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1ST DECISIONS ON THE MERITS ISSUED BY THE UPC CENTRAL DIVISION (1/2): WHAT DOES THE UPC SAY ABOUT THE ASSESSMENT OF INVENTIVE STEP COMPARED TO THE EPO?

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INDUSTRY - INDUSTRIAL PROJECTS

*Since the entry into force of the Unified Patent Court (UPC), one of the burning questions that practitioners have in mind is whether the UPC will apply the problem-solution approach of the European Patent Office (EPO) in its assessment of the inventive step. While it is still too early to draw any conclusions, it would appear from the decisions we have studied that the UPC applies its own standards, drawing inspiration from the EPO's problem-solution approach**[1]** without duplicating it. We offer here a first analysis of how UPC assessed inventive step up to the recent decisions of the Central Division issued on 16 July (Sanofi v. Amgen**[2]** and Regeneron v. Amgen**[3]**). A second publication will focus on the Central Division's decisions of July 19 (Meril v. Edwards Lifesciences**[4]**).*

Until now, decisions on inventive step have not been very detailed

To study how UPC assesses inventive step, until recently we had to make do with an analysis of decisions handed down on preliminary injunctions[5]. However, these decisions fail to reveal any clear trend regarding assessment of inventive step. The first four decisions on the merits handed down in this July, three of which dealing with inventive step, were therefore eagerly awaited.

The first decision on the merits is the one issued by the Düsseldorf Local Division on 3 July in the case Franz Kaldewei v. Bette,[6] in which the Court declared the patent as granted invalid for lack of inventive step but found the patent as amended valid and infringed.

The second decision on the merits, to be analysed here, is the decision of the Paris Local Division of 4 July in the case DexCom v. Abbott.[7] The two other studied decisions on the merits are the twin decisions of the Central Division (Munich section) of 16 July dealing with the same patent EP 3 666 797 B1 issued in the parallel cases Sanofi v. Amgen and Regeneron v. Amgen.[8]

In the decision of 4 July, the Paris Local Division provides a succinct but clear analysis of inventive step. It relies on a line of reasoning close to the problem-solution approach, without following it to the letter. In the decisions of 16 July, the Central Division offers a more detailed analysis of inventive step, beginning with a presentation of the rules it will apply, which appear in the headnotes of the decision.[9] The decisions of 16 July thus enable us to consider more concretely what principles should be applied in terms of inventive step.

An objective approach from the skilled person's point of view

In its 16 July decisions, the Central Division stresses the importance of adopting an **objective approach** when assessing inventive step, specifying that neither the subjective ideas of the applicant or inventor, nor the fact that the invention is the result of serendipity or of systematic work involving (potentially costly and laborious) experimentation, are relevant. What matters is what the claimed invention actually contributes to the prior art, which is what underlies the problem-solution approach. It should be noted that in the preliminary injunction cases studied, and in the decision of 4 July of the Paris Local Division, the importance of the objective approach was not as expressly recalled, but such an approach was indeed adopted.

In its 16 July decisions, the Central Division recalls that inventive step is to be assessed from the **point of view of the skilled person** on the basis of the state of the art as a whole, i.e. **including the skilled person's general knowledge. In the four preliminary injunction cases studied and in the 4 July decision of the Paris Local Division, the UPC had also assessed the inventive step from the skilled person's point of view, in accordance with Article 56 of the European Patent Convention (EPC) and had always defined it (except in one decision**[10]**).**

Choice of starting point

One of the key points of the 16 July Central Division's decisions, compared with the other decisions studied is that they remind us that one must start from a starting point in the prior art, and the court explains its choice of starting point.

It further states that it is necessary to **select a realistic starting point** which is **not necessarily the closest prior art**. Several realistic starting points may be considered, **without it being necessary to identify the "most promising"**, as already indicated by the UPC Court of Appeal in 10x Genomics v. Nanostring (by selecting only one document whose teaching, according to the Court, was of interest to the skilled person).

This step of selecting the starting point is in line with the EPO's guidelines, which state that, in the event of refusal or revocation, it is sufficient to show on the basis of a relevant piece of prior art that the claimed subject-matter lacks inventive step, so that it is not necessary to discuss which document is "closest" to the invention: what matters is whether the document used can serve as a starting point for assessing the inventive step. In other words, the patent applicant or owner cannot rebut the argument of lack of inventive step by arguing that there is a more promising starting point.[11]

In the twin decisions of 16 July, the Central division selected the document proposed by Sanofi and Regeneron, which was of interest to the skilled person. It rejected the document proposed by Amgen, without even studying it, even though it had been retained as the closest prior art by the EPO examiner. Besides, the Central division points out that Amgen has not brought forward any concrete arguments as to why the document proposed by the adverse parties would not be a realistic starting point.

By comparison, in its decision of 4 July, the Paris Local division only assessed the inventive step in relation to one document only, without explaining why it has chosen this document. Unlike the Paris Local division and the Central division, in the preliminary injunction decisions studied here, the judges chose to examine several (or all) documents submitted by the parties. And when the concept of closest prior art was used by judges, it was less to select a single starting point than to set aside the document under discussion.

Assessing evidence: pointers taken into account

In its 16 July decisions, the Central division first identifies the differences between the starting point and the claimed solution and indicates that these differences must be taken into account when assessing the obviousness or non-obviousness of the claimed solution.

This stage of the reasoning is classic in this field.

Before assessing *in concreto* the obviousness of Amgen's solution, the Central division reminds that a claimed solution is to be considered obvious **if the person skilled in the art would be motivated to consider this** solution and to implement it as a next step in developing the prior art, and that it may be relevant, in this context, to know whether the skilled person would have expected any **particular difficulties** in taking any next step(s).

Without paraphrasing ihem expressly, the Central division remains in line with the EPO guidelines, which state that in the field of biotechnology, obviousness is considered at hand not only when results are clearly predictable, but also when there is a reasonable expectation of success. However, a “reasonable expectation of success” is not to be confused with the “hope to succeed”.[12]

The Central division also emphasises that a **technical effect or advantage achieved** by the claimed subject matter compared to the prior art may be an indication for inventive step. Conversely, a feature selected in an arbitrary way out of several possibilities cannot generally contribute to inventive step.

Following a detailed analysis, the Central division concluded that the person skilled in the art would, in this case, have ended up with the claimed subject matter in an obvious manner. In particular, it dismisses Amgen's arguments based on the excessive effort required to achieve the invention, the absence of a reasonable of achieving it and the random nature of the result obtained.

The Central division actually adopts an approach similar to that of the EPO recalled in the Guidelines regarding the assessment of inventive step in relation to antibodies, according to which the subject matter of a claim defining a new antibody binding to a known antigen does not involve an inventive step unless a surprising technical effect is shown in the application or unless there was no reasonable expectation of success of obtaining antibodies having the required properties.[13]

Following this in-depth analysis, the Central division revoked the patent as granted.

In comparison, in the preliminary injunction decisions studied, the UPC did not canonically follow the problem-solution approach either, as it never selected a single closest prior art, and it never applied the *could-would* approach. However, in the course of its analyses of inventive step made in these cases, it also adopted some criteria taken into account by the EPO, as for example ruling out any a posteriori analysis and taking into account the reasonable expectation of success.

In the same vein, in its 4 July decision, the Paris Local division stressed the importance of **defining the specific technical problem** encountered by the skilled person.

Inventive step of auxiliary requests and dependent claims: the need to develop a specific argument for each claim

In its 16 July twin decisions, the Central division dismisses requests to amend the patent, pointing out that the patent holder merely states that the amended claims would be inventive for the same reasons as for the patent as granted, without providing specific arguments to support their own validity.

It should be noted that, for the same reasons, the Paris Local division, in its 4 July decision, held the dependent claims to be invalid for lack of inventive step, emphasizing that the parties must provide reasons in support of their claims, and that DexCom has not presented any specific arguments to support the validity of the dependent claims.

Assessment of inventive step by the UPC: for the time being, inspiration rather than adoption of the EPO approach

While no UPC decision has yet strictly applied the EPO's problem-solution approach, the various assessments of inventive step provided up to now by the UPC are not so different from the EPO's reading grid, i.e. an objective analysis of the prior art and the claimed solution, from the point of view of a person skilled in the art.

In particular, the assessment made by the Central division in its decisions of 16 July remains faithful to the principles recalled in the EPO Guidelines in the specific field of biotechnological inventions,[14] and more specifically antibodies.

The door to a more canonical application of the problem-solution approach is undoubtedly not closed and will perhaps be opened to other technical fields which better fit to it.

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[1] See EPO Guidelines, G-VII, 5.

[2] UPC, Central division (Munich Section), 16 July 2024, UPC 1/2023, Sanofi v. Amgen.

[3] UPC, Central division (Munich Section), 16 July 2024, UPC 14/2023, Regeneron v. Amgen.

[4] 3 identical decisions from UPC, Central division (Paris Section), 19 July 2024, UPC_CFI_255/2023 and EPC_CFI_15/2023, Meril v. Edwards Lifesciences.

[5][5] UPC, Düsseldorf Local division, 11 December 2023 (*ex parte*) and 9 April 2024 (*inter partes*), UPC_CFI_452/2023, Ortovox v. Mammut ; UPC, Munich Local division, 19 September 2023, UPC_CFI_2/2023, Nanostring v. 10x Genomics followed by UPC, CoA, 26 February 2024, UP C 335/2023, 10x Genomics v. Nanostring ; UPC, Düsseldorf Local division, 30 April 2024, UPC_CFI_463/2023, 10x Genomics v. Curio Biosciences ; UPC, Munich Local division, 21 May 2024, UPC_CFI_443/2023, Dyson Technology Ltd. v. SharkNinja.

[6] UPC, Düsseldorf Local division, 3 July 2024, UPC_CFI_7/2023, Franz Kaldewei v. Bette.

[7] UPC, Paris Local division, 4 July 2024, DexCom v. Abbott, UPC_CFI_230/2023.

[8] See abovementioned orders UPC 1/2023 and UPC 14/2023 of 16 July 2024. These two decisions are identical, with only the plaintiffs being different. They were handed down in a case between the Sanofi and Regeneron groups, on the one hand, and the Amgen group, on the other, and form part of a wider global dispute between the parties, involving patents from both groups relating to anti-PCSK9 antibodies. The decisions of the Munich Central Division both relate to Amgen's patent EP 3 666 797 B1, which Sanofi (in a revocation action) and Regeneron (in a counterclaim for revocation) have sought to have declared invalid. For further explanations on the technical field concerned, we refer to the technical introduction made by the Central Division in these two decisions, whose educational efforts are to be commended.

[9] As can be seen from the headnotes, these two decisions also addressed questions of claim interpretation and the *same invention* criterion for claiming priority.

[10] Case 10x Genomics v. Nanostring abovementioned.

[11] See EPO guidelines G-VII, 5.1 §§4-5

[12] See EPO Guidelines G-VII, 13

[13] See EPO Guidelines G-II, 6.2.

[14] It should be noted that in the case of 10x Genomics v. Nanostring before the Court of Appeal of the UPC cited above, mentioned on several occasions in the studied decisions, the invention was also in the biotechnology field.