA_511/2024
Order: ORD_61000/2024
Parties: Meril Life Sciences PVT Limited & Ors v Edwards Lifesciences Corporation
Date: 21 November 2024
Decision: dycip.com/ord-61000-2024

Decision level: UPC Court of First Instance, Nordic Baltic Regional Division
Case: UPC_CFI_380/2023
Order: ORD_65290/2024
Parties: Meril Life Sciences PVT Limited & Ors v Edwards Lifesciences Corporation
Date: 11 December 2024
Decision: dycip.com/ord-65290-2024

Related webinar: UPC case law

UPC Case Law, Observations & Analysis Webinar, 1pm 18 June 2025
Anthony Albutt, Rachel Bateman and Tom Pagdin presents the latest developments in UPC case law:
dycip.com/upc-webinar-jun2025

Unified Patent Court decisions to stay proceedings are subject to its discretion

- Proceed with the infringement proceedings, but reschedule the oral hearing to take place after the EPO issues its oral or written decision;
- Hold the oral hearing as scheduled, but request the parties to inform the court of the outcome of the opposition proceedings, and then decide whether further procedural steps are required; and
- Proceed with the infringement proceedings, and exercise the powers granted under Rule 118.2(b) RoP to stay proceedings during the oral proceedings, when the case is ready for a decision.

Remittal

Given that the Court of First Instance has discretion to stay the proceedings, and was more familiar with the particular circumstances of the case, the Court of Appeal remitted the case back to the Court of First Instance.

The Court of First Instance once again acknowledged that the UPC aims to allow a final oral hearing to take place within one year. This aim had not been met in the Meril v Edwards case, and rescheduling the oral hearing would significantly further delay the UPC's decision on the merits.

In contrast, the Court of First Instance recognised that the EPO opposition division normally announces its decision at the end of oral proceedings. Therefore, even holding the oral hearing as scheduled, the EPO's decision was expected to be available to the court before it issues its decision on the merits. In addition, the opposition division's decision is likely to be appealed.

Therefore, taking into account the interests of the parties and the relevant circumstances, the Court of First Instance exercised its discretion in dismissing the request to stay the proceedings again.

However, the court planned to request the parties to inform them of the outcome of the opposition proceedings, and then decide whether further procedural steps are required, as had been suggested by the Court of Appeal.

Decision of the EPO opposition division

During the oral proceedings, the EPO opposition division decided to maintain the patent as amended on the basis of an auxiliary request.

The same auxiliary request was filed in the UPC infringement proceedings, and we await the UPC's decision with interest.

Comment

Overall, the Court of Appeal has made clear that a court may stay infringement proceedings where the opposition division of the EPO is expected to give a rapid decision, even if such decision is likely to be appealed. However, such a decision to stay proceedings is subject to the court's discretion, and the court should take account of the interests of all parties, and the relevant circumstances when making its decision.

The EPO will accelerate opposition proceedings if it is informed of parallel UPC infringement or revocation proceedings. However, given that the UPC aims to allow a final oral hearing to take place within one year, it seems unlikely that UPC courts will stay infringement proceedings even if an EPO decision is expected imminently. Nevertheless, it appears that EPO decisions should be taken into account by UPC courts, with the aim of preventing conflicting parallel decisions.

Author:
Laura Jennings

UPC rejects cost awards for access requests

No legal basis for costs on pleadings and evidence access

Case details at a glance
Decision level: Court of First Instance, Paris Central Division
Order: ORD_59519/2024
Parties: Meril Italy srl, Meril Life Science Private Limited, Meril GmbH
Date: 08 January 2024
Decision: dycip.com/upc-ord-59519-2024

Decision level: Court of First Instance, Nordic Baltic Regional Division
Order: ORD_42124/2024
Parties: KIPA AB
Date: 21 January 2024
Decision: dycip.com/upc-ord-42124-2024

The UPC Court of First Instances have held there to be no legal basis for costs to be awarded following a request for access to written pleadings and evidence under Rule 262.1(b) of the UPC Rules of Procedure. These rulings provide welcome reassurance for third parties that they are unlikely to be held liable for costs of the parties to proceedings involved in responding to their request.

Background

Following initial uncertainty, the principles to be applied when considering requests for access to written pleadings and evidence under Rule 262.1(b) of the UPC Rules of Procedure have become clearer following the decision of the UPC Court of Appeal in Ocado v Autostore.

Related article
For further information on this decision, see our earlier article "UPC Court of Appeal provides positive step in transparency of proceedings", 11 April 2024: dycip.com/ocado-autostore-upc-appeal

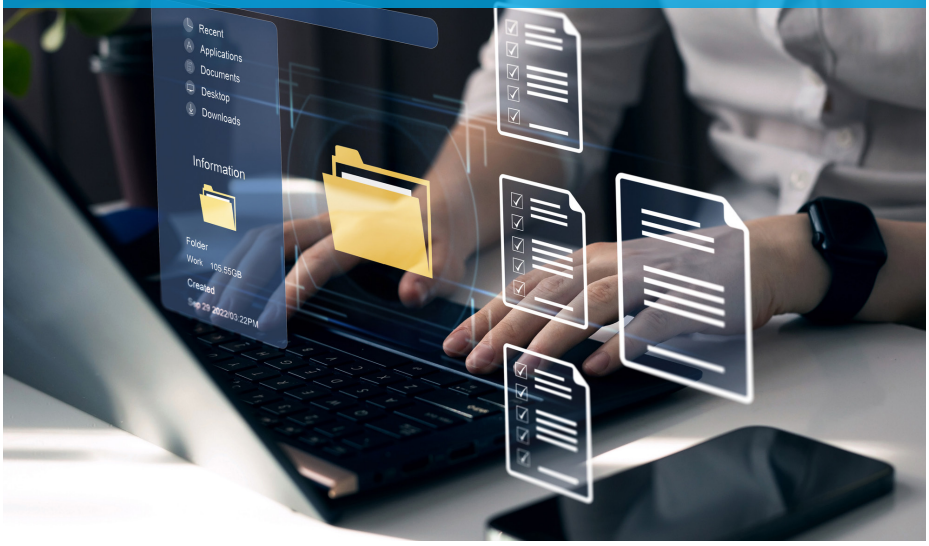
However, it had until recently not been considered whether an applicant for access to written pleadings and evidence could be held liable for the costs of the parties to proceedings in the event that their request was unsuccessful. Two recent decisions of the UPC Courts of First Instance would now appear to confirm that such costs awards are **not** applicable to requests for file access under Rule 262.1(b) of the UPC Rules of Procedure.

ORD_59519/2024

In the earlier decision, issued 08 January 2025, the Paris Central Division considered an application for costs filed by a party to proceedings following an unsuccessful request for file access filed by a third party. The division noted that, according to Rule 150 of the UPC Rules of Procedure, a decision to award costs may be awarded only after a "decision on the merits".

The division considered that a "decision on the merits" must be understood as a decision that **concludes litigation proceedings**.

The UPC has rejected cost awards for access requests



An application for access to pleadings and evidence was, in contrast, held by the division to serve the purpose of increasing transparency of judicial activity, and not for the protection of interests of the parties to the dispute.

The Paris Central Division thus held that an order deciding on a request under Rule 262.1(b) does not represent a "decision on the merits" and accordingly dismissed the application for a cost decision.

ORD_42124/2024

In a later decision, issued 21 January 2025, the Nordic Baltic Regional Division also held there to be no legal basis for a costs decision following a request for register access, **but on different grounds**. The division in this case firstly noted that the wording of Article 69(1) of the UPC Agreement (which provides for the possibility of legal costs being borne by the unsuccessful party) mirrors that of Article 14 of the Enforcement Directive (2004/48/EC), an EU directive seeking to harmonise the way in which IP rights are enforced within the Union. The division reasoned that since the Enforcement Directive does not contain any provisions concerning public access to court files, there is no evidence that Article 69(1) was intended to apply to requests for file access by members of the public.

The division also noted that Article 69(1) limits the costs recoverable by the successful party to a ceiling set in the Rules of Procedure, but that no such limit for requests under Rule 262.1(b) has been adopted in these rules. The division further examined the language of Rule 262.1(b) itself, noting that this provision states that a decision on whether to grant file access is taken only after **consulting** the parties. This language was interpreted by the division as indicating that the parties to the main proceedings are not considered parties to the proceedings concerning the request for access to documents. The Nordic Baltic Regional Division therefore dismissed the application for reimbursement of legal costs.

Summary

Despite the different reasoning applied by the two divisions, they both reached the conclusion that there is no legal basis in the UPC Agreement to hold a member of the public liable for costs incurred by the parties to proceedings when responding to a request for written pleadings and evidence under Rule 262.1(b). These decisions provide some welcome reassurance for third parties who may be considering such requests, especially where a successful outcome is uncertain.

Author:
Khalil Davis

G 1/24
Oral proceedings before the Enlarged Board of Appeal

Useful links

EPO news release G 1/24:
dycip.com/epo-news-oral-proceedings-g124

EPO decision T 0439/22:
dycip.com/epo-t043922

EPO European Patent Register EP3076804:
dycip.com/epo-ep3076804

England and Wales Court of Appeal (Civil Division) decisions, [2008] EWCA Civ 192:
dycip.com/2008-ewca-civ-192

European Central Bank v Document Security Systems Inc:
dycip.com/central-bank-document-security

On 28 March 2025 the Enlarged Board of Appeal of the European Patent Office (EPO) held oral proceedings in referral G 1/24 ("Heated aerosol"), made by Technical Board of Appeal 3.2.01 by interlocutory decision T 439/22 relating to European patent EP3076804.

The referral concerns the following three questions:

1. Is Article 69(1), second sentence EPC and Article 1 of the Protocol on the Interpretation of Article 69 EPC to be applied on the interpretation of patent claims when assessing the patentability of an invention under Articles 52 to 57 EPC?
2. May the description and figures be consulted when interpreting the claims to assess patentability and, if so, may this be done generally or only if the person skilled in the art finds a claim to be unclear or ambiguous when read in isolation?
3. May a definition or similar information on a term used in the claims which is explicitly given in the description be disregarded when interpreting the claims to assess patentability and, if so, under what conditions?

Article 69(1) EPC (Extent of protection) is located in Chapter III (Effects of the European patent and the European patent application) of the articles of the European Patent Convention (EPC) and states that "the extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims."

The legislator of the EPC 1973 and the revised EPC 2000 foresaw separate provisions of Substantive Patent Law: Articles 52-57 EPC in Chapter I (Patentability) and Articles 63-70 EPC in said Chapter III (Effects of the European patent and the European patent application).

This separation has led to somewhat different measures to be applied during examination of the European patent application before the EPO and later during litigation before national courts in the contracting states, where national parts of the granted European patent are, according to Article 2 EPC, "subject to the same conditions as a national patent granted by" the contracting states.

This dichotomy may enable the applicant of a patent application to argue a narrower scope of the claim in order to obtain a patent, and later, as the proprietor of the granted patent, to argue a larger scope of protection in order to enforce the patent against an infringer.

Famously, Lord Justice Jacob in the Supreme Court of the United Kingdom final appeal relating to UK part of European patent EP0455750 said that "Professor Mario Franzosi likens a patentee to an Angora cat:

> "When validity is challenged, the patentee says his [sic] patent is very small: the cat with its fur smoothed down, cuddly and sleepy. But when the patentee goes on the attack, the fur bristles, the cat is twice the size with teeth bared and eyes ablaze"

(European Central Bank v Document Security Systems [2008] EWCA Civ 192, [5].)

Whereas the vivid analogy of the Angora cat was originally used in national proceedings regarding patent infringement and revocation before a court of a contracting state, it is comprehensible to extend the concept of a common scope of protection to the examination to the patent application, for the sake of legal certainty.

However, the EPC was conceived and agreed upon after years of intense negotiations during a diplomatic conference of 03 October 1973 and revised once on 29 November 2000. As legislator, the contracting states clearly intended to separate the provisions governing patentability and the provisions governing the effects of the European patent and the European patent application.

The Enlarged Board of Appeal has preliminary recognised the interest in uniform application of the principles of claim interpretation both in patent grant proceedings before the administrative departments of the EPO and the Boards of Appeal, and also in post-grant revocation and infringement proceedings before the courts of the contracting states and the Unified Patent Court (UPC).

The oral proceedings ended at 14:27 CET, 28 March 2025, and the Enlarged Board of Appeal will issue a written decision in due course.

> Whereas Article 69 EPC prescribes that the description and drawings shall ("must") be used to interpret the claims, in contrast, "[consulting] the description and figures … when interpreting the claims to assess patentability" seems less stringent and more reasonable.

Thus, it may be expected that the Enlarged Board of Appeal follows the legislator's intention, and it remains to be seen whether Article 69(1) EPC, second sentence EPC and Article 1 of the Protocol on the Interpretation of Article 69 EPC, are not to be applied on the interpretation of patent claims when assessing the patentability of an invention under Articles 52 to 57 EPC, as this would strengthen trust in the European patent system as such.

It appears that questions 2 and 3 that are not expressively linked to Article 69 EPC allow the Enlarged Board of Appeal to provide guidance, without bending the EPC.

Author:
Hanns-Juergen Grosse

SPCs post-Brexit
UK Court of Appeal sticks with the CJEU on SPCs in Merck decision

The UK Court of Appeal has recently handed down its decision in the much awaited Merck Serono v Comptroller-General of Patents case [2025] EWCA Civ 45. In its decision, the Court of Appeal outlined that it was bound by its own previous decision, which aligned with assimilated Court of Justice of the European Union (CJEU) case law holding that supplementary protection certificates (SPCs) are not available for second medical uses of previously authorised pharmaceutically active products. Nevertheless, the court also indicated that even if it could deviate from its own previous case law, it would not do so in this case.

SPCs extend the term of patents for medicinal and plant protection products in Europe which have been granted a marketing authorisation (MA). However, Article 3(d) of Regulation (EC) 469/2009 (the SPC Regulation) requires that the MA is the "first authorisation to place the product on the market as a medicinal product".

This decision relates to the issue of whether an MA can be considered to be the "first authorisation" if it is directed to a new therapeutic application of an active ingredient that has previously been authorised for a different therapeutic use. This issue has been a key topic in the field of SPCs for many years and this decision was hotly anticipated in view of the possibility that the UK Court of Appeal could depart from previous CJEU case law in this area, as it has the power to do following Brexit.

Background to the case

The case relates to an SPC application filed by Merck in respect of the product Mavenclad, which comprises the active ingredient cladribine. Mavenclad is a disease modifying drug for very active relapse remitting multiple sclerosis. The SPC application relied on the basic patent EP1827461 and the marketing authorisation EU/1/17/1212 for Mavenclad.

The SPC application was refused by the UK Intellectual Property Office (UKIPO) examiner for failing to meet the requirement of Article 3(d) of the SPC Regulation, because cladribine had already been the subject of two MAs for a different indication (hairy cell leukaemia). As a result, the UKIPO examiner objected that the MA for Mavenclad could not be the "first authorisation to place the product on the market as a medicinal product".

Merck appealed the decision by the UKIPO to the Patents Court. However, the Patents Court dismissed the appeal on the grounds that it was bound by the CJEU decision in C-673/18 (Santen), which decided that it is not possible to obtain an SPC for a new therapeutic application of a previously authorised active ingredient.

Related article
"Santen (C-673/18): CJEU takes a restrictive view on "first authorisation" for new therapeutic applications", 14 August 2020: dycip.com/santen

Merck subsequently appealed that decision to the UK Court of Appeal, which interestingly provided the possibility of the UK diverging from CJEU law and particularly the Santen decision, since post-Brexit, the Court of Appeal (unlike the Patents Court) could decide to diverge from the CJEU position.

The decision of the UK Court of Appeal thus touched on two key areas:

1. Could the UK Court of Appeal depart from the CJEU's decision in Santen, given that it had already followed it when reaching its own previous decision in Newron?

2. Was Santen wrongly decided, such that the Court of Appeal should depart from its reasoning and therefore allow the possibility to obtain an SPC for a new therapeutic application of a previously authorised active ingredient?

Is the UK Court of Appeal bound by Santen and its own application of this Case law in Newron?

As a first element to the decision, the UK Court of Appeal considered the notion of binding case law. In particular, the court referred to a statutory Instrument entitled the European Union (Withdrawal) Act 2018 (Relevant Court) (Retained EU Case Law) Regulations (SI 2020/1525) outlining that a relevant court (such as the UK Court of Appeal) is bound by retained EU case law so far as there is post-transition case law which modifies or applies the retained EU case law which is binding on the relevant courts.

In the context of the present case, the Santen decision is to be considered "retained EU case law" and relevant to the "post-transition case law" was a recent decision of the UK Court of Appeal in Newron, in which the same court applied Santen in arriving at its decision, albeit in a slightly different context.

The UK Court of Appeal aligned with the CJEU on SPCs in its Merck decision

Useful link
Young v Bristol Aeroplanes Co Ltd [1944] KB 718 (PDF), Incorporated Council of Law Reporting for England and Wales (ICLR): dycip.com/young-bristol

Case details at a glance
Jurisdiction: England & Wales
Decision level: Court of Appeal
Parties: Merck Serono SA (appellant) v The Comptroller-General of Patents, Designs and Trade Marks (respondent).
Date: 28 January 2025
Citation: [2025] EWHA Civ 45
Decision: dycip.com/2025-ewca-civ45

Related webinar: SPC case law

SPC Case Law & Strategic Insights Webinar, 1pm 10 June 2025
Garreth Duncan presents the latest developments in SPC case law: dycip.com/webinar-spc-jun2025

In view of the above statutory instrument, the court in the present case concluded that it was bound by Newron (and thus Santen) and therefore had no power to depart from this CJEU judgment. For this reason alone, the Court of Appeal dismissed Merck's appeal.

As part of its decision, the court, and in particular Lewison LJ, noted that there are exceptions to this principle of a court being bound by its own decision as set out in the commonly cited Young v Bristol Aeroplanes Co Ltd [1944] KB 718. These exceptions are:

1. the court is entitled and bound to decide which of two conflicting decisions of its own it will follow;

2. the court is bound to refuse to follow a decision of its own which, though not expressly overruled, cannot stand with a decision of the Supreme Court; and

3. the court is not bound to follow a decision of its own if it is satisfied that the decision was given per incuriam (that is, through lack of due regard to the law or the fact).

Lewison LJ held that none of the above exceptions applied in this case, such that the court was bound by its own decision in Newron.

Was Santen wrongly decided such that the Court of Appeal should depart from it?
Despite the above, the UK Court of Appeal also considered whether, even if it was not bound by Newron (and thus Santen), it would arrive at the conclusion that Santen has been wrongly decided such that the UK Court of Appeal should depart from it. Some had hoped the UK Court of Appeal would steer away from the CJEU ruling in Santen so that it would be possible to obtain SPCs for new therapeutic applications of previously authorised active ingredients.

The Court of Appeal held that even if it could diverge from Santen, it would not in the present circumstances.

The Court of Appeal's decision in this regard referred to the fact that any criticisms of the Santen decision by Merck were "unsound" and that Santen brought a sense of coherence to the assessment of Article 3(d) of the SPC Regulation. The Court of Appeal also suggested that the Santen decision substantially reduced the legal uncertainty caused by Neurim, where the CJEU somewhat surprisingly suggested that contrary to previous decisions, SPCs could be available for second medical uses of previously authorised products in some circumstances.

Related article
"Sheep don't follow authorisation: CJEU decides on Neurim SPC application", 24 July 2012: dycip.com/neurim

Indeed, the Court of Appeal referred to the deficiencies of the Neurim decision in terms of complicating the SPC assessment process, failing to indicate how it aligns with previous case law in this area and failing to "face up to the wholesale reorganisation of the way the regulation would need to be interpreted" based on this decision.

Arnold LJ further highlighted that since SPC law applicable in the UK post-Brexit has not been amended in any relevant respect from the EU SPC Regulation that previously had direct effect in UK law, it follows that it is the will of the UK Parliament that the legislation continue to be harmonised with that of the EU. As a result, the UK courts should continue to interpret the legislation in harmony with the CJEU unless convinced that the CJEU's interpretation is wrong.

Moreover, Lewison LJ referred to the following six factors relevant for reaching a conclusion as to whether, if it could, the Court of Appeal would depart from the Santen decision as applied in Newron:

1. The power to depart from a previous decision should not be invoked merely because the later court thinks that the earlier decision of that court was wrong.

2. The power should be more sparingly used where the point in issue is the interpretation of a statutory provision, rather than the scope of a principle of the common law.

3. It is relevant to consider whether the earlier decision has been criticised by academics, judges or practitioners.

4. Where the provision in question concerns a legal instrument with international application, it is relevant to consider how that instrument has been interpreted in other jurisdictions.

5. It is relevant to consider whether there has been a relevant change in circumstances since the earlier decision, such as changes in public policy.

6. It is relevant to consider whether the earlier decision defeats the purpose of the provision in question or has given rise to incoherence in the law.

Lewison LJ held that none of these factors applied to this case, such that it would not be suitable to depart from the Santen decision as applied in Newron.

Implications of [2025] EWCA Civ 45

The decision of the Court of Appeal acts to maintain the status quo when it comes to the assessment of Article 3(d) of the SPC regulation, which will therefore continue to bar SPCs based on second medical uses of previously authorised active ingredients. In indicating that the Court of Appeal would follow the decision in Santen, the key question when considering an SPC filing strategy remains whether the active ingredient (or combination of active ingredients) has ever before been the subject of an MA for any therapeutic application. If this is the case, it appears likely that the UKIPO will maintain that an SPC is not available.

Of course, it is possible that Merck may seek permission to appeal the decision from the UK Court of Appeal. In this instance and unlike in the present case, the UK Supreme Court would have the option to depart from the Court of Appeal's previous decision in Newron, and thus the precedent set by Santen. We will continue to monitor the case and keep you informed of developments.

Author:
Oliver Cartwright & Garreth Duncan

SPCs in Europe
What's round the corner?

The European Union is planning sweeping changes to supplementary protection certificates (SPCs), the most significant reform to the SPC system since it was introduced in the early 1990s. SPCs extend the term of patents for medicines and plant protection products which require a marketing authorisation (regulatory approval) before they can be put on the market.

> The term extension conferred by a supplementary protection certificate is up to five years, making SPCs hugely valuable to the pharmaceutical and agricultural sectors.

How does the current SPC system work and why does the EU wish to change it?
Although the legal basis for SPCs is EU regulations, there is no current EU-wide SPC filing system. All SPCs must be filed separately at the national patent office of each country where SPC protection is required. The EU considers that the current SPC system is costly and creates legal uncertainty for applicants, and that the progress of SPCs is difficult for third parties to monitor compared with basic European and national patents.

What changes are the EU proposing?
The EU is proposing to introduce a centralised system of filing and examination of SPC applications. The use of this system will be mandatory where (as for most medicines) the basic patent relied upon is a European patent and the marketing authorisation is a centralised one issued by the European Medicines Agency (EMA). As detailed below, the centralised examination procedure will result in a binding examination opinion and subsequent "bundle" of SPCs then granted by national patent offices.

Alongside this, the EU plans to introduce a unitary SPC, which will be based on a unitary patent and a centralised EMA marketing authorisation, and valid in the EU countries participating in the Unified Patent Court (UPC) system. It will be possible to file a single, combined SPC application requesting grant of a unitary SPC together with a "bundle" of national SPCs for those countries outside the UPC system. This will also undergo the centralised examination procedure.

How is the EU proposing to do this?
In order to bring the proposed changes into effect, the EU has proposed four new regulations, two each for medicines and plant protection products. For each type of product, the proposed legislation will amend the existing SPC Regulation to allow for centralised examination, and a new SPC Regulation will be brought in alongside it to allow for unitary SPCs.

Who will administer the centralised filing and examination procedure?
Under the current proposals, the European Union Intellectual Property Office (EUIPO) will administer the new centralised filing and examination system. The EUIPO currently handles only EU trade marks and EU registered designs, and has no experience in patent or SPC matters. In an attempt to allay concerns regarding this lack of experience, the EU is proposing that SPC applications will be examined by a panel of three examiners, one from the EUIPO and two specialist SPC examiners from the national patent offices.

The panel will issue a positive or negative examination opinion. This opinion will be binding on national patent offices: they must grant or reject the SPC based on it. There are only limited exceptions, for example, when the basic patent is no longer in force in that country.

Will there be any changes to substantive SPC law?
No changes are proposed to the present four criteria for grant of an SPC as reflected in Article 3 of the medicines and plant protection SPC Regulations. However, some of the existing case law on SPCs of the Court of Justice of the European Union (CJEU) is reflected in the recitals of the proposed legislation. Under EU practice, recitals can be used to interpret the intention and purpose behind the law.

Two important substantive changes are being proposed:

1. The existing practice which allows two SPCs to be granted for the same product to different patent holders will continue, but only if those patent holders are not economically linked. However, it is not yet clear how linked they must they be for this provision to apply. Subsidiaries of the same overall parent company would likely fall under this provision, but an otherwise unattached licensor and licensee may not.

2. As with the current system, the SPC will still be granted to the holder of the basic patent. However, if the product is the subject of a marketing authorisation held by a third party, an SPC will not be granted without the consent of that third party. The practice of patent holders filing SPCs without the marketing authorisation holder's consent has been a controversial one, and it appears the EU wishes to prevent it in the future.

How can third parties object to SPC applications under the new system?
Under the current proposals, there will be two means for third parties to object to SPC applications:

1. Third party observations will be allowed within three months of the SPC application being published. As with the current European patent system, filing observations will not make the observer a party to the proceedings.

2. Pre-grant oppositions may be filed within two months of the examination opinion. The grounds for opposition may only be the four criteria under Article 3. The proposed pre-grant opposition system has raised concerns that third parties will file oppositions and delay the opposition procedure to prevent SPCs being granted before the basic patent expires, enabling them to get products on the market while the SPC is still pending.

Related webinar: SPC case law

SPC Case Law & Strategic Insights Webinar, 1pm 10 June 2025
Garreth Duncan presents the latest developments in SPC case law:
dycip.com/webinar-spc-jun2025

Who will be able to represent SPC applicants under the new system?
National patent attorneys, European patent attorneys, and lawyers authorised to practice before member state courts and established in the EU will all be able to represent SPC applicants. With offices in both the UK and Germany, D Young & Co will be able to act for applicants in this regard, even if the EUIPO becomes the filing office for centralised SPCs.

Will paediatric extensions of SPCs still be possible under the new system?
Medicines which have undergone paediatric studies in compliance with a paediatric investigation plan (PIP) are currently entitled to a further six-month extension of the SPC, regardless of the outcome of the paediatric studies.

This will continue under the new system, will provisions that largely parallel those proposed for SPCs. In particular, it is proposed that paediatric extensions applications must also be filed at the EUIPO if the EMA was the regulatory route for agreeing the PIP and confirming that the studies have been carried out in compliance with it.

When are the changes likely to come into force?
The EU Parliament approved the four draft Regulations in February 2024. Under the EU's normal legislative procedure, the draft legislation has now reverted to the EU Council and Commission for their review.

Although it is difficult to predict exactly when the legislation will come into force, it is possible that it will do so late 2025 or 2026. We will keep you informed of developments as to its progress.

Author:
Garreth Duncan

EPO

Updated EPO guidelines 01 April 2025

The 2025 European Patent Office (EPO) guidelines, which supersede the March 2024 version, entered into force on 01 April 2025. Having reviewed the previews of the 2025 guidelines, below we discuss three key updates.

Digital transformation
The EPO is continuing with its digital transformation and, as part of that, it is no longer possible to file by fax. In its place, the EPO is enhancing its use of MyEPO Portfolio, the EPO's new digital tool for managing communications and correspondence with representatives.

As part of the digital transformation, the EPO is encouraging the use of MyEPO portfolio by financial incentives; for instance, if certified copies of a European patent application are requested using MyEPO, then no fee needs to be paid. Accordingly, there are various amendments throughout the guidelines to delete references to faxes and include references to MyEPO Portfolio, in particular to highlight the financial incentives of using MyEPO Portfolio.

Continuing the theme of digital transformation, the guidelines have been amended to add that it is also now possible during consultations for examiners and representative to have real-time interactions on documents.

Artificial intelligence
With the increasing interest in using artificial intelligence (AI), the EPO has amended the guidelines to remind parties and their representatives that, regardless of whether a document has been prepared with the assistance of AI, they are responsible for the content of their patent applications and submissions to the EPO and for complying with the requirements of the European Patent Convention (EPC).

Further guidance has been added regarding the patentability of AI and machine learning (ML) based inventions. These revisions to the guidelines reflect the current approach of EPO examiners assessing AI and ML based inventions.

Unitary patent
A new section has been added to the guidelines which dedicated to the unitary patent. This new section is based on the Unitary Patent Guide (which the EPO plans to abolish) and outlines the practice and procedure involved in obtaining, maintaining and managing unitary patents.

The consultation on the EPO guidelines is open for comment until 07 April 2025.

Author:
Stephanie Wroe

Useful links
Preview of the EPC Guidelines (PDF):
dycip.com/epc-guidelines-draft

Preview of the PCT-EPO Guidelines (PDF):
dycip.com/pct-epo-guidelines-draft

Preview of the unitary patent guidelines (PDF):
dycip.com/upc-guidelines-draft

The 2025 EPO guidelines entered into force on 01 April 2025

And finally...

D Young & Co news

Promotions & appointments
01 April 2025

D Young & Co senior promotions April 2025

We are delighted to acknowledge the expertise and commitment of our IP professionals with a series of senior promotions across our UK and German offices.

We congratulate Chartered and European Patent Attorneys Martin Bicker and Arun Roy on their promotions to partner within our electronics, engineering & IT team. Martin is experienced in drafting and prosecuting patent applications over a wide range of technologies including electronic devices, sports and exercise equipment, process control systems, and medical devices. Arun's specialises in the fields of image processing, broadcasting, audio/video standards, mobile telecommunications and financial transaction systems.

Both Arun and Martin bring significant experience to their practice area and their leadership will further strengthen the success of the D Young & Co partnership.

In Germany we are pleased to announce the promotion of German and European Patent Attorney Mathias Smolarski to Senior Associate.

In the UK, patent attorneys from our biotechnology, chemistry & pharmaceuticals team Joseph Flood, Rebecca Price, and Nathaniel Wand, as well as patent attorneys Ben Hunter and Samuel Keyes of our electronics, engineering & IT team, have been promoted to Senior Associate. Sean McCann, Keith Daly, William Smith, Oliver Cartwright, Gemma Seabright, Leon Harrington, Matthew Gallon, and Szymon Pancewicz, have been promoted to Associate.

As we continue to grow and evolve in response to client needs, we are proud to support the career progression of our talented professionals. Congratulations to all on their achievements!

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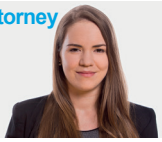

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