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European biotech patent case law

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Latest European biotech patent case law

- T 0295/22: new mode of administration is capable of establishing novelty for further medical use claim.
- T 0816/22: post-published negative Phase III trial data used to raise doubts as to sufficiency.
- T 0314/20: interpreting G 2/21.

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

T 0295/22 (Amgen): Mode of administration is a limiting feature of a second medical use claim

T 0295/22: background

- Methods of treatment *per se* are excluded from patentability under Art. 53(c) EPC.
- Substances/compositions for use in such methods are patentable under Art. 54(4) and (5).
- Under the previous European Patent Convention (1973), such claims were permitted in “Swiss form”.
- Under the EPC 2000, medical use claims are instead permitted in the form “substance X for use as a medicament” and “substance X for use in treating disease Y” (First and further medical use claims respectively).

T 0295/22: background

- The patent in the present case related to the compound apremilast, and the Main Request in appeal proceedings related to:

  apremilast in greater than 80% by weight of the (+) enantiomer and less than 20% by weight of the (-) enantiomer, for use as a medicament, **wherein the medicament is administered orally**

- Novelty hinged on whether oral administration was a limiting technical characteristic of the claim.

T 0295/22: background

- What can constitute a specific use pursuant to Art. 54(5) EPC?
  - Substance for use in the treatment of a specific disease/condition
  - Substance for use in a *different* treatment by therapy of a same illness (where the general use of the substance is known) – this includes dosage regimes (G 2/08)
  - What about specific modes of administration?

T 0295/22: guidelines and previous case law

- According to the Guidelines for Examination, G-VI 6.1.2:

  "*The mode of administration…has been considered as a limiting feature, but **only** in relation to a further (specific) medical indication…the feature 'by topical administration' is **merely illustrative** and **not** a **restrictive technical feature** capable of establishing novelty*" – citing T 051/93

- T 051/93 precedes the EPC 2000, and discusses both "*Swiss type*" claims and "*Process for making X for use Y*" type claims.

T 0295/22: Board decision

- Board in this case rejected the Guidelines interpretation of T 051/93:
  - T 051/93 **did** state that a mode of administration was merely illustrative (and therefore non-limiting), but **only** in relation to "*Process for making X for use Y*" claims.
  - T 051/93 in respect of "*Swiss-type*" claims **instead** recognised that even if the mode of administration in such a claim was the only novel feature, it **was sufficient to distinguish** the claim in terms of novelty over the prior art.
- The "*Process for making X for use Y*" claim does not correspond to either the "*Swiss type*" claim nor the EPC 2000 further medical use claim format.

T 0295/22: Board decision

- G 2/08 is a landmark decision relating to different therapies for the same illness as valid further medical use claims.
- T 0295/22 Board considered G 2/08, specifically that:

  "*5.10.3…there can be only one sensible way of construing the requirement underlying the specificity of the use, namely merely **by contrast** to the **generic broad protection** conferred by the first claimed medical application of a substance or composition, which is in principle **not confined to a particular indication**.*"

- Analogously to the dosage regimes focused on in G 2/08, the Board here concluded that the mode of administration **was a characterising technical feature** of the claim, independent of limitation to a particular indication or dose.

T 0295/22: Board decision

- Board considered the main request novel.
- But what about inventive step?
  - D1 of proceedings describes apremilast in a form with an optical purity of more than 95% as useful in the treatment of inflammatory diseases.
  - Difference over D1 was therefore **only** the feature of oral administration of the compound.
  - Data in the application showed evidence of functional activity (selective inhibition of PDE-4) following oral administration, and evidence of good aqueous solubility.
  - Objective technical problem formulated as:

    the provision of an administration route for steromerically pure apremilast which allows for the safe and well-tolerated effective treatment for PDE4-mediated diseases.

T 0295/22: claims lack inventive step

- Board acknowledged that oral administration of PDE4 inhibitors represented challenges.
- However, Board considered reporting of these challenges in the prior art to "*reflect the skilled person's compelling motivation to seek the oral administration…which represents typically his first choice…because of the ease of administration*"
- Board acknowledged that the skilled person may not have predicted the actual level of tolerability and solubility indicated in the patent
- However, Board considered that there would have been a **reasonable expectation** that oral administration of apremilast would result in safe and well-tolerated effective treatment from the prior art.
- Board cited T 1356/21 in reference to the "one way street situation" due to the lack of "practical alternatives" (i.e. lack of other practical administration modalities).

T 0295/22: key takeaways

- Board in this case appears to have taken opportunity to address what appears to be inconsistencies of the Guidelines with current case law (inc. G 2/08).
- It is clear that, as indicated in G 2/08, a mode of administration recited in an EPC 2000 medical use claim is indeed to be considered **a characterising feature of the claim**, and be capable of establishing novelty.
- However, inventive step is a key consideration for such features, especially if the mode of administration does not provide a particularly unexpected effect or is a preferred mode.

T 0816/22 (Takeda): Post-published negative Phase III trial data and sufficiency

T 0816/22: background

- Granted patent related to:

  A C1 esterase inhibitor (C1-INH) for use in a method of treating antibody-mediated rejection (AMR) of an organ allograft in a patient in need thereof, wherein the method comprises IV administration of C1-INH at a dose of 5,000 – 25,000 units in divided doses over 10-20 days

- Validity hinged on sufficiency of the medical use claim under Art. 83 EPC.

T 0816/22: sufficiency of medical use claims

- The claimed therapeutic effect of medical use claims regarded as a functional technical feature of the claim.
- The application must make it plausible that the claimed therapeutic effect can be achieved.
  - Clinical data are not always required but mere verbal statements are not enough - T 0609/02

T 0816/22: data in the application

- Application contained:
  i. Phase II clinical data related to Takeda's C1-INH Cinryze used for treatment of kidney-transplant patients
     - In a Cinryze clinical arm, 1 out of 7 patients had chronic glomerulopathy, compared to 3 out of 7 in the placebo arm.
  ii. a mechanistic explanation of the mode of action of C1-INH.
- Board assumed OD was correct in their decision that these data/mechanistic explanation made it plausible to the skilled person at the time of filing that a therapeutic effect on antibody-mediated rejection.

T 0816/22: post-published evidence used to contest sufficiency by opponent

- D15, D16 and D54 relate to Takeda's phase III clinical trial (NCT02547220), which used the same dosage regimen as the examples in the application and was within claim scope.
- The trial was terminated at 36 months due to meeting the pre-specified criteria for **futility**.
- The **only** primary endpoint reported that the percentage of subjects with new or worsening transplant glomerulopathy at month 6 was 47.5% in the placebo arm, and 50% in the Cinryze group.
- No data in respect of secondary endpoints relating to treatment efficacy was collected due to the termination (D54).

T 0816/22: post-published evidence

- The patentee argued that:
  1. the primary endpoint was “binary” data, and did not take into account **severity** of the glomerulopathy
  2. the **efficacy data** which would have been collected for the secondary endpoints could have demonstrated beneficial effects, and
  3. beneficial effects of treatment could have arisen over **a longer period** had the clinical trial been continued as planned.

T 0816/22: Board decision

- Board decided that the level of efficacy related to the futility threshold was not relevant.
- Board acknowledged that therapy is not limited to completely curing a disease or condition – but can include alleviating or lessening symptoms.
- However, crucial was **whether the skilled person was able to reproduce the invention** i.e. achieve the therapeutic effect in kidney transplant antibody mediated rejection.
- Since D54 showed the **complete absence of any therapeutic effect** with the claimed dosage regimen, this was sufficient to raise serious doubts based on verifiable facts that the therapeutic effect was achieved.

T 0816/22: Board decision

- The patentee was not able to dispel these serious doubts raised by the data from the Phase III trial.

- Board considered the invention as claimed to not be reproducible, and therefore not to meet requirements of Art. 83 PCT.

T 0816/22: key takeaways

- Board content to agree with OD that a therapeutic effect in a small number of patients, in combination with mechanistic rationale, is **enough to make it credible that a claimed therapeutic effect is achieved**.
- In this case, while the effect was found to be credible (so post-published data could have been used to evidence this effect being achieved) the case instead depended on the opponents citing a Phase III failure that raised serious doubts as to the therapeutic effect being achieved.
- The patentee's arguments along the lines that failed outcomes of trial endpoints are not necessarily indicative of a lack of an underlying, subtle, or longer-term therapeutic effect were not found persuasive.
- If such data about subtle therapeutic effects had been collected, the outcome might have been different.
- If a Phase III trial of a claimed therapy fails, can the underlying patent still be of value?

T 0314/20 (Boehringer): Interpretation of G 2/21

T 0314/20

- Inventive step: Article 56 EPC
- Post-published evidence of a technical effect
- Interpretation of G 2/21

T 0314/20: decision of G 2/21

Brief summary:

- G 2/21 provided a threshold for reliance on a purported **technical effect** for inventive step.
- If the skilled person would derive said effect as being:

  i. **encompassed** by the **technical teaching**; and

  ii. **embodied** by the same **originally disclosed invention**

  of the application.

T 0314/20: background

EP2187879 : Compositions for treating conditions including diabetes.

Oppositions rejected. Decision appealed by 4 opponents.

Claim 1 relates to:

- Pharmaceutical composition comprising empagliflozin (SGLT2 inhibitor) and linagliptin (DPP IV inhibitor).

T 0314/20: background

Cited prior art included:

- D2 – Disclosing combinations of SGLT2 inhibitors (including empagliflozin) with DPP IV inhibitors such as vildagliptin and sitagliptin (but **not** linagliptin) for use in treatment of diabetic conditions.
- D3 – Disclosing linagliptin (among other alternatives) as a suitable combination partner for SGLT2 inhibitors.

T 0314/20: background

Proprietor submitted 3 post-published documents to support a technical effect of the specific combination of **empagliflozin** and **linagliptin**.

- D56 – Showed an increased plasma level of active GLP-1 in patients with diabetic diseases that was stronger and more prolonged with **empagliflozin + linagliptin** than for **empagliflozin** with either **sitagliptin** or **vildagliptin**.

T 0314/20: key issue

Opponents argued this technical effect (increase in GLP-1 levels) was not derivable from the application.

- Absent a technical effect, choice of linagliptin from D3 was allegedly an obvious alternative.

Board had to consider whether the technical effect (possibly evidenced by D56) could be taken into account in view of G 2/21.

T 0314/20: interpretation of G 2/21

Board identified challenges in interpreting G 2/21:

1. The requirements (i) “encompassed by technical teaching” and (ii) “embodied by the same originally disclosed invention” are **not used** in the preceding “plausibility” case law that led to the referral – relation to this case law remains to be defined.

2. EBoA did **not expressly define** these requirements in G 2/21.

3. The **purpose** of these requirements was **not expressly stated**.

T 0314/20: criticism of T 0116/18

T 0314/20 considered some inferences in T 0116/18's approach **not supported** by G 2/21:

- Board in T 0116/18 concluded test to be applied in assessing requirement (ii) was the *ab initio* implausibility test.
- G 2/21 does **not** state that requirement (ii) is met "unless the person skilled in the art would have had legitimate reasons to doubt that the purported technical effect would have been achieved on the filing date".

T 0314/20: agreement with T 0116/18

Agreeing with T 116/18, the Board stated that:

> "point 2 of the order of decision G 2/21 aimed to prevent speculative inventions (point 11.8 of decision T 116/18), namely the filing of applications directed to speculative (armchair) inventions made only after the filing date"

While not stated in G 2/21, Board considered it reasonable to conclude that intention was to provide a safeguard to ensure only inventions already made are granted patent protection.

T 0314/20: application of G 2/21

Board considered it **did not need to answer** whether it can endorse all of the conclusions of T 0116/18 regarding requirements (i) and (ii) as set out in G 2/21.

Board noted that the **purpose** of these requirements – in alignment with T 0116/18's view – is to prevent grant of patents for inventions that are not complete at the filing date.

> "Such speculative applications arise where either the existence of the claimed technical effect or its generalisation is speculative. This may occur because relevant data have not yet been generated or, if available to the patent applicant, have not been disclosed in the patent application."

T 0314/20: conclusion on the facts

Patentee cannot rely on the alleged technical effect (increase in GLP-1 levels):

> "because a skilled person would not expect the technical effect in question - an increase in active GLP-1 levels from the combination of empagliflozin and linagliptin compared to increases in active GLP-1 levels achieved with combinations of emplagliflozin with sitagliptin and vildagliptin, respectively - on the basis of the original disclosure of the application itself."

> "effect is not only unsupported and not made credible by the application as originally filed; it even contradicts its technical teaching. Therefore, whatever the meaning of the two requirements in G 2/21, they cannot be met in the present case if patenting for inventions not made at the filing date is to be excluded."

T 0314/20: conclusion on the facts

The application as filed identified a technical effect:

> "The glucopyranosyl-substituted benzene derivative in combination with the DPP IV inhibitor will exhibit higher active GLP-1 concentrations and lower glucagon concentrations than the glucopyranosyl-substituted benzene derivative alone"

However, Board concluded this effect is attributed to all combinations.

T 0314/20: conclusion on the facts

Board noted the application describes:

> "linagliptin as one of twelve preferred DPP IV inhibitors according to a first embodiment"

And it was further noted that:

> "the application as originally filed presents combinations of empagliflozin with linagliptin, sitagliptin, vildagliptin, saxagliptin or alogliptin at an equal level of preference"

T 0314/20: conclusion on the facts

"It follows from the analysis made in points 6.20 to 6.24 above that the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would not derive the increase in plasma levels of active GLP-1 relied on by the respondent (see point 6.25 above) as being encompassed by the technical teaching of the claimed invention and embodied by the same originally disclosed invention."

T 0314/20: conclusion on the facts

Technical effect relied on rests on experimental data which does not confirm the technical teaching in the application.

> "the increase in active GLP-1 levels relied on by the respondent for acknowledgement of inventive step of the claimed subject-matter forms the basis of an invention which has not been made or disclosed at the filing date of the application. Consequently, this technical effect cannot be taken into account for formulating the objective technical problem"

T 0314/20: conclusion on the facts

> "…the objective technical problem to be solved by the claimed invention merely involves providing a specific combination of a glucopyranosyl-substituted benzene derivative of formula I as shown in document D2 with a DPP IV inhibitor in the context of diabetic diseases. The selection of empagliflozin from among the 17 glucopyranosyl-substituted benzene derivatives of formula I disclosed on page 26 of document D2 has not been shown to be connected to any particular effect and therefore constitutes an arbitrary choice from the compounds listed on this page."
>
> "The same holds true for the selection of linagliptin from among the 30 DPP IV inhibitors disclosed on page 25, line 22 to page 28, line 20 of document D3."

Patent lacks an inventive step and was revoked.

T 0314/20: summary

- Case law interpreting G 2/21 is still developing.
- T 0116/18's interpretation of G 2/21 may be scrutinised further in future.
- The present Board provided its view on the purpose of the requirements:
  - Safeguard that only inventions **already made and disclosed at the filing date** are granted patent protection.

Webinar invitation

UPC case law, observations and analysis

1pm, Wednesday 18 June 2025

An analysis of the Unified Patent Court's decisions, with D Young & Co's observations and analysis. Presented by UPC representatives Anthony Albutt, Rachel Bateman & Tom Pagdin.

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