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European biotech patent case law

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Latest European biotech patent case law

- G 1/24: claim interpretation and relevance of the description
- T 0345/20 & T 0326/22: sufficiency of antibody claims defined by discontinuous epitopes
- T 1390/22: distinguishing second medical use claims using a disclaimer

A link to download these slides and a recording of this webinar will be emailed to you later this week.

G 1/24
Claim interpretation

G 1/24: background

- Enlarged Board of Appeal decision on use of description and drawings in claim interpretation.
- Case law had diverged on whether the description and drawings are to be used during interpretation of the claims when assessing patentability.
- Referral on point of law of fundamental importance.

G 1/24: referring decision T 439/22

- Patent relates to an article for a “heat not burn” vaping device.
- Claim recites an aerosol-forming substrate comprising a “**gathered** sheet” of material (tobacco).
- Prior art discloses a **spirally** wound tobacco sheet.
- Does **gathered** = **spirally** wound? If so, claim is **not novel.**

G 1/24: referring decision T 439/22

- Patentee: “**gathered** sheet” has clear meaning in the industry:

  “**folded** and **convoluted** to occupy a tri-dimensional space”

- But description provides a broader definition:

  “the term 'gathered' denotes that the sheet of tobacco material is **convoluted**, **folded**, or otherwise **compressed** or **constricted** substantially **transversely to the cylindrical axis of the rod**“

- Under this definition, “**gathered**” encompasses “**spirally wound**” and the claim lacks novelty.

G 1/24: referring decision T 439/22

The Board in T 439/22 identified divergent case law:

1. What is the legal basis for construing patent claims for patentability?
2. Is it a prerequisite that a term be unclear or ambiguous in isolation in order to consult the description and drawings?
3. To what extent can a patent serve as its own dictionary?

Legal basis for claim interpretation

Divergent case law considers Art. 69 EPC (and protocol on interpretation) or Art. 84 EPC as legal basis for claim interpretation

Art. 69(1) 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.

Art. 84 EPC: The claims shall define the matter **for which protection is sought**. They shall be clear and concise and be supported by the description.

G 1/24: first question

- Is Article 69(1), second sentence, EPC and Article 1 of the Protocol on the Interpretation of Article 69 EPC to be applied to the interpretation of patent claims when assessing the patentability of an invention under Articles 52 to 57 EPC?

Does a term have to be unclear to consult the description?

- Some case law only allows consultation of the description if, and only if, the wording of a claim on its own is unclear or ambiguous.
- Some case law always takes the description into account.
- Some case law considers that claims must always be read in complete isolation from the description.

G 1/24: second question

- 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?

To what extent can a patent serve as its own dictionary?

- Put another way, how can definitions in the description influence the interpretation of terms in the claims?
- Some case law allows terms to be given a special meaning in light of the description.
- Other case law follows the principle of the primacy of the claims, where the description should not modify meaning beyond what the skilled person would understand the term to mean in the claim.

G 1/24: third question

- 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?

Q1: “No clear legal basis”

- EBA considers neither Art. 69(1) or 84 EPC provides suitably clear legal basis for claim interpretation when assessing patentability.
- EBA does provide guidance:
  - Previous Boards of Appeal **have** applied the wording of those Articles to claim interpretation when assessing patentability.
  - This case law can be used to extract principles of claim interpretation.
  - The fact that the claims are the starting point and the basis for assessing patentability is settled case law.
  - But when the description/drawings may be referred to has been the subject of diverging case law (leading to question 2).

Q2: using description *only* when unclear is contrary to wording of Art. 69 EPC

- Wording and principles of Article 69 EPC inconsistent with interpretation that description should **only** be referred to in cases of a term being unclear or ambiguous.
- EBA also noted practical implications:
  - Practically, national courts and the UPC do not apply this approach: harmonisation is beneficial.

Q2: answer

“The Enlarged Board finds it a most unattractive proposition that the EPO deliberately adopt a contrary practice to that of the tribunals that are downstream of its patents. On this point, the Enlarged Board agrees with the harmonisation philosophy behind the EPC ”

Q2: answer

“The description and any drawings are always referred to when interpreting the claims, and not just in the case of unclarity or ambiguity.”

Q3: inadmissible

- EBA considered Question 3 to be encompassed within Question 2.

G 1/24: the order

- “The claims are the starting point and the basis for assessing the patentability of an invention under Articles 52 to 57 EPC. The description and drawings shall always be consulted to interpret the claims when assessing the patentability of an invention under Articles 52 to 57 EPC, and not only if the person skilled in the art finds a claim to be unclear or ambiguous when read in isolation”

G 1/24: practice points

- Drafting: caution in including definitions of terms that may differ from a commonly understood meaning in the art.
  - A patent may be its own dictionary but this may not always be to the patentee's advantage.
- Amendment: care with possible added matter implications of amendments to the description impacting claim terms.

G 1/24: practice points

- Examination: the Enlarged Board of Appeal highlights the importance of the examining division properly assessing clarity during examination.
- Opposition: consider impact on claims of definitions in description, and how any amendments to description might affect interpretation.

G 1/24: practice points

- Remains to be seen how this decision might affect the developing case law in respect of the requirement to amend the description in line with the claims.
- Although, there may be a possible further referral to Enlarged Board of Appeal in this regard (T 697/22).

T 0345/20 & T 0326/22
Sufficiency of antibody claims defined by discontinuous epitopes

Background

- EPO generally applies a relatively low bar regarding the level of disclosure required for antibodies.
- T 431/96: raising and screening antibodies involves only **routine experimentation** provided that it is known:
  1. which **antigens** are suitable for raising antibodies having the desired properties; and
  2. which **screening process** should be used to select these antibodies without undue burden

Background

EPO Guidelines for Examination (G-II, 6.1.3):

- An antibody may also be claimed by **reference to its epitope**, i.e. the structurally defined part of the antigen that it specifically binds to.
- The application **must enable the skilled person to produce further antibodies** having the claimed functional property without undue burden.

T 0345/20: background

- Filing date Aug 2006, decision date Jul 2022
- Claims 1 and 2:

1. An antibody, or antigen binding fragment thereof, that binds to human IL-23p19 **at an epitope comprising residues 82-95 and residues 133-140** of SEQ ID NO: 29.

2. The antibody, or antigen binding fragment thereof, of Claim 1, that binds to an epitope comprising residues E82, G86, S87, D88, T91, G92, E93, P94, S95, H106, P133, S134, Q135, P136, W137, R139 and L140 of SEQ ID NO: 29.

T 0345/20: background

- Patent disclosed an **example antibody** 7G10 which bound at the claimed epitope.
- Examples included humanization of mouse anti-human IL-23p19 7G10, affinity assays, and x-ray crystallography to determine the epitope.
- Description included details of methods to raise antibodies against IL-23, some screening methods including cross-blocking assay, and epitope mapping methods.

T 0345/20: background

- On the face of it the patentee seemed in a reasonable position: it appears that **at least one way** of performing the invention is described.
- However, the patent did **not** disclose:
  - How the mouse anti-human IL-23p19 7G10 antibody was prepared.
  - What **antigen** should be used for the generation of antibodies that bind to hIL-23p19 at the claimed conformational epitope.
  - No **screening** method to reliably identify antibodies that bind a conformational epitope on the p19 subunit of hIL-23.

T 0345/20: board's decision

- The patent does **not** disclose **a suitable antigen**:
  - It was undisputed that peptides consisting of the primary sequence of the conformational epitope are unsuitable
  - It was undisputed that the patent does not disclose how antibody 7G10 was prepared
  - The patent does not teach that the complete hIL-23 heterodimer should be used
- Assuming the skilled person were to choose the hIL-23 heterodimer for raising antibodies, they would obtain **a pool of antibodies**, which may or may not comprise antibodies having the required properties.

T 0345/20: board's decision

- There is **no teaching** in the patent regarding **pre-screening** antibodies for p19 specificity:
  - The patent does not disclose **which antigen** should be used in an ELISA to screen a pool of antibodies to obtain those antibodies that bind a conformational epitope on the p19 subunit of hIL-23.
  - No common general knowledge documents to support this proposition.
- There is **no teaching** in the patent for **other pre-screening methods** e.g. for antibodies that bind to the hIL-23 heterodimer but do not bind to the related hIL-12 heterodimer (which lacks the p19 subunit).

T 0345/20: board’s decision

- The skilled person could **not** narrow down an initial pool of anti-hIL-23p19 antibodies to a smaller group of candidates by a conventional **cross-blocking assay** without undue burden:
  - Antibody 7G10's footprint on hIL-23 was only disclosed in a post-published document.
  - Not all cross-blocking antibodies necessarily bind at precisely the same epitope, since cross-blocking may result from steric hindrance.

T 0345/20: board's conclusion

- The skilled person wanting to perform the claimed invention would have to develop **an elaborate screening process**.
- There is **no guarantee** that even a single antibody having the same specificity as the exemplified antibody 7G10 would be generated.
- Therefore, the functional definition of the claimed antibody amounts to **an invitation to perform a research program without any guarantee of success**. Such a situation is considered to amount to an undue burden.

T 0326/22: background

- Filing date February 2013, decision date August 2024.
- Claim 1:

1. An isolated monoclonal antibody or immunologically active fragment thereof that binds to human CD47, wherein the antibody or immunologically active fragment thereof **binds to a discontinuous epitope on CD47**, wherein the discontinuous epitope comprises amino acids residues Y37, K39, K41, K43, G44, R45, D46, D51, H90, N93, E97, T99, E104, and E106 of CD47 when numbered in accordance with SEQ ID NO: 147, and wherein the antibody or immunologically active fragment thereof **prevents CD47 from interacting with signal-regulatory-protein α (SIRPα)** and **does not cause a significant level of agglutination of cells** after administration.

T 0326/22: background

- Patent disclosed **an example antibody** 2A1 which bound at the claimed epitope.
- Examples included humanization of mouse CD47 2A1, affinity assays, and x-ray crystallography to determine the epitope.
- Description included details of methods to raise antibodies against CD47, and some screening methods including cross-blocking assay.

T 0326/22: background

- On the face of it the facts seem similar to those of T0345/20.
- However, the patent **did** disclose:
  - How the mouse anti-CD47 2A1 antibody was prepared.
  - The CD47-IgV **antigen** should be used for the generation of antibodies that bind to CD47 the claimed conformational epitope.
  - **Screening methods** to help identify antibodies that bind a conformational epitope on CD47 (a SIRPα blocking assay and a hemagglutination assay).

T 0326/22: background

The **functional features** were related to the **unique epitope**:

- the structure of 2A1 in complex with CD47 revealed binding of the antibody to CD47 near the membrane in an unexpected and **unique head to side orientation.**
- it is primarily the VK domain that physically **precludes SIRP α binding** to CD47.
- the orientation of the 2A1 VH region in a membrane proximal position are critical features of this antibody that **prevent a significant level of red blood cell hemagglutination** by constraining the antibody such that it cannot bridge to CD47 molecules on adjacent cells.

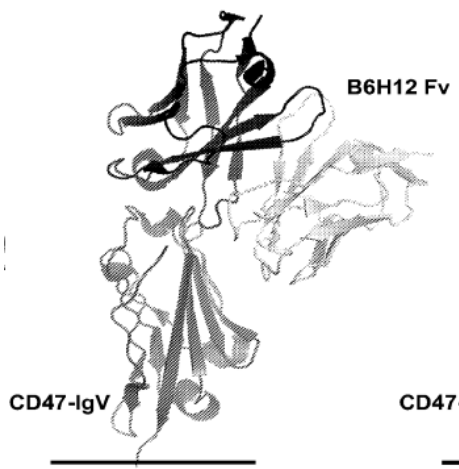

FIG. 11B

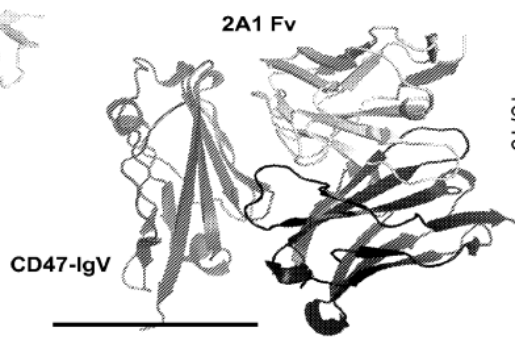

FIG. 11C

T 0326/22: board's decision

The patent application described **at least one antibody** having the claimed functional features:

- The patent application provides the sequence information of the 2A1 antibody and of various derivatives thereof.
- Antibodies with these sequences fulfil the functional properties indicated in claim 1.
- It is uncontested that varying these sequences and obtaining further antibodies are routine and hence impose no undue burden on the person skilled in the art.

T 0326/22: board’s decision

The skilled person would arrive at further antibodies **without undue burden**:

- The skilled person would be able to repeat the immunisation protocol using the described **antigen** to arrive at further antibodies that bind to the claimed epitope.
- Examples 3 to 5 of the patent application disclose two independent **pre-screening assays** to generate a sub-pool of antibodies which show SIRPalpha-blocking and non-cell agglutination properties.
- There would be a **relatively low number of candidate antibodies** because 2A1 “was the only antibody in Figure 4B with absent or reduced hemagglutinating activities”.
- This has the effect that candidate antibodies competing with 2A1 for the binding to the claimed epitope in a **competitive binding assay** have a high "likelihood" that they bind to the claimed epitope as well.

T 0326/22: board's conclusion

- **The fact situation differs from T 435/20** where the patent in suit neither disclosed: (1) a suitable **antigen** for raising antibodies; nor (2) appropriate **screening assays** for selecting antibodies that specifically bound to the claimed epitope.
- It is credible that the skilled person by applying the teaching of the patent application and taking common general knowledge into account would arrive **without undue burden** at further antibodies falling within the scope of claim 1.

T 0345/20 & T 0326/22: factors for sufficiency

- Suitable **antigen** for raising antibodies and a suitable **pre-screening assays** for selecting antibodies that specifically bound to the claimed epitope.
- A **competitive-binding assay** and an **example antibody** are supportive, but not enough.
- The fact that the generation of new antibodies is **based on chance** is not decisive.
- The fact that there are no other antibodies is immaterial.

T 0345/20 & T 0326/22: take-home messages

- **Antibody claims defined by discontinuous epitopes are allowable but the bar for enablement is relatively high.**
- Critical factors: (1) a suitable **antigen** for raising antibodies; and (2) appropriate **screening assays** for selecting antibodies that specifically bound to the claimed epitope.
- As an opponent, there are a **variety of attacks** that can be raised regarding: antigen, screening, epitope mapping etc.
- As a patentee, consider whether **functional features** can be inserted in the claim which correspond to screening assays.

T 1390/22
Distinguishing second medical use claims using a disclaimer

T 1390/22: background

Claim at issue:

1. Pibrentasvir or a pharmaceutically acceptable salt thereof for use in a method of treatment for HCV, comprising administering an effective amount of pibrentasvir or a pharmaceutically acceptable salt thereof to an HCV patient, **regardless of the specific HCV genotype(s) that the patient has, wherein said patient is not genotyped for said treatment**.

- Opposition Division found the claim to lack inventive step starting from D2.

T 1390/22: background

- Second medical use claims for the **same disease** can still be distinguished based on other features related to a further "therapeutic use":
  - based on the group of subjects to be treated (for example, T 19/86).
  - different mode of administration (for example, T 51/93).
  - new dosage regimen (for example, G 2/08).
- T 2056/17: features which do not change the **clinical situation** nor contribute to the **therapeutic effect** do not distinguish.

T 1390/22: board's decision

- The assessment of the HCV genotype was **standard practice** at the time of the priority date for the patent (see D19 and D20).
- The intentional omission of the HCV genotyping therefore represents **a technically meaningful characteristic** of the defined therapeutic treatment.
- This technically meaningful characteristic of the defined therapeutic treatment involving the use of pibrentasvir is suitable to characterize the claimed subject-matter in terms of a **specific use** (see G 2/08).

T 1390/22: board's decision

- D2 **does not explicitly disclose** the utility of pibrentasvir in treatment of HCV in which the assessment of the HCV genotype is intentionally omitted.
- D2 describes compounds of formula IB to be **suitable** for treating patients infected with HCV genotype 1a, 1b, 2a, 2b, 3a, 4a, 5a or 6a and identifies pibrentasvir as an advantageous example thereof.
- **However, D2 did not disclose any quantitatively consistent activity of pibrentasvir against a spectrum of HCV genotypes that might imply that in treatment of HCV patients with pibrentasvir the HCV genotyping could be omitted.**

T 1390/22: board's decision

- In contrast to D2, the patent provided **experimental results** concerning the mean IC50 values of pibrentasvir for HCV genotypes 1a, 1b, 2a, 2b, 3a, 4a, 5a and 6a and additional data for a variety of mutants.
- The patent **credibly demonstrates** that in the treatment of HCV an appropriate dose of pibrentasvir should be effective regardless of the specific genotype of the HCV infection.
- The objective technical problem was the provision of an effective treatment of HCV **regardless of the HCV genotype**, which evidently represents a significant simplification in the conventional treatment of HCV.

T 1390/22: board's decision

- From D2 the skilled person could not derive any **reasonable expectation** that pibrentasvir would be suitable for treatment of patients infected with HCV irrespective of the specific HCV genotype without the need for genotyping.
- D1 and D4-D10 also do not provide the skilled person with any additional information allowing for a reasonable expectation. On the contrary, there was **a broad range of EC50 values reported** for different NS5A inhibitors for different genotypes.
- Therefore, the claimed subject-matter was **deemed inventive** (contrary to the Opposition Division's decision).

T 1390/22: Take-home messages

- Any “**technically meaningful characteristic**” may be used to distinguish a second medical use claim from the prior art. This includes **omissions of steps/features** which are normally carried out.
- **Common general knowledge** documents can be very persuasive in the context of novelty and inventive step.
- Advantageous **experimental data** which goes beyond the teaching of the prior art can also be very persuasive.

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