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European biotech patent case law

18 November 2025

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Latest European biotech patent case law

- G 1/23: enablement requirement for products placed on the market forming part of the state of the art
- Round up of recent decisions: subsequent data and second medical use claims
  - T 0709/23: post-published evidence undermining sufficiency
  - T 0883/23: priority entitlement and the “same invention”
  - T 0867/23: post-published evidence to support medical use claims

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

G 1/23: enablement requirement for products placed on the market forming part of the state of the art

G 1/23: background

- A product placed on the market can constitute prior art disclosure "by use", since use can "take the form of producing, offering or marketing or otherwise exploiting a product" (CLBA I.C.3.2.4 a)".
- Can be important in EPO opposition proceedings where a marketed product may be relevant prior art.

G 1/23 – previous case law: G 1/92

- G 1/92 considered the extent to which the composition or internal structure of a product is available as prior art if a product is available to the public.

  “The chemical composition of a product is considered to be part of the state of the art if the product itself is available to the public and can be analysed and reproduced by a person skilled in the art, irrespective of whether there are particular reasons for analysing the composition.”

  “If the skilled person can deduce the composition or internal structure of the product and reproduce it without undue effort, both the product and its composition or internal structure are part of the state of the art.”

G 1/23 – previous case law: G 1/92

G 1/92 has been subject to interpretation:

- What, if anything, needs to be analysable and reproducible for a) the product to be prior art and/or b) the composition/internal structure to be prior art.
- Are analysis and reproducibility to be viewed as two separate criteria?
- Is a “product placed on the market” limited to man-made products or does it also include naturally occurring products?
- When is a product deemed “reproduced”?
- How is “without undue burden” to be understood?

G 1/23 – referring case: T 0438/19

- The commercially available ethylene copolymer (ENGAGE® 8400) was cited as closest prior art.
- The opponent alleged lack of inventive step: literature disclosed that ENGAGE® 8400 satisfied all features of the claims, except for the aluminium content.
- None of the cited documents disclosed the manufacturing method, the exact composition or internal structure of ENGAGE® 8400.
- The patentee argued that ENGAGE® 8400 is not reproducible and therefore not prior art.

G 1/23: questions

The referring board put three questions to the EBoA:

1. Is a product put on the market before the date of filing of an EP application to be excluded from the state of the art within the meaning of Article 54(2) EPC for the sole reason that its composition or internal structure could not be analysed and reproduced without undue burden by the skilled person before that date?
2. If the answer to Q1 is no, is technical information about said product … state of the art …, irrespective of whether the composition or internal structure of the product could be analysed and reproduced without undue burden…?
3. If the answer to Q1 is yes or the answer to Q2 is no, which criteria are to be applied in order to determine whether or not the composition or internal structure of the product could be analysed and reproduced without undue burden...?

G 1/23 – referring case: T 0438/19

- Question of law of fundamental importance.
- Not about having physical access to the product.
- Accessibility to the skilled person as a point of law.
- Do the requirements of enablement implicitly form part of the term “made available to the public”?

G 1/23: questions

Before answering the questions, the EBoA considered some of the terms in the decision of G 1/92:

- Reproducibility in G 1/92: being able to reproduce the product by a different route than obtaining the product in its readily available form.
- Reproduction does not involve an undue burden where the product can be made on the basis of the skilled person's common general knowledge.
- Analysis does not need to be assessed independently from reproducibility. Reproducibility is the decisive criterion.
- Man-made products and naturally occurring products are both effectively products placed on the market.

G 1/23: reproducibility

EBoA first considered how to interpret the reproducibility requirement of G 1/92:

- If the skilled person can deduce the composition or internal structure of the product and reproduce it without undue effort, both the product and its composition or internal structure are part of the state of the art.
- Two divergent interpretations of the reproducibility requirement exist in case law based on whether "it" is read as referring to…
  a) "the product" (for example T 1833/14 and T 0023/11); or
  b) "the composition or internal structure" (for example T 946/04 and T 1666/16).

G 1/23: reproducibility

- Under a), the emphasis is on the reproducibility of the product:
  - If the product is reproducible, then the product and its composition and internal structure are prior art.
  - If the product is **not** reproducible, neither the product nor its composition or internal structure are prior art.
- Under b), the emphasis is on the reproducibility of the composition and internal structure:
  - If the composition and internal structures **are reproducible**, they are prior art and should not be disregarded irrespective of whether the specific commercial material could be reproduced.
  - If the composition and internal structure **are not reproducible**, they are not prior art.

G 1/23: reproducibility

The EBoA rejected the interpretation under a):

- Would mean that any non-reproducible product (including e.g. atoms) is not prior art and hence can also not belong to the common general knowledge that the skilled person would rely upon to obtain the product.

  "there are no products on earth that are in the end not based on materials that themselves cannot be reproduced"

- If the person skilled in the art is assumed to rely on standard (non-reproducible) starting materials, the exclusion of the non-reproducible product from the state of the art is "no longer justified".

- The skilled person would therefore not ignore non-reproducible products.

G 1/23: reproducibility

EBoA also rejected the interpretation under b):

- If reproducing to "retain certain properties", as for interpretation a) the skilled person would again not be able to avoid eventually turning to a **material they cannot reproduce**.
- Under this interpretation, there would again be "no material left for the skilled person to work with" and this interpretation also has to be rejected.

G 1/23: reproducibility

- The contradiction in the interpretations of the reproducibility requirement of G 1/92 disappear if reproducibility is interpreted as including…

  … obtaining the product from the market in its readily available form

  not just

  …. being able to reproduce the product by a different route than obtaining the product in its readily available form

- Under this interpretation, the product is considered reproducible if it is put on the marked and can be analysed.

G 1/23

Answer to Q1

A product put on the market before the date of filing of a European patent application cannot be excluded from the state of the art within the meaning of Article 54(2) EPC for the sole reason that its composition or internal structure could not be analysed and reproduced without undue burden by the skilled person before that date.

G 1/23: reproducibility

Reproducibility requirement

In the context of Q1, “reproducibility” in G 1/92 refers to the narrower interpretation of reproducibility “by a different route”. This requirement is made redundant by the product being placed on the market.

> “the chemical composition of a product is part of the state of the art when the product as such is available to the public and can be analysed by the skilled person, irrespective of whether or not particular reasons can be identified for analysing the composition”.

G 1/23: analysis and undue burden

Analysis requirement

- Did not need to be considered in isolation to answer Q1, since analysis and reproducibility (the main criterion) are a joint condition of Q1.

Future analysis requirement?

- Does not mean that "analysis without burden" will not arise **as an issue**.

G 1/23: legal v factual

The Enlarged Board also considered legal and factual questions arising from the potential disappearance of a product put on the market:

- Disappearance of a product from the market does not prevent its disclosure from becoming permanently state of the art
- The absence of proof that the product put on the market has a certain property has no bearing on the "legal character of the product as belonging to the state of the art"
- It is also irrelevant for the prior art status of the product whether it has ever been analysed.

G 1/23: matters of fact

- Establishing what exactly became state of the art is a problem of proof and evidence.
- What was put on the market? When was this done?
- Is this the same as what has been analysed?
- May remain difficult to establish the relevant technical teaching at a later time.
- Certainty beyond reasonable doubt (T 1469/08).

G 1/23: key takeaways

- The requirements of G 1/92 are **recast** to include products that – at some point before the effective filing date – were obtainable from the market in their readily available form.
- No requirement to establish reproducibility of the product or the composition/features of the product.
- Analysable + undue burden requirements still appear relevant.
- Still need to establish – as a matter of fact – what was **made available as part of the state of the art**.

Subsequent data and second medical use claims: round up of recent decisions

- T 0709/23: post-published evidence undermining sufficiency
- T 0883/23: priority entitlement and the “same invention”
- T 0867/23: post-published evidence to support medical use claims

- **T 0709/23:** post-published evidence undermining sufficiency

Background: sufficiency of medical use claims

- The claimed therapeutic effect of medical use claims is regarded as a functional technical feature of the claim (CLBA II.C.7.2.2).
- The EBoA confirmed in G 2/21 that:
  - the application at the filing date must make it credible that the therapeutic agent is suitable for the claimed therapeutic application.

T 0709/23: claimed subject-matter

- Two example antibodies provided in the application
- Claims define the antibody solely in terms of two functional features (no structural definition)
- Main Request claim 1:

  An isolated antibody that specifically binds to feline IL-31, wherein said antibody reduces, inhibits or neutralizes feline IL-31-mediated pSTAT signaling in a cell based assay, for use in treating a pruritic condition or an allergic condition in cats.

T 0709/23: content of the application

- The identification of an IL-31 epitope that shows sequence conservation between canine and feline IL-31.
- Generation of two example mAbs “11E12” and “34D03”.
- *In vitro* evidence of a felinised version of antibody 34D03 binding and inhibiting canine and feline IL-31.
  - Suggestion that the conserved epitope on feline IL-31 may be a suitable target for inhibition of this cytokine in cats.
- Data showing therapeutic efficacy of example anti-IL-31 antibodies in dogs only for the treatment of pruritus.

T 0709/23: board's decision

- Two issues were raised under Article 83 EPC:
  1. Whether the therapeutic effect demonstrated in dogs, as disclosed in the patent application, could be credibly extrapolated to cats.
  2. Whether the skilled person would be able to carry out the invention over the entire scope of claim 1 without undue burden.
- The board decided that it was not necessary to answer the first question – assumed that the effect observed in dogs was credibly achieved in cats.

T 0709/23: board's decision

- The skilled person, attempting to carry out the invention in cats as claimed, would have followed the teaching of the patent application.
- The central teaching of the patent application was considered to be that antibodies binding the conserved epitope between dog and cat IL-31 would be effective at treating pruritus in cats.

T 0709/23: post-published evidence

- D51 tested 11E12 and 15H05 antibodies.
  - 11E12 binds to the conserved epitope on feline IL-31.
  - 15H05 binds to a distinct epitope on IL-31.
- D51 demonstrated that an *in vivo* effect on reducing IL-31-induced pruritus in cats was only obtained for variants of antibody 15H05, whereas both of the tested 11E12 antibody variants did not show the claimed therapeutic effect.

T 0709/23: board's conclusions

- The data in D51 demonstrate that there is no clear correlation between the functional features recited in the claim and the *in vivo* efficacy in treating a pruritic or allergic condition in cats.
- This cannot be regarded as an occasional failure: it must be assumed that this **entire class of antibodies** is not suitable for treating pruritus in cats.
  - No evidence or any indication to support this was an isolated failure.

T 0709/23: board's conclusions

- The central teaching of the patent application of a conserved region between dog and cat IL-31 which could be targeted by an antibody would have led to failure when aiming at providing an antibody for treating pruritus in cats.
- The patent application contains no indication of any epitope located outside the conserved region identified in the patent application.
- The patent was revoked.

T 0709/23: takeaways

- Illustrates the risks of filing a broad invention too early:
  - subsequent filings may impact upon the sufficiency of earlier filings; and
  - earlier filings may impact upon the patentability of subsequent filings to lead candidates.
- For broad claims, any impact on sufficiency may apply to the entire class of actives.
- For functionally defined actives, establish a reliable association between the recited function and the claimed therapeutic effect in the application as filed.

- **T 0883/23:** priority entitlement and the “same invention”

T 0883/23: background

- Landmark decision on priority G 2/98 set a test for valid priority of “same invention” which requires that:

  > “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”.

- In the case of a medical use claim, what if the “functional technical features of the claim” are not disclosed in the priority application?
- How does it affect the requirement of “same invention”?

T 0883/23: claimed subject-matter

- Claim 1 as granted related to:
  - Liposomal irinotecan for use in a defined combination treatment of metastatic adenocarcinoma of the pancreas in a patient who has not previously received chemotherapy.
- The claim specified a combination of liposomal irinotecan, oxaliplatin, leucovorin, and 5-fluorouracil at specific doses, including 60 mg/m^2 of liposomal irinotecan and 60 mg/m^2 of oxaliplatin.

T 0883/23: content of the priority application

- Claim 1: A method of treating pancreatic cancer in a human patient who had not previously received chemotherapy, which involves the administration of liposomal irinotecan.
- Dependent claims specify the combination therapy and various specific dosages, including:
  - Dependent claim 5 – the administration of 60 or 80 mg/m^2 liposomal irinotecan.
  - Dependent claim 8 – the administration of 60, 75 or 85 mg/m^2 oxaliplatin.
- Table 7: A study protocol for a dose escalation/de-escalation trial.

T 0883/23: content of the priority application

Level	Oxaliplatin		5-FU/LV		Nal-IRI	
	Dose (mg/m^2)[a]	Dose Day[c]	Dose (mg/m^2)[b]	Dose Day[c]	Dose (mg/m^2)	Dose Day[c]
1	60	1, 15	2400/400	1, 15	80	1, 15
-1[d]	60	1, 15	2400/400	1, 15	60	1, 15
2[e]	85	1, 15	2400/400	1, 15	80	1, 15
-2A[d]	75	1, 15	2400/400	1, 15	80	1, 15
-2B[d]	85	1, 15	2400/400	1, 15	60	1, 15

a First dose administration in conjunction with first dose of nal-IRI; oxaliplatin to be administered 2 hours after the completion of the nal-IRI infusion in Part 1.

b 46 hour infusion, no bolus is given; leucovorin and 5-FU will be administered last, following the completion of the oxaliplatin infusion

c Day indicated is part of a 28-day cycle

d Dose levels shaded in grey above are for de-escalation only. Enrollment in these dose levels will only be initiated upon agreement of the Investigators, the Sponsor, and the Medical Monitor.

e Dose level 2 is the target dose for Arm 1, based on Conroy *et al.* [1], and will be used in Part 2 of the study following dose confirmation according to methods described herein .

Note: The dose of nal-IRI and 5-FU/LV in Dose Level 1 and 2 above is the same dose and schedule that was previously used in the NAPOLI-1 Phase 3 study.

T 0883/23: content of the priority application

- However, the priority application did not disclose:
  - any experimental data accompanying the study protocol; or
  - any indication of the tolerability or otherwise of any dosage regime.

T 0883/23: data added to the PCT application

- The patent application contains the data from the study protocol included in the priority application.
  - Dosage regime 1 (80 mg/m^2 liposomal irinotecan and 60 mg/m^2 oxaliplatin) found not tolerable for patients.
  - Claimed regime (dosage regime -1: 60 mg/m^2 liposomal irinotecan and 60 mg/m^2 oxaliplatin) found tolerable.
- This data shows that dosage regimes encompassed by claims 5 and 8 of the priority application containing 80 mg/m^2 liposomal irinotecan are not suitable for use in the claimed therapeutic treatment.

T 0883/23: board's decision

- Board summarised existing case law:
  - Attaining claimed therapeutic effect of medical use claim is a functional technical feature of the claim (Case Law of the Boards of Appeal, 11e, 2025, II.C.7.2.2).
  - The tolerability of a treatment is a prerequisite for therapeutic efficacy (T 2506/12).
- Held that the tolerability of the dose combination as defined in claim 1 of the Main Request, is thus a functional technical feature of the claim.
- This feature concerns information on the tolerability of the claimed dose which is not directly and unambiguously derivable from the priority application – not provided by the "mere outline" for the study given in the priority application.

T 0883/23: “same invention”

The catchword for the present decision reads (emphasis added):

“The Enlarged Board of Appeal determined in G 2/98 that it is a condition for the compliance with the requirement of "the same invention" that the claimed subject-matter is directly and unambiguously derivable from the earlier application. However, the Enlarged Board did **not** conclude that the requirement of "the same invention" is necessarily satisfied if this condition is fulfilled, irrespective of any technical information associated with the claimed subject-matter, which is **only** described in the subsequent patent application”.

T 0883/23: sufficiency at the priority date

- The board also commented on sufficiency of disclosure for second medical use claims at the priority date.
- The board highlighted that the case law “confirms the need for sufficient disclosure of the claimed invention in the priority document”.

T 0883/23: takeaways

- Sufficiency must be satisfied at the priority date, and not just at the filing date.
- The EPO appears to apply a strict standard for a valid priority claim for the claimed dosage regime.
  - The Board found that a study protocol was not enough in this case where the results of the clinical trial showed that some of the dosage regimes disclosed in the priority document were not tolerated.

- **T 0867/23:** post-published evidence to support medical use claims

Background: case law

- The EBoA confirmed in G 2/21 that:
  - the application at the filing date must make it credible that the therapeutic agent is suitable for the claimed therapeutic application; and
  - this must be the case for post-filing data to be admissible.
- T 609/02:

  "… then post-published (so-called) expert evidence (if any) may be taken into account, but only to back-up the findings in the patent application in relation to the use of the ingredient as a pharmaceutical, and not to establish sufficiency of disclosure on their own."

T 0867/23: claimed subject-matter

- Granted patent related to:

  Trans-4-{2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl}-N,N-dimethylcarbamoyl-cyclohexylamine [cariprazine] and/or pharmaceutically acceptable salts and/or hydrates and/or solvates and/or polymorphs thereof for use in treating primary negative symptoms of schizophrenia.

- "Negative" symptoms relate to absence of normal behaviour (e.g. lack of motivation or social withdrawal)
- "Primary" meaning symptoms directly related to the schizophrenia and not from comorbidities (e.g. depression)

T 0867/23: data in the application

- Clinical results of a post-hoc study that was double-blind, placebo- and risperidone (alternative treatment)-controlled.
- The claimed compound showed a stronger decrease in negative symptoms in a subgroup of patients compared to the entire intent to treat population which was not seen with risperidone.
- The subgroup of patients exhibit negative symptoms and low to moderate positive symptoms (i.e. predominantly negative symptoms).
  - Study design could not directly conclude that decreased negative symptoms were all primary.
  - However, rationale that impacts of secondary negative symptoms were minimal was present in the application as filed.

T 0867/23: post-published evidence

- D13 was a randomised, double-blind, phase 3b trial carried out specifically on patients with predominantly negative symptoms.
- D13 selection criteria more restrictive than the trial in the application, which permitted the direct conclusion that the decreased negative symptoms were primary.
- D13 confirmed the findings of the application: cariprazine is effective on primary negative symptoms.

T 0867/23: board's decision

- D13 was admissible in this case.
- Board first considered if the application rendered credible the therapeutic effect:
  - The data in the patent comparing the general population with the sub-population with predominantly negative symptoms, together with the explanations and data, suggest that cariprazine has a therapeutic effect on primary negative symptoms of schizophrenia.
- D13 was admitted to "backup the findings" in the application and "refute the appellants' criticisms" of the initial data disclosed therein.
- Considered sufficiently disclosed and the appeals were dismissed.

T 0867/23: board's decision

- In reaching its decision, the board also provided some guidance on when post-filed data may be considered admissible.
- Following G 2/21, a reliance on post-published evidence is not ruled out generally in the context of sufficiency of disclosure for second medical use claims.
- Ability to rely on post-filed data also cannot be limited to situations where it serves no useful purpose, i.e. when the effect is already convincingly proven in the application.

T 0867/23: board’s decision

- The EBoA concluded the following in G 2/21 (see point 77):

  “The reasoned findings of the boards of appeal in the decisions referred to above make clear that the scope of reliance on post-published evidence is much narrower under sufficiency of disclosure (Article 83 EPC) compared to the situation under inventive step (Article 56 EPC). In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, the proof of a claimed therapeutic effect has to be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved. A lack in this respect cannot be remedied by post-published evidence.”

- In the board's view, this statement does not set a new standard for reliance on post-published evidence in the context of sufficiency of disclosure.

T 0867/23: takeaways

- Provided that the application renders it credible to the skilled person that the therapeutic effect is achieved, it is possible to rely upon post-published evidence in the context of sufficiency of disclosure for second medical use claims.
- There is no new standard set in G 2/21, which departs from the case law summarised in that decision.
- Ability to rely on post-filed data also cannot be limited to situations where it serves no useful purpose.

Related webinar

UPC Case Law, Observations & Analysis
1pm GMT, Wednesday 10 December 2025
www.dycip.com/webinar-upc-dec2025

Rachel Bateman, David Al-Khalili and Laura Jennings will discuss the latest UPC case law and procedures, including:

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- Procedural aspects v the EPO
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