



HOFFMANN EITLE

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Subsequent Request For Patent Amendment as a Defence in UPC Revocation Actions

In proceedings before the UPC for the revocation of a patent, the defendant is required to present a robust and expeditious defence. The Rules of Procedure establish strict timeframes, stipulating that the statement of defence must be filed within a period of two months following the service of the statement for revocation, according to Rule 49(1) RoP. The UPC places significant emphasis on a front-loaded procedure, which requires that all potential defence arguments be presented in the statement of defence, rather than in a subsequent brief. As part of the statement of defence, the Rules of Procedure provide for the possibility of an application to amend the patent, which may be conditional (Rule 30 RoP). This defence is of particular relevance in the context of revocation proceedings.

The Paris Central Division was presented with the opportunity to clarify the prerequisites for a subsequent request for patent amendment as a defence in a revocation action. In addition to the revocation action, there were parallel counterclaims for revocation before a Local Division. The Paris Central Division stated that a later filed counterclaim for revocation in a parallel infringement action is not a sufficient justification for a subsequent request for patent amendment in the original revocation action.¹

I. Facts of the case

In two Orders,² the Central Division dealt with determining the admissibility of a request for patent amendments in ongoing proceedings between Meril Life Sciences and Edwards Lifesciences, both of which are prominent players in the medical technology industry.

A revocation action was commenced by Meril Italy srl (Claimant) against EP 3 646 825 (EP'825) before the Central Division of the UPC at the Paris seat (CD) on 4 August 2023. The registered proprietor of patent EP'825, Edwards Lifesciences Corporation (Defendant), filed its statement of defence on 16 October 2023, together with a request to amend the patent based on 9 conditional amendments and 84 auxiliary requests (in this article referred to as the "Original Amendment Request").

In response to Claimant's reply to the statement of defence, Defendant filed a rejoinder to the reply on 22 January 2024, requesting leave to amend its case in accordance with Rule 263(1) RoP and filing a new main request to amend the patent, together with 41 auxiliary requests based on 9 individual amendments (in this article referred to as the "Subsequent Amendment Request").

Defendant set forth the rationale for changing its requests for patent amendment with reference to the co-pending infringement action initiated by Defendant before the UPC Munich Local Division (LD) based on EP'825 against two affiliates of Claimant, namely Meril Life Sciences Pvt Ltd. and Meril GmbH (UPC_CFI_15/2023). In response to the infringement action before the LD, the affiliates of Claimant filed a counterclaim for revocation. In turn, Defendant (claimant in the infringement action) filed a request to amend the patent. The counterclaims for revocation before the LD were based on grounds that were not identical to those of Claimant's revocation action before the CD. Defendant further explained that it was compelled to align its requests to amend the patent in both proceedings to ensure consistency and procedural economy.

¹ These orders are also addressed in the article "Defense in UPC revocation actions – Admissibility of subsequent requests for patent amendment" authored by Dr. Dirk Schüßler-Langeheine, Dr. Thorsten Bausch and Dr. Katrin Winkelmann published on 22 August 2024 in GRUR Patent 2024, 310.

² UPC CFI CD Paris, Order of 27 February 2024 – CFI 255/2023 – Meril Italy srl v. Edwards Lifesciences Corporation and UPC CFI CD Paris, Order of 30 April 2024 – CFI 255/2023 – Meril Italy srl v. Edwards Lifesciences Corporation.

The proceedings continued with Claimant requesting on 8 February 2024 that both the Original and the Subsequent Amendment Request be refused. In response, Defendant requested on 15 February 2024 that the Subsequent Amendment Request be allowed on the grounds of Rule 30(2) RoP.

The judge-rapporteur referred the case to the panel, which subsequently rejected the Subsequent Amendment Request.

Following an interim conference, Defendant lodged a further application to amend the patent on 12 April 2024, comprising one unconditional amendment and six auxiliary requests (in this article referred to as the "Second Subsequent Amendment Request"). Meanwhile, the counterclaims were all referred to the seat of the CD.

In a statement of 26 April 2024, Claimant left the admission of the Second Subsequent Amendment Request at the discretion of the Court.

The judge-rapporteur permitted the Second Subsequent Amendment Request on 30 April 2024 and granted the Claimant a period of one month to file an additional reply.

II. Decisions of the CD

1. Applicable rules for subsequent patent amendments

Regarding the admissibility of Defendant's change of the application to amend the patent, the CD discusses the interrelation between Rule 50 and Rule 263 RoP. While Rule 263 RoP grants a party the right to "change its claim" or "amend its case", Rule 50 RoP, which pertains to patent amendments, expressly refers to Rule 30(2) RoP. This latter rule specifies that the admissibility of any "subsequent request to amend the patent" is contingent upon the Court's permission.

In accordance with the CD, a request for a subsequent amendment to the patent is subject to Rule 50(2) RoP in conjunction with Rule 30(2) RoP and may only be granted with the permission of the Court. The term "subsequent" is to be understood as any request made after an original application to amend the patent. The CD goes on to establish that Rule 30(2) RoP gives the Court discretionary powers to decide whether to admit a subsequent request for patent amendment even after the closing of the written procedure.

In the final Decision,³ the CD further stated that for a subsequent patent amendment to be admissible, the first patent amendment must be admissible. A subsequent request for a patent amendment inherently presupposes that a previous request was validly submitted. Consequently, the original request for a patent amendment must be submitted by the designated deadline, which is two months following the service of the statement for revocation. Additionally, the information outlined in Rule 30(1) (a), (c) RoP must be provided, including an indication of whether the proposed amendments are conditional or unconditional, as well as an explanation as to why the amendments satisfy the requirements set forth in Articles 84 and 123(2)(3) EPC and why the proposed amended claims are valid.

2. Sufficiency of justification for subsequent amendment requests

In the cases under consideration, the CD has determined that Defendant's Subsequent Amendment Request was not sufficiently justified, whereas the Second Subsequent Amendment Request was. It is the responsibility of the patent proprietor to provide a rationale for the necessity of further amending the patent.

³ UPC CFI CD Paris, Decision of 19 July 2024 – CFI 255/2023 – Meril Italy srl v. Edwards Lifesciences Corporation.

It is important to note that the UPCA does not preclude deviating decisions on the validity of the same patent per se, as long as different subject matters are concerned, for example due to different parties, different claims, or deviating grounds for revocation. It is not expected that the patent proprietor will align all of its defences across all potentially pending proceedings. In the case at hand, the Subsequent Amendment Request was a reaction to revocation counterclaims in a different proceeding on different grounds, and thus falls outside the scope of the current proceedings before the CD.

Moreover, the CD is not convinced that the Subsequent Amendment Request would promote procedural economy. It might rather result in a prolongation of the proceedings and an increase in the number of parties' submissions and judicial actions.

The Second Subsequent Amendment Request, however, contributes to the procedural efficiency of the proceedings by reducing the number of amendments to only one unconditional request and six auxiliary requests. Furthermore, Claimant did not object to the Second Subsequent Amendment Request, which might have been a result of the judge-rapporteur's possible attempt to negotiate an agreement of the parties on the proposed modifications to the claims during the interim conference.

The CD also corroborated that the Original Amendment Request was submitted in a timely manner and in accordance with the requirements set forth in Rule 50 RoP. Despite the considerable number of amendments included in the Original Amendment Request, it does not appear to be an unreasonable request, particularly given the intricate nature of the case, the significance of EP'825 and the interrelationship with other judicial and administrative proceedings.

III. Practice notes

1. Handling of parallel validity challenges

With a revocation action pending before the CD and a parallel infringement action with revocation counterclaim(s) pending before a local division, the parties and local division need to decide on the way forward. This is due to the potential for inconsistencies in decisions among the different divisions of the UPC. The optimal course of action may be contingent upon several factors, including the extent to which the validity attacks diverge from one another, the timing of the pertinent legal actions, the potential interconnection of the involved parties, and other considerations. From the perspective of defence strategies, it may be advantageous for the patent proprietor to have the revocation counterclaim consolidated with the co-pending stand-alone revocation action before the central division.

In terms of consistency, the CD notes that divergent decisions rendered by different divisions are not inherently inconsistent, provided that the subject matter of the relevant cases also differs. The CD's rejection of Defendant's attempt to align its defence with the co-pending revocation counterclaim results in a deviation in subject matter between the two proceedings, such that there may in fact be no (risk of) inconsistent decisions. However, patent proprietors may encounter difficulties in defending their patents in overlapping, co-pending proceedings, particularly if (a group of) competitor companies make excessive use of deviating invalidity attacks.

2. Strategic foresight needed for patent amendments

The current decisions illustrate that a patentee is exposed to considerable risks in relation to patent amendments. It is possible that multiple, even partially concurrent revocation actions may emerge over the course of a patent's lifetime. In such instances, the patentee is exposed to the risk that defending the patent with a particular claim amendment in one proceeding may preclude broader or divergent amendments in other proceedings.

Those accustomed to a more flexible approach to subsequent patent amendments (before national courts or the EPO) will have to adapt their litigation strategies to align with the strict timeframes of the UPC. It is therefore imperative to adopt a meticulous and strategic approach when considering amendments to patents. The drafting and filing of requests for amending the patent, both initial and subsequent, can be pivotal in determining the outcome of a case. Consequently, they require considerable expertise and a broad foresight, including the anticipation of potential parallel and/or future proceedings before the UPC and/or national courts or the EPO. This necessitates, on the one hand, a comprehensive grasp of the specific technical field in general and, ideally, also of the evolution of the patented invention in particular. On the other hand, a high level of expertise in the procedural intricacies of filing and amending auxiliary requests in view of the complex interplay between the regulations relevant for proceedings before the UPC is also required. It is of utmost importance that these two specialised technical and legal competencies are closely interlinked, given the tight deadline regime of the UPC.

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At the Front-Line of Europe's New Patent Court: the First Hearing of a Main Action at the UPC Paris LD

The UPC has been held out as making patent litigation in Europe more accessible, more consistent, and more effective for both domestic and international parties. The first hearing of a main action before the Paris Local Division was undertaken by two partners of Hoffmann Eitle alongside a team from Bird & Bird's Paris office. Their experiences reveal the UPC user experience as a predominantly written procedure, with the oral hearing a last chance to focus the Court's attention on the parties' key arguments, and demonstrate the benefits to litigants of fielding a mixed team of patent attorneys and attorneys at law.

From its legal establishment in February 2013, and in particular since it opened its doors to litigants in June 2023, much has been written about how Europe's new Unified Patent Court would be expected to operate. With its first hearings and decisions on provisional measures in June 2023, what had been merely theory became practice. However, until the summer of 2024, litigants and observers could only imagine how the UPC would conduct an oral hearing of a full action on the merits, addressing together infringement, validity, and ancillary legal issues. The present author was privileged to be part of the advocacy team for the UPC's second ever main action hearing, and the first before the Paris Local Division (LD).



David Sproston and Mark Jones

The UPC has provision for an interim conference between the parties and the Court to enable the Court *inter alia* to identify the main issues and establish a schedule for the further proceedings. In the present action,⁴ the interim conference was held just over a week before the oral hearing, and was based on a memorandum issued a few days earlier setting out the Court's high-level understanding of the issues in dispute, and a proposed schedule for the day allowing for just under six hours of pleading.

During the interim conference, some reallocation of the pleading time between the issues was allowed, but no extension overall, with the schedule intended to be strictly observed. The parties also agreed to file bundles with the Court shortly before the hearing reproducing parts of the evidence and written pleadings to which they intended to refer, and to exchange these with their counterparty on the day of the hearing. Given the relatively compressed pleading times, this measure was important to avoid losing time in navigating the otherwise unwieldy Court file when pleading.

The hearing itself ran essentially as timetabled, with the introduction by the Court confining itself to announcing the subject-matter of the dispute and the parties, and then inviting each party in turn to present. The compressed timetable forced each party to deliver a focussed presentation of only the key lines of argument and evidence in their favour, and on the key perceived defects and weaknesses in their counterparty's case, with little opportunity even for rebuttals.

⁴ Case number UPC_CFI_230/2023.

With pleadings and evidence on file for each side extending to hundreds of pages of technical and legal reasoning, an initial impression might have been that the oral hearing merely scratched the surface of the case. However, even though the legal judges on the panel typically gave little away as to the Court's own opinion of the case, a small number of probing questions from the technical judge, former EPO Board of Appeal member Alain Dumont, revealed a precise understanding of the legal and technical issues in dispute at the heart of the parties' respective validity cases.

At the close of the procedure, the Court announced a schedule for handing down its written decision in early July 2024, slightly in excess of one year after the Court opened its doors. That decision has been discussed in detail elsewhere, and will not be addressed in this article, except to mention that the Court's analysis of the case in that decision was, as might have been expected, not based predominantly on the parties' presentations during the oral hearing, but rather on the written pleadings, refined through the lens of the presentation before the Court.

So what can we learn from this experience? Firstly, the UPC is, as anticipated, a highly front-loaded system, with the initial pleadings exchanged by the parties defining their respective positions, the further written pleadings refining these positions, and the oral hearing representing an opportunity to focus the Court on two or three key arguments per issue in dispute. Those practicing in other venues who are used to, for example, the back-and-forth pleading and counter-pleading of European Patent Office oral proceedings or the detailed exploration of the relevant law and evidence in a British High Court trial will need to adjust their expectations accordingly. As in every endeavour, proper preparation is key, and to get the most out of the oral hearing, advocates will need to develop a focussed and comprehensible style which assists the Court in identifying and resolving the key issues.

In contrast, the written pleadings exchanged before the oral hearing do not represent merely an opportunity to set out a position and lay traps for the counterparty, but themselves are to be the main opportunity to persuade the Court. The compressed timetable for exchanging these pleadings, beginning with an initial

three months between statement of claim and statement of defence and counterclaim, and then allowing progressively shorter periods for exchanging replies and rejoinders, requires a careful balance to be struck between thoroughness and clarity of argument, as there will not be time in the oral procedure to walk the Court through every credible line of argument and clarify misunderstandings or oversights. This is particularly in view of the relatively limited role of the interim conference, which at least before the Paris LD was limited to agreeing timetables and topics, and involved no active case management of the sort seen in other jurisdictions.

That said, the presence of technical judges in each case involving a counterclaim for revocation, many drawn from the ranks of those who have substantial experience before the EPO, means that advocates will need to be well prepared to answer searching technical questions from the bench, as well as to clearly outline their clients' positions. In this regard, the adoption of mixed teams of lawyers and patent attorneys for advocacy before the UPC delivers substantial advantages in engaging with panels with mixed technical backgrounds and representing a fusion of different legal principles.

The UPC has shown that the justice it delivers matches its ambition to be a fast and powerful forum for patent dispute resolution in Europe. Only time will tell whether it manages to deliver a fair and consistent jurisprudence against a procedural timetable which seems to favour rightsholders over accused infringers. Those who might, through their business activities in Europe, find themselves enmeshed in an UPC action must recognise the strong asymmetry inherent in the front-loaded UPC procedure, and that having their day in court is no substitute for a powerful written defence and counterclaim.

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The UPC Takes an EPO-Inspired but Independent Approach on Validity

The first revocation decision by the UPC came out at around the same time as the first main infringement decisions by its Local Divisions (LD) in Dusseldorf and Paris which also decided on validity.⁵ The decisions confirm the favorable impression from provisional injunction proceedings and show that this Court is fully up to the task. On validity, the UPC takes a sober, fresh and critical look at the patents at stake.

The Central Division (CD) Munich held Amgen's patent EP 3 666 797 regarding the use of a PCSK9-inhibiting antibody invalid for lack of inventive step and ordered Amgen to reimburse a total of EUR 2,750,000 in legal cost.⁶ This outcome is not surprising in view of the fact that the Board of Appeal (BoA) at the European Patent Office had previously revoked the parent patent (EP 2 215 124) based on similar considerations.⁷ While the CD's approach largely follows the BoA case law, there are some differences. Below are six lessons taken from the CD's decision.

Lesson 1: Claim interpretation – The description matters, always

Headnote 1 summarizes the CD's general approach on claim interpretation:

1. When interpreting a patent claim, the person skilled in the art does not apply a philological understanding, but determines the technical meaning of the terms used with the aid of the description and the drawings. From the function of the individual features in the context of the patent claim as a whole, it must be deduced which technical function these features actually have individually and as a whole. The patent description may represent a patent's own lexicon.

This approach is based on Art. 69 EPC and the Protocol on the Interpretation thereof and is fully in line with the established national jurisprudence in the UPC member states, notably with German case law. Each claim

feature is open to interpretation, and its technical meaning must be determined with the aid of the description and drawings (if any). The interpretation should be oriented to the function that the individual features have in the context of the patent claim. The description may represent a patent's own lexicon, meaning that terms of a claim may be given a different meaning than they usually have, if the description so requires.

The latter approach may have consequences that patent practitioners all over the world should never underestimate. Many practitioners, particularly in the US, draft patent applications in the least limiting way possible. While this may help to secure a broad scope of protection, it has the inevitable consequence that the claim gets vulnerable when its validity is challenged. So, better think twice before using boilerplate language and open-ended terms such as "comprising" ad infinitum. For example, if the claim, as here, requires the "binding" of an antibody to the "catalytic domain" of a protein named PCSK9, and is supposed to "prevent or reduce" the binding of LDLR to PCSK9 so as to lower blood cholesterol levels, a court may very well consider, in the absence of a narrower definition of "binding" in the description, that the term "binding to the catalytic domain" does not exclude the additional binding to other parts of the protein. And if you write in the description that "prevent or reduce" the binding of LDLR to PCSK9 means the reduction of the quantity of binding partner by at least about 1-20% and up to 98-99% or more, then a court will draw the broadest possible inferences against you on validity.

⁵ Dusseldorf LD, Franz Kaldewei v. Bette, decision of 3 July 2024 (UPC CFI 3-2023) and Paris LD, DexCom v. Abbott, decision of 4 July 2024 (UPC CFI 230/2023).

⁶ The CD Munich combined the proceedings in UPC CFI 1/2023, a stand-alone revocation action brought by Sanofi, and UPC CFI 14/2023, a counterclaim for revocation brought by Regeneron that was referred to the CD Munich by the LD Munich from the parallel infringement action filed by Amgen (UPC CFI 14/2023).

⁷ Technical Board of Appeal, decision of 29 October 2020 (T 0845/19).

Lesson 2: Priority will be determined according to the EPO's "gold standard"

The CD Munich put this in its second headnote as follows:

2. A claimed invention is to be considered the "same invention" as meant in Article 87 EPC (priority right) if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole.

and explicitly referred to G2/98 in the reasons of the decision. National courts across Europe generally follow this approach. But there are differences on how exactly the famous words "directly and unambiguously, using common general knowledge" are filled with life. The CD Munich did not follow a literal or photographic approach in this regard, instead focusing on the skilled person's technical understanding. This allows the court to be a bit more flexible than the EPO, similar as German Courts usually are. For example, the CD Munich did not hold it against the patentee that Fig. 26, which explicitly depicted the sequence of the catalytic domain of PCSK9, was only disclosed in the fourth priority document (P4). The court opined that Fig. 26 does not contain any new information with respect to the amino acid sequence of the catalytic domain of PCSK9 relative to the whole contents of the third priority application (P3) on which Patentee relied.⁸

Lesson 3: The UPC will not apply the problem-solution-approach as developed by the EPO

While the CD's decision includes a discussion of inventive step in terms of a problem-solution framework, it does not rigorously proceed according to the EPO's problem-solution approach, which generally requires the determination of the "closest prior art" as a first step. In contrast, the CD merely requires that the analysis starts from a "realistic starting point", as succinctly stated in Headnote 3:

3. The assessment of inventive step starts from a realistic starting point in the prior art. There can be

several realistic starting points. It is not necessary to identify the "most promising" starting point.

Although widely applied, the EPO's approach is not required by the European Patent Convention and some BoA decisions do not religiously follow this approach either. It will be interesting to see whether the EPO will now reconsider and modify its approach somewhat.

In the case at issue, it seemed uncontroversial that prior art reference "Lagace" was a possible and realistic starting point. Hence, the Court proceeded from there, even though the EPO had used a different reference ("Graham") as the closest prior art. While the CD acknowledged this fact, it was satisfied that Lagace was a realistic starting point for the analysis of obviousness and found that the invention was obvious in view of Lagace. In the Court's own words:

Having concluded that Lagace is a realistic starting point, the Central Division does not have to examine in detail whether another starting point, in particular Graham as suggested by the Defendant, is "more promising". As set out above, the claimed subject matter has to be inventive over any realistic starting point.

Lesson 4: For the UPC, "obvious" is the "next step"

The notion of a next step, which is usually the obvious one, is perhaps somewhat "UPC-special", but the CD decided to follow the Court of Appeal's approach in the 10x Genomics case.⁹

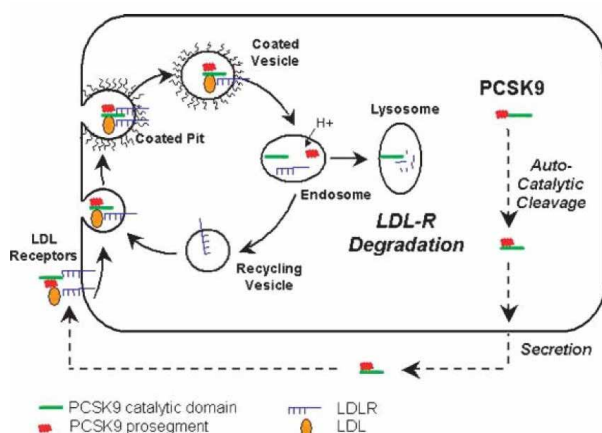
4. In general, a claimed solution is obvious if the skilled person would be motivated to consider the claimed solution and would implement it as a next step in developing the prior art. It may be relevant whether the skilled person would have expected any particular difficulties in taking any next step(s). The absence of a reasonable expectation of success (or more in general: non-obviousness) does not follow from the mere fact that other ways of solving the underlying problem are also suggested in the prior art and/or (would) have been pursued by others. The decisive question that has to be answered is whether the claimed solution is non-obvious.

⁸ See reasons 7.11.

⁹ CoA, 10x Genomics v. NanoString, decision of 26 February 2024 (UPC CoA 335/2023).

It is still an open question how the UPC will decide in cases where more than one step is necessary to proceed from the “realistic starting point” to the claimed invention, particularly if there was a motivation to take more than just one step. A motivation seems to be required in any case, which as such is perhaps not very surprising.

In the case at issue, claim 1 (slightly simplified) pertained to a monoclonal antibody for use in treating or preventing diseases associated with an elevated cholesterol level, wherein the monoclonal antibody binds to the catalytic domain of a PCSK9 protein of the amino acid sequence of SEQ ID NO: 1, and prevents or reduces the binding of PCSK9 to LDLR. LDLR is the “low density lipoprotein receptor”, which mediates the uptake and degradation of cholesterol-rich lipoproteins in certain cells and thus lowers the blood cholesterol level. PCSK9 in turn acts by decreasing LDLR levels, as shown in the following schematic drawing taken from the decision:¹⁰



Amgen’s problem is that this mechanism was already known and, even more problematic, that Lagace also drew the following conclusion therefrom, which the court quoted in its decision:¹¹

If PCSK9 functions as a secreted factor as suggested by the current data, then additional approaches to neutralize its activity, including the development of antibodies to block its interaction with the LDLR or inhibitors to block its action in plasma, can be explored for the treatment of hypercholesterolemia.

The CD acknowledged that Lagace did not disclose any concrete antibodies that bind to the catalytic domain

of PCSK9 and block the interaction between PCSK9 and LDLR, nor does it actually use such antibodies for the treatment of hypercholesterolemia. However, it found that implementing this proposal by developing antibodies that block the interaction between PCSK9 and LDLR would have been the next step taken by the skilled person, and that pursuing this route, the skilled person would have ended up with antibodies as claimed without inventive skill.

Lesson 5: Inevitability is not required for obviousness

Amgen argued that it was not clear that a skilled person would have used antibodies to block PCSK9. For example, Graham, a paper authored by scientists working in this field, did not use antibodies, but antisense single oligonucleotides (ASOs). Thus, in Amgen’s view, the only implementation of an agent blocking PCSK9 did not use antibodies. However, the CD was not impressed by this argument, since antibodies had also been suggested for precisely this purpose by Lagace. While it would also have been possible for a skilled person to turn to ASOs, this did not render the use of antibodies inventive:

5. For assessing inventive step it is not the question whether the skilled person would inevitably arrive at the same result (falling within the scope of the claim or not). Rather, it is sufficient (but also necessary) for denying inventive step that the skilled person would without inventive contribution arrive at a result which is covered by a claim.

Lesson 6: Features that appear arbitrary do not generally support inventive step

There was disagreement about which effect was associated with the binding to the catalytic domain of PCSK9 as required by the claim. In the CD’s view, there was no apparent causal technical connection between the feature “binds to the catalytic domain” and the reduction of the binding of PCSK9/LDLR and, ultimately, the therapeutic effect claimed. The CD therefore was of the opinion that the feature of binding to the catalytic domain could not contribute to inventive step. The skilled person knew at the relevant date that PCSK9 consisted of three domains. Specifying

¹⁰ See reasons 8.48.

¹¹ See reasons 8.29.

that the antibodies bind to the catalytic domain, as interpreted by the skilled person, is an arbitrary choice out of several possibilities that cannot render the claimed subject matter inventive,¹² as summarized in the following headnote:

6. A technical effect or advantage achieved by the claimed subject matter compared to the prior art may be an indication for inventive step. A feature that is selected in an arbitrary way out of several possibilities cannot generally contribute to inventive step.

Conclusion

The first decisions set first clear signposts of how the UPC will deal with validity. For EPO and German practitioners there are practically no surprises so far. The UPC's approach on validity closely resembles the approaches taken by the EPO Boards of Appeal. This does not exclude that differences may emerge in the future. The fact that the UPC may not rigidly apply the EPO's problem-solution approach is unlikely to result in vastly different outcomes in practice.

Contrary to what some patentees may have hoped, the UPC is – at least so far – not more generous or patentee-friendly than national courts or the EPO, and certainly has no problem with invalidating patents.

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¹² See reasons 8.78.

Hamburg LD on UPC PI Proceedings: The EPO's View Matters

So far, about half of the UPC provisional injunction (PI) requests were rejected, most of them for lack of certainty of the validity of the asserted patent. A PI requires that the court considers it “more likely than not” – based on its own assessment – that the asserted patent will survive an invalidity attack. In a recent decision, the Hamburg LD did not find the asserted patent invalid but still refused a PI due to the “reasonable likelihood” that the EPO will adopt a different view on claim interpretation and will revoke the patent.

1. Background

Alexion Pharmaceuticals is the registered owner of EP-UE 3 167 888 B1 (EP'888) on the treatment of paroxysmal nocturnal hemoglobinuria patients with an inhibitor of complement component 5 (C5). The granting of the patent was preceded by arduous examination proceedings. The light chain sequence of the anti-C5 antibody that is described in the application comprises 22 amino acids that are not commonly found in mature antibodies and function as a so-called “signal peptide”. During examination, Alexion argued that the skilled person would immediately identify the signal peptide sequence and recognize its inclusion as an obvious error, because therapeutic antibodies generally do not contain a signal peptide. Using this argumentation, Alexion tried to obtain a claim that is directed to the antibody without the 22 erroneously included amino acids.

The EPO Examining Division (ED) disagreed that the skilled person would immediately recognize an error and consequently refused the application for added matter. The Technical Board of Appeal (TBA) agreed with the ED's assessment, and only allowed an auxiliary request directed to an antibody with the full sequence of the light chain, including the signal peptide sequence. The TBA considered that such a claim was sufficiently disclosed despite the presence of the signal peptide sequence, relying on Alexion's allegation that the sequence is “sufficiently distanced” from the parts of the antibody which are instrumental for its C5 binding properties that are required by the claim.¹³

Shortly after grant, Alexion filed separate PI requests against Amgen¹⁴ and Samsung Bioepis¹⁵, alleging that their products Bekemv® and Epysqli®, both biosimilars to Alexion's Soliris®, are infringing. Only Samsung Bioepis filed an opposition against EP'888.¹⁶

2. Decision

Before the Hamburg LD, Alexion argued that the asserted claim 2 on a pharmaceutical composition comprising the antibody should be interpreted to not require the signal peptide sequence. To support this claim interpretation, and in contrast to the position taken before the EPO, Alexion now presented evidence to show that an antibody with the full sequence, including the signal peptide, would not be able to bind C5 and therefore not be suitable to be used in a pharmaceutical composition.

Unlike the TBA, the Hamburg LD agreed that the skilled person would recognize that the light chain sequence includes a signal peptide, which should not be present in a therapeutic antibody, and that the skilled person would identify its 22 amino acids. The Hamburg LD thus found that the skilled person would interpret that the light chain of the claimed antibody consists of the disclosed sequence but without the signal peptide. According to the court, this understanding is in line with the description: the preferred embodiment is an antibody without the signal peptide sequence and this embodiment would only be covered under the court's interpretation.

¹³ TBA decision T 1515/20 of 21 September 2023, reasons 35.

¹⁴ UPC CFI 124/2024.

¹⁵ UPC CFI 125/2024.

¹⁶ Dr. Leonard Werner-Jones and Dr. Sebastian Giese of Hoffmann Eitle's biotechnology team represented the defendant in the proceedings before the Hamburg LD and in the EPO opposition proceedings.

The Hamburg LD noted that its interpretation is not irreconcilable with the TBA's interpretation since those proceedings were based on a different set of facts. In the EPO proceedings, no evidence was presented by Alexion that an antibody with the signal peptide sequence does not bind to C5. This new evidence was introduced by Alexion in the PI proceedings for the first time and remained undisputed. Also, the TBA did not have the opportunity to consider further new evidence that the skilled person could have noted the presence of the signal peptide and identified its sequence.

Based on this interpretation, the Hamburg LD did not consider that the patent was invalid for lack of sufficient disclosure. Indeed, if the claim is interpreted to cover an antibody that does not include the signal peptide sequence, there is no reason to doubt that the antibody binds C5 as required by the claim.

However, the Hamburg LD did not ignore the fact that the TBA had interpreted the patent differently. If the patent is construed – as the TBA had previously done – to require an antibody with the full sequence, including the signal peptide sequence, then the new evidence submitted by Alexion that the signal peptide will hinder the interaction with C5 results in the patent being invalid for a lack of sufficient disclosure.

The Hamburg LD noted that, in PI proceedings, it has to interpret the patent and assess its validity based on its own view, but where an opposition is pending at the EPO it also has to consider the likelihood of the opposition division revoking the patent. Although assessment of a patent's validity should generally be the same before the EPO and the UPC, if the court interprets the claim differently than the EPO, the outcome on validity can differ as well.

The court also considered that all attempts by Alexion to obtain a claim wording corresponding to the court's interpretation that the antibody does not include the signal peptide sequence had failed. The TBA only allowed claims on an antibody with the additional sequence, which based on Alexion's new evidence is insufficiently disclosed. Therefore, the court considered it "reasonably likely" that the EPO will maintain its claim interpretation and that the patent will be revoked in opposition proceedings due to a lack of sufficient disclosure. The court thus rejected Alexion's PI requests.

3. Open questions

This case highlights interesting aspects of the UPC system. The UPC is bound to apply the EPC, but this does not preclude that it arrives at different conclusions than the EPO. Also, UPC proceedings are designed to be faster than opposition proceedings. The question is: how can the UPC ensure that the possibility of different outcomes before the EPO are adequately considered?

For PI proceedings, the Hamburg LD developed a workable approach. When it is reasonably likely that the asserted patent will be revoked in opposition proceedings, a PI shall be rejected.

However, the approach may be different in main infringement proceedings. Under Art. 33.10 UPCA, the UPC may stay its proceedings when a "rapid" decision can be expected from the EPO. This provision mainly considers the timing of the expected decision and not its outcome. It is unclear whether the Hamburg LD will consider that a main infringement action shall be stayed where it is "reasonably likely" that the patent will be revoked although the EPO's decision is not "rapidly" expected. So far, the UPC has refused to stay infringement actions pending a decision in EPO oppositions where it was not "rapidly" expected without even considering the likelihood of a revocation by the EPO, and the UPC has emphasized its goal to ensure that the oral hearing shall normally take place within one year.¹⁷

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¹⁷ Rules of Procedure of the UPC, Preamble 7; CoA, decision of 28 May 2024, BITZER Electronics v. Carrier (UPC CoA 22/2024); Nordic-Baltic RD, decision of 20 August 2024, Edwards v. Meril (UPC CFI 380/2023).

Shall I Stay or Shall I Go – How to Interpret Claims Before the EPO

The EPO case law on claim interpretation is somewhat divergent. Whilst in some cases, it is required to refer to the description and the drawings at least in some circumstances, according to a different line of jurisprudence the claims are to be understood by themselves. In this article, we review this case law as well as a currently pending referral to the Enlarged Board of Appeal to clarify this divergence.

1. Claim interpretation under the EPC

With European patents, as with any other type of patent, the question of protective scope is of critical importance. Arguably the most relevant part of the EPC relating to this topic is Art. 69(1) EPC, reproduced below, together with the Protocol on the Interpretation of Art. 69 EPC:

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.

As is clear from this Article, the claims of a patent are of utmost importance when it comes to determining the protective scope offered by it. Yet, on the other hand, it is also made clear that the description and the drawings are to be referred to for interpreting the claims.

The question remains what the required reference to the description and the drawings means in practice. A further, related question is whether Art. 69(1) EPC is only to be relied on when assessing whether a claim meets the material requirements for patentability, such as novelty and inventive step, or whether it only comes into play when assessing protective scope for infringement and for testing whether the protective scope has been extended post-grant. If this Article is not to be relied on when it comes to assessing patentability, the legal basis for turning to the description and the drawings is less clear, with some Boards relying on Art. 84 EPC instead.

In the following, we will explore how the reference to the description in interpreting the claims is understood in different Board of Appeal decisions.

2. Can the description and drawings only be referred to when the claims are ambiguous?

In several cases, such as T 177/22 and T 918/21, it was found that the description and, if present, the drawings are always to be taken into consideration. On the other hand, some decisions, such as T 1473/19, make it clear that it is the claims that take precedence, in particular if there is wording that is only found in the description but not in the claims. Meanwhile, some decisions go as far as stating that the claims should always be interpreted on their own and without consulting the description and the figures (cf. T 675/22 and T 1924/00).

Therefore, there is a divergence in the case law as to the role to be played by the description and the drawings when interpreting a claim – should they always be referred to, should they be ignored, or should they only be referred to in certain situations?

3. Can definitions found in the description be relied on when interpreting features in the claims?

A further point of divergence in the case law is the question as to what happens if the description contains a definition or a similar explanation that could change the otherwise clear meaning of a term found in a claim.

According to some decisions, such as T 620/08 or T 1321/04, a term that is used in a claim should be given its normal meaning in the technical field, unless the description gives the term a special meaning. This line of case law, which emphasises that a patent document acts as its own dictionary, makes it clear that if a definition of a claim feature (or an equivalent explanation) is mentioned in the description of a patent document, this definition is to be taken into consideration when interpreting this feature, which can

lead to that feature being given a different meaning than would be apparent from reading the wording of the claim by itself.

Another line of case law emphasizes the primacy of the claims (cf. T 169/20 and T 450/20). According to those decisions, the description cannot be used for restricting or modifying what is claimed. If a definition is to be read into a claim, that definition needs to be recited in it. Absent such a recitation, it would be contrary to the principle of the primacy of the claims to read this feature into the claims.

4. The referral questions

As is clear from the above, there are a wide variety of different ways of interpreting Art. 69(1) EPC, starting from the question of whether it is indeed applicable for assessing patentability or only protective scope. To resolve these issues, which became relevant in a currently pending appeal case (T 439/22), the responsible Board of Appeal decided to refer questions to the Enlarged Board of Appeal, which handles this referral under the reference G 1/24. In essence, those questions ask for clarification as for the following points:

- 1) Are the provisions which require a reference to the description and the figures (that is, Art. 69(1) EPC and the Protocol on its interpretation) applicable when assessing patentability of a claim?
- 2) Are the description and the figures to be referred to generally or only when a claim contains an ambiguity?
- 3) Can a definition or similar statement in the description be disregarded when interpreting a claim?

The Enlarged Board of Appeal referral has the potential of harmonizing EPO practice when it comes to this fundamental aspect of European patent practice. With so many diverging approaches to reflect upon, it is difficult to predict how the Enlarged Board will decide this case. The Enlarged Board could look to the Japanese Supreme Court decision “Lipase” for inspiration relevant to points 1) and 2) above.¹⁸ In this decision, the Japanese Supreme Court took the view that for novelty and inventive step, the claimed subject matter must be determined based on the terms used in the claim, with the proviso that the description and drawings may be taken into account when doing so only under special circumstances. This approach is not dissimilar to that used in some EPO case law: time will tell whether G 1/24 aligns the EPO with Japan on these points.

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¹⁸ As suggested in “Claim Construction in Japan: Has Japan Provided a Response to the Referral Questions in G1/24?”, SAEGUSA & Partners, www.saegusa-pat.co.jp. July 2024.

Inconsistencies in the Application of the EPO Rules of Procedure of the Boards of Appeal Concerning Case Amendments

The EPO Boards of Appeal routinely apply their Rules of Procedure to hold elements of appeal cases inadmissible. In doing so, they sometimes come to inconsistent conclusions, or apply different principles, leading to a lack of legal certainty.

The Rules of Procedure of the Boards of Appeal (RPBA) determine the outcome of many appeal cases at the EPO. This is because the RPBA give the Boards wide discretion on whether to admit amendments in the appeal case (i.e. requests, facts, objections, arguments and evidence on appeal other than those on which the decision under appeal was based). Many patents stand or fall depending on whether these amendments in the appeal case are admitted into the appeal proceedings. For example, the Board may disregard a highly relevant objection or an otherwise allowable auxiliary request if they are found to be inadmissible amendments in the appeal case. Unfortunately, in exercising this discretion on admissibility, the Boards have arrived at different conclusions in similar situations, or apply different principles. This makes it difficult to predict, for any given case, whether amendments in the appeal case will be admitted. In the following, we compare and contrast several cases to illustrate this point.

Filing new auxiliary requests with the Grounds of Appeal responding to objections raised in the first instance but not followed by the Opposition Division (OD)

Similar scenarios arose in T 141/20 and T 614/21. In both cases, the opponent had raised several objections in the first instance, but the OD had not followed these in their preliminary opinion and decision, instead favouring Patentee's arguments. Patentee therefore had not filed auxiliary requests dealing with all these objections in the first instance, and did so only with their Grounds of Appeal. The Board then held that one of Opponent's objections was indeed valid. The

question was then whether the auxiliary requests filed on appeal dealing with the objection were admissible.

In T 141/20 reason 5.4.1, Board 3.3.10 held that the requests were admissible and maintained the patent on this basis. They reasoned that in the above scenario:

It is within the responsibility of the patent proprietor to counter objections that it considers to be unfounded by means of arguments only. If the opposition division follows these arguments in its decision, non-admission of auxiliary requests filed at the beginning of the appeal proceedings that take these objections into account cannot be justified under Article 12(6) RPBA 2020 solely on the grounds that the request could have been filed in the opposition proceedings. (translation of excerpt)

In contrast in T 614/21, at reason 3.2 Board 3.5.03 found the requests inadmissible in this scenario, stating that:

[...] a party prevailing in opposition proceedings is not relieved from its duty to timely prepare its case for the event of subsequent appeal proceedings. Indeed, each party should take into account that [...] the board of appeal may depart from the preliminary view expressed by the opposition division and adopt an opposing view. The patent proprietor should prepare the relevant "fallback positions" for that eventuality. There is however no right to present on appeal "fallback positions" that could have been presented already in the first instance proceedings. Anything else would be contrary to the primary purpose of the appeal proceedings as laid down in Article 12(2) RPBA 2020, i.e. the judicial review of the decision under appeal.

The reasoning of the Boards in these cases is difficult to reconcile: in one case the patentee in the first instance may opt to deal with objections by argument only, while in the other they have a duty to timely file auxiliary requests already in the first instance. They also demonstrate just how important this issue of admissibility is for the final outcome of the cases: in T 141/20 the patent was maintained on the basis of one of the auxiliary requests, while in T 614/21 the patent was revoked following non-admittance of the requests.

Raising objections against auxiliary requests before they are refiled on appeal

A common scenario at the EPO is that auxiliary requests are filed late in the first instance but not discussed in the oral proceedings or decision because a higher-ranking request is allowed. For an opponent, the question arises whether to raise objections against these requests in the first stage of the appeal proceedings, when it is unclear whether the requests will even be maintained by patentee.

T 664/20 dealt with such a scenario, where the opponent only filed a new document D24 dealing with the auxiliary requests shortly after learning that they had been maintained on appeal by patentee. Board 3.3.10 did not admit this document into the proceedings, stating in the headnote that:

The statement setting out the grounds of appeal of an appellant (opponent) must include all grounds covering all requests pending before the opposition division, including those which were not considered in the contested decision. Failing this, the appellant risks having the grounds filed after the brief setting out the grounds for the appeal and relating to auxiliary requests pending before the opposition division and filed in response to the appeal brief by the patent owner being dismissed. (translation of headnote 1)

Again, this may have had a critical impact on the outcome of the proceedings: the patent was ultimately upheld on the basis of one of the auxiliary requests against which D24 was cited.

Although relating to a different scenario, the approach in T 664/20 is not entirely consistent with the principles set out by Board 3.2.01 at reason 3.3 of T 2843/19:

*Insofar as the appellant cannot submit part of its submissions already in the statement of grounds of appeal [...] because it concerns the reply to attacks or auxiliary requests that were not already the subject of the contested decision but were submitted by the respondent in the reply to the appeal, **a reply to this is the appropriate means of choice for the appellant to submit its response in good time.** (translation of excerpt)*

Thus, in one case the Board requires filing, already in the first stage of the appeal procedure, objections against requests not considered in the decision under appeal, while in another case the Board finds it appropriate to react only once the requests are filed on appeal.

Admissibility of requests that amendments in the appeal case be held inadmissible

As can be taken from the above, the admissibility of amendments in the appeal case can be critical to the outcome of EPO appeal proceedings. But if the request to hold new amendments in the appeal case inadmissible is itself filed late, then the question arises whether the inadmissibility request is inadmissible.

This might sound like a purely intellectual exercise, but Board 3.3.02 followed this approach in T 500/16 reason 6.2. In this case, opponent attempted to avoid discussing whether one of their objections was an inadmissible amendment in their appeal case on the basis that patentee's inadmissibility objection was itself raised too late. Ultimately, the Board found that patentee's inadmissibility objection could be admitted and on this basis found opponent's objection inadmissible. Again, this illustrates that this issue can have an impact on substantive aspects of EPO appeal cases, by changing the objections available to opponent.

This approach though is inconsistent with the principle outlined in T 1006/21.¹⁹ Although this dealt with a different scenario to that above, Board 3.3.08 held at reasons 27 and 29 that a request that amendments in the appeal case be held inadmissible cannot itself be late filed:

*Procedural requests on questions that have to be taken up ex officio may relate to [...] **(non-) admission and consideration of claim requests, allegations of facts or evidence (Article 114, Rule 116(1) EPC)** [...] None of these procedural requests are subject to the provisions of Articles 12 and 13 RPBA 2020. **They can therefore be made at any time during the appeal proceedings and must be considered by the board, regardless of when they are made.***

Thus in one case, the Board scrupulously analysed the admissibility of an inadmissibility objection, while another Board generally states that such admissibility issues must be considered regardless of when they are raised.

Conclusion

The take-home message for EPO users should be clear: introducing new elements only on appeal risks them being found inadmissible. This risk can be minimized by front-loading the case such that all requests, facts, objections, arguments and evidence are filed in the first instance where reasonable. Realistically though, opposition proceedings are dynamic processes, meaning that amendments in the appeal case are often necessary. For this reason, it is hoped that the future case law converges to make it easier to predict when such amendments in the appeal case will be admitted, to improve legal certainty for EPO users.

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¹⁹ See also Adam Lacy, Nicolas Douchamps, "T 1006/21: you say admissible, I say inadmissible – let's call the whole thing off?", Kluwer Patent Blog, April 23, 2024.

Emotional AI Is Nothing to Get Excited About, Rules UK Court of Appeal

The British Court of Appeal has overturned a surprising judgment of the British High Court ruling artificial neural networks, and their use in general, as being outside the “computer program” statutory exclusion. The Court of Appeal makes clear that an artificial neural network as such is merely another sort of computer, and the weights and biases in that neural network are nothing more than a program for that sort of computer, even when generated by training rather than coding. As such, merely using an artificial neural network does not escape the statutory exclusion. The Court of Appeal however leaves open the door to the application of neural networks to technical problems as being worthy of patent protection, maintaining at least a degree of consistency between the conceptually distinct UK and EPO jurisprudence on this issue.

Last winter, *the Hoffmann Eitle Quarterly* brought you news of a landmark judgment of the British Patents Court in *Emotional Perception AI v Comptroller* (citation [2023] EWHC 2948 (Ch)),²⁰ ruling that artificial neural networks represented a new class of machine, and so, even if emulated in software, had inherent technicality suitable for patent protection. It is recalled that the UK approach to the question of excluded subject-matter focusses on the contribution made by the claimed invention, and not purely the entity claimed. Therefore, a general-purpose computer running a new computer program as such could be regarded as excluded matter, if the contribution made by the invention were to lie solely in the program as such. According to the Patents Court, this was not the case for an artificial neural network.

Following the handing down of that decision, the British Patent Office updated its examination guidelines to remove from the examples excluded from patentability the scenarios of “*optimising a neural network*”, “*avoiding unnecessary processing using a neural network*” and “*active training of a neural network*.” Given the break this represented relative to the more restrictive EPO practice, not least as reinforced by the G 1/19 *Bentley Systems* Enlarged Board of Appeal decision, a number of applicants active in the field of AI who had the opportunity to file British applications did so in the hope of securing protection under the apparently more lenient UK law.

Now, the British Court of Appeal has washed that landmark away in its recent review of that judgment on appeal (citation [2024] EWCA Civ 825²¹), leaving applicants facing unexpected rejections and proprietors who succeeded in obtaining grant of patents during this period with insecure rights. In particular, the Court of Appeal rejected the contention that an artificial neural network was anything more than a machine which processed information (paragraph [9] of the judgment), namely a computer (paragraphs [61] and [68]), that the weights and biases in the neural network, which are adjusted during training of the neural network, are a set of instructions for that computer, namely a computer program (paragraph [68]), and that this was as true for the hardware artificial neural network as for the emulation of that hardware neural network in software (paragraph [70]). The Court expressly acknowledged that the EPO’s Technical Boards of Appeal had reached the same conclusion in T 702/20 *Mitsubishi* (paragraph [69]).

Having found that Emotional Perception’s invention failed the test of whether the invention was inherently technical, the Court of Appeal then considered whether the invention nevertheless solved a technical problem by using the artificial neural network, placing the artificial neural network on the same footing in a patentability analysis as a general-purpose computer, which can control an X-ray machine (patentable) or generate legal documents (unpatentable) (paragraph [71]).

²⁰ Mark A.G. Jones, Axel T. Esser, AI in the UK - Not Coded by a Human, No Problem, *HOFFMANN EITLE Quarterly*, December 2023, pp. 2-5.

²¹ *Comptroller General of Patents, Designs and Trade Marks v Emotional Perception AI Ltd* [2024] EWCA Civ 825 (19 July 2024) (baillii.org).

Unfortunately for Emotional Perception, the Court of Appeal then held that the task that the artificial neural network was to perform, namely to make improved file recommendations based on subjective preferences (paragraphs [75] to [81]), was not a technical task as such, but rather an aesthetic or semantic one, and so held that this could not recover patentability. The claimed invention was excluded from patentability.

EPO practitioners here might recognise parallels with the EPO approach. In that approach, the entire claimed invention is first assessed as to whether it constitutes excluded subject-matter as such, with the recitation of even one non-excluded claim feature taking the invention outside the excluded area. Then, the concept of excluded matter re-enters the picture when inventive step is assessed, with only inventions solving a technical problem, i.e. a problem outside the excluded domain, being deemed to involve an inventive step. Therefore, the judgment maintains a degree of consistency between the UK approach and the EPO approach, although the conceptual underpinnings remain different.

Perhaps more importantly, the judgment of the Court of Appeal pours cold water on the hopes of practitioners, investors, and inventors for whom the initial Patents Court decision represented a beacon of hope that patent protection could be obtained for inventions applying artificial neural networks and similar technologies in all manner of recommendation

engines and similar endeavours. Those who believe that a broad, rather than narrow, approach to the computer program exclusion should be adopted to preserve freedom to operate for programmers and data scientists, as well as those who look nervously on any further divergence between continental and British jurisprudence, will in contrast be relieved that the status quo appears to be preserved.

However, the reasoning of the Court of Appeal does not fully close the door to patentable AI, but rather restricts the patentability of the use of AI to solve technical problems. That no British Court (or, to the knowledge of this author, any other Court) has yet delivered a clear definition of technicality, but rather allows the concept to evolve on a case-by-case basis, allows substantial scope for future decisions to confirm the existence of islands of patentability around the application of AI to solve certain well-defined problems which the Court would acknowledge as being technical. The beacon of hope is therefore dimmer, but not extinct.

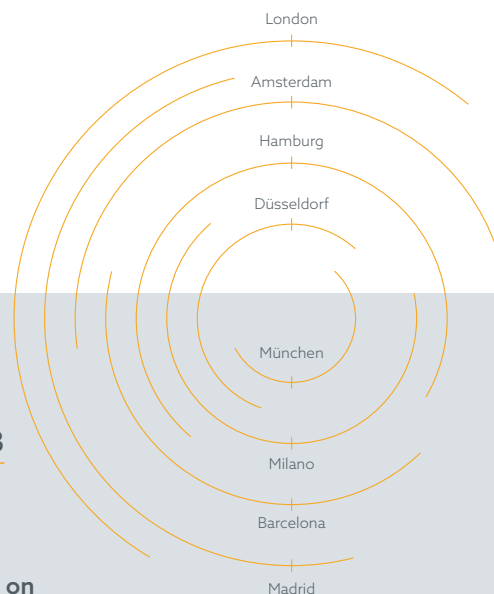
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