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European biotech patent case law

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Speakers

Simon O’Brien
Partner, Patent Attorney
swo@dyoung.com

Nathaniel Wand
Senior Associate, Patent Attorney
now@dyoung.com

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Latest European biotech patent case law

- T 0136/24 & UPC_CFI_496/2024
  Phase 3 clinical trials and inventive step
- An update on G 2/21
  Post-filed data for inventive step
- T 0738/23
  Lack of novelty of medical use claims reciting a “composition for use in…”

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Phase 3 clinical trials and inventive step: T 0136/24 & UPC_CFI_496/2024

Clinical trial protocols

Clinical trials are conducted to assess the efficacy and risks of drugs.

Information about clinical trials protocols are often publicly available, creating problems for patent filings.

Clinical trials protocols usually not novelty destroying for second medical use claims but more often prejudices the inventive step

Should you file before publication of clinical trial protocol when no results available?

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Inventive step in view of clinical trial protocol

Growing body of case law that clinical trial protocols provide the skilled person with a **reasonable expectation of success**, unless the state of the art provides **evidence to the contrary** / an **expectation of failure** (see for example, T 1123/16, T 2506/12, T 239/16, T 96/20).

Will depend on the facts of each case.

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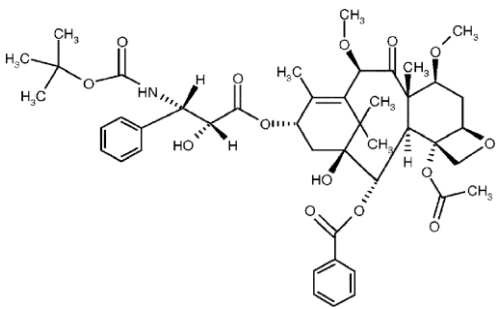
EP2493466

Claim 1: Compound of formula



which may be in base form or in the form of a hydrate or a solvate, in combination with prednisone or prednisolone, for use in treating prostate cancer, in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment

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Background

EPO

- Patent maintained as granted by OD
- OD decision upheld on appeal – Decision dated 3 June 2025
- Claims found inventive

UPC

- Sanofi launched infringement actions against Stada, Dr Reddy's, Zentiva and Accord. Each counterclaimed for revocation
- Munich Local Division revoked the patent on the basis that the granted claims did not possess an inventive step – OPs 14 & 15 October 2025, Decision dated 12 December 2025

France

- Patent revoked for lack of inventive step – Decision dated 6 September 2024

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Key documents

- **D1**, **D2**, and **D6** – TROPIC Phase III clinical trial protocol
  - mCRPC patients which had to have been previously treated with a docetaxel-containing regimen
  - Experimental study arm – cabazitaxel and prednisone
  - Control arm – mitoxantrone and prednisone
  - Primary objective – overall survival in patients in the study group compared to the control group
  - Start date and estimated completion date of the study - study was ongoing/active
  - No experimental data are disclosed

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Key documents

- **D4** – Phase I study
  - Phase I: Cabazitaxel in 25 patients with different advanced solid tumours
  - 8 patients had prostate cancer – responses were observed in two of these patients and only one had been treated with docetaxel prior
  - Does not disclose that the patients also received prednisone or prednisolone

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Key documents

- **D13** – Phase II study in breast cancer
  - All patients had previously been treated with a taxane, with most having received docetaxel (65% docetaxel alone and 10% more than one taxane)
  - Favourable outcomes for cabazitaxel in patients with taxane-resistant metastatic breast cancer
  - Concluded that the results supported further clinical trials
  - But not followed up with a phase III study in breast cancer, line of development for breast cancer discontinued – **D20**
  - Proprietor relied on this data to have the TROPIC trial in prostate cancer approved

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Inventive step approaches: EPO v UPC

EPO “problem-solution”

i. Determine the “closest prior art”

ii. Establish the “objective technical problem” to be solved, and

iii. Consider whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

UPC “holistic approach”

i. Establish the objective problem from the perspective of the skilled person with their CGK,

ii. Determine a realistic starting point from the prior art

iii. Determine whether the skilled person, wishing to solve the objective problem, would, from a realistic starting point, have arrived at the claimed solution and have expected to do so

Edwards v Meril; Amgen v Sanofi

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CPA/starting point

EPO

- D1, D2, D3, D6, D7 and D37 – **TROPIC phase III trial** – experimental arm or control arm
- D4 – phase I study
- D7, D39 and D110 – established treatment options of mCRPC after treatment with a docetaxel-based regimen

UPC

- D2 – TROPIC phase III clinical trial protocol

Difference:

- for use in treating prostate cancer, in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment
- Therapeutic efficacy not directly and unambiguously disclosed in the prior art/only disclosed in the form of a hypothesis that is currently being verified

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Problem to be solved

EPO

"to put into practice the effective treatment of prostate cancer with cabazitaxel in co-administration with prednisone in patients with mCRPC who have been previously treated with a docetaxel-based regimen and who have prostate cancer that progressed during or after that treatment"

UPC

"to provide a therapeutic option for treating patients suffering of castration resistant metastatic prostate cancer who have been previously treated with docetaxel-based regimen and have prostate cancer that progressed during or after that treatment"

- Commented that the TBA formulation of the objective technical problem contains parts of the solution and thus does not avoid hindsight
- More weight on the data in the application as filed

"effective treatment" v "therapeutic option"

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Reasonable expectation of success?

EPO

- Success in the context of a clinical study means meeting the primary endpoint
- In the present case, an expectation of success for improved overall survival must have been present

UPC

- The question of reasonable expectation of success of the approach disclosed in the TROPIC trial documents, in terms of assessing an inventive step, is not the same as the question of whether the TROPIC trial will meet its primary endpoint
- The objective problem and the primary end point of the TROPIC trial are different – objective problem includes both increased overall survival and palliative treatment

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Reasonable expectation of success?

- Both agreed that ongoing clinical studies does not automatically establish a reasonable expectation of success and each case must be assessed based on its circumstances
- Both decisions were also based on balancing positive and negative pointers

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Pointers: discussed in TBA decision (as put forward by the opponents)

a) Docetaxel was known for its efficacy in mCRPC and its superiority in comparison with a mitoxantrone-based regimen

b) Cabazitaxel was of the same class as docetaxel and had been designed to overcome cellular resistance to docetaxel

c) The data known from preclinical, phase I and phase II testing were encouraging.

d) Phase III clinical trial had been approved with phase II skipped.

e) The person skilled in the art would have inferred that the regulatory agency had been supplied by the study sponsors with additional data in favour of cabazitaxel not publicly available and would have contributed to an expectation of success on the part of the regulatory agency (D15 and D21 as evidence).

f) The fact that the study was nearing completion at the priority date of the patent and had not been terminated prematurely.

g) Without a realistic expectation of success, the patent proprietor as the study sponsor would not have invested money into the TROPIC study.

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Pointers: UPC

Pointers discussed in Munich LD decision:

- Each of D7 (review), D13 (Phase II), D9 (review), and D4 (Phase I) alone and considered collectively
- Study was nearing completion
- Other Phase III taxane trials discontinued

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Phase I and phase II studies (D4 & D13)

EPO

- Phase I data – only a single patient in the population to be treated had been reported
- Phase II data – did not allow any insights on a possible increase in overall survival
- Overall survival is linked to type of cancer and stage of disease progression, a phase II clinical study on breast cancer cannot be taken into account as a matter of principle

UPC

- Phase I data – Acknowledged that a single patient may not be sufficient for a reasonable expectation of success, but only if there was no phase III trial which was almost complete, without interruption or discontinuation.
- Phase II data – Acknowledged that the study related to a different type of cancer, but considered that the study sheds light on an interesting property of cabazitaxel with regard to the treatment of patients who are resistant to a first taxane, namely docetaxel

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Phase I and phase II studies (D4 & D13)

EPO

- The TROPIC study cannot be considered a confirmatory study as earlier data are lacking

UPC

- While the previous studes are limited, they are also encouraging.
- The results justified the continuation of the clinical development of this agent and demonstrated activity even when the strictest resistance criterion was used.
- No evidence against cabazitaxel's efficacy in the treatment of mCRPC as a second-line treatment

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Study nearing completion

EPO

- The fact that a study is nearing completion per se, in the absence of knowledge of the parameters selected for monitoring, is neither a positive nor a negative pointer when assessing expectation of success

UPC

- Did acknowledge board's view, but put weight on this factor on the basis that the skilled person would be aware of the process and an expectation of success could therefore be inferred

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Outcome

EPO

- “no reasonable expectation of success and that the person skilled in the art could at most have entertained a hope to succeed in solving the objective technical problem [improved overall survival]”
- Claims are inventive

UPC

- “the person skilled in the art would have considered that, compared to mitoxantrone plus prednisone, which he knew had only a first-line palliative effect and was not even approved for second-line use, the second-line cabazitaxel plus prednisone experiment in progress in a phase III trial for more than three years, had a reasonable chance of showing a favourable effect including the (moderate) increase in survival”
- Claims lack inventive step

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Summary: similarities

- A clinical trial protocol is not novelty destroying
- A clinical trial protocol does not implicitly give rise to a reasonable expectation of success - should be assessed based on the specifics of each case
- Positive and negative pointers assessed

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Summary: differences

- Formulation of the problem to be solved – “effective treatment” vs “therapeutic option”
- Threshold for “reasonable expectation of success” – primary objective of clinical trial vs any therapeutic effect at all
- EPO put more weight on the fact that the phase II trial was for a different therapeutic indication
- Munich LD put more weight on the knowledge that the Phase III trial was nearly complete, particularly in combination with the Phase I and Phase II studies
- More reliance on expert testimony by Munich LD

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Conclusions

- Both decisions confirm that clinical trial protocols will be considered on a case by case basis
- In this case, the Munich LD seemed overall more persuaded by the positive pointers than the EPO
- Potentially indicate that the threshold for an expectation of success before the UPC will not be restricted to the primary outcome of the clinical trial protocol and may be as broad as any therapeutic effect

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When to file?

File prior to publication of clinical trial protocol?

- Pros – avoids prior art
- Cons – lack of data – implication for lack of sufficiency and/or justification of inventive step – file post published data – G2/21?

File after publication of clinical trial protocol?

- Pros – Have data in application
- Cons – can be very difficult to establish inventive step

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An update on G 2/21 Post-filed data for inventive step

G 2/21: background

- “A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, **would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention**.”

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T 0116/18: two-step test

- (1) “Encompassed by the technical teaching” - the purported technical effect together with the claimed subject-matter **need only be conceptually comprised** by the broadest technical teaching of the application as filed. It may be sufficient that the skilled person recognises that said effect is **necessarily relevant** to the claimed subject-matter.
- (2) “Embodied by the same originally disclosed invention” unless the skilled person, having the common general knowledge on the filing date in mind, and based on the application as filed, would have **legitimate reason to doubt** that the purported technical effect can be achieved with the claimed subject-matter.

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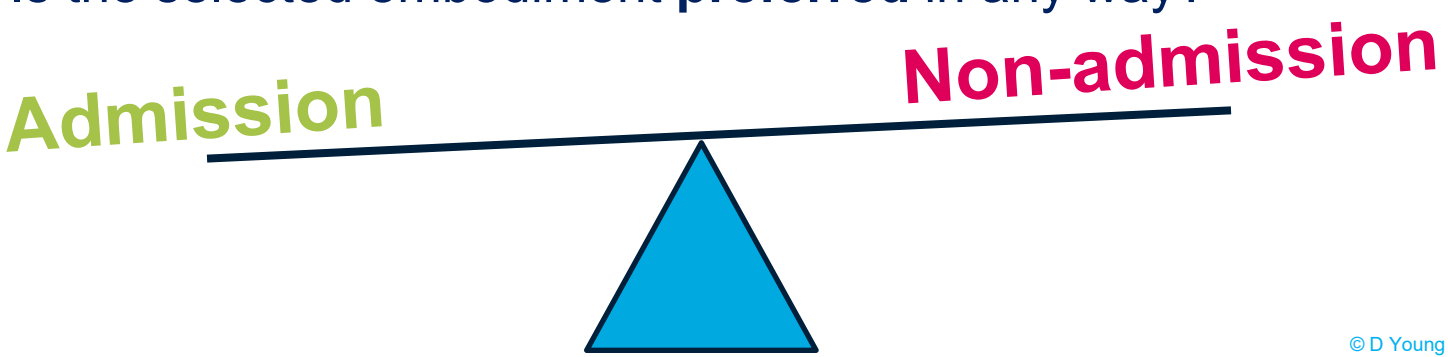
Factors for applying G 2/21 test

- Is the effect “encompassed by” the technical teaching and “embodied by” the same originally disclosed invention?
  1. Is a **relationship** between the claimed matter and effect known?
  2. Are there any **reasons to doubt** the effect?
  3. Is the selected embodiment **preferred** in any way?



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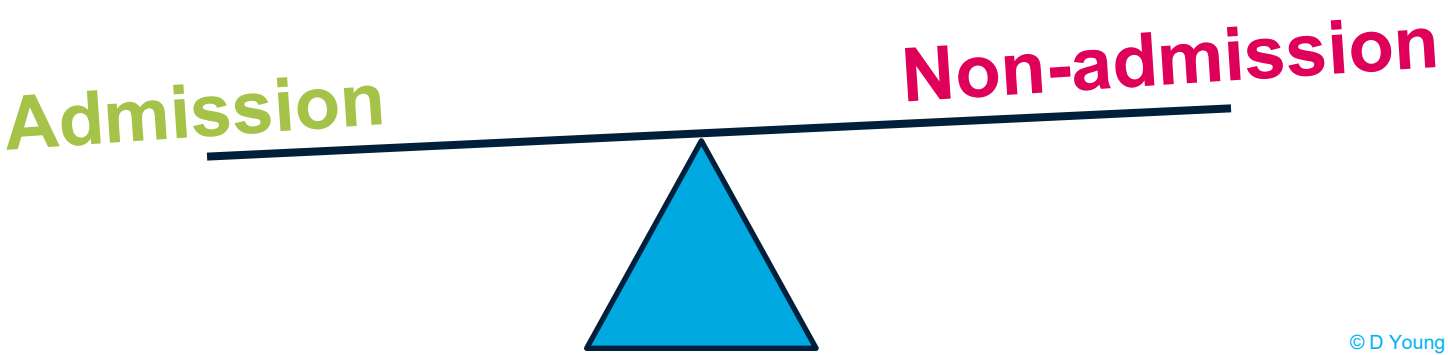
1. Is a relationship between the claimed matter and effect known?

Relationship disclosed in patent

Relationship previously unknown



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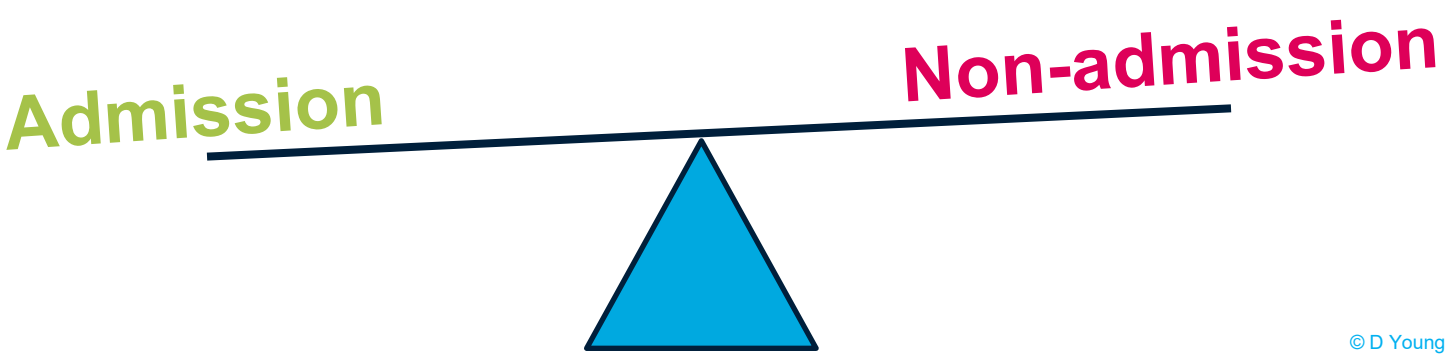
1. Is a relationship between the claimed matter and effect known?

Relationship disclosed in patent

Is relationship common general knowledge?

Relationship previously unknown



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T 1989/19: relationship known from CGK

- Claim related to a crystalline micronisate.
- “the skilled person was **well aware** before the priority date …that the stability of the particle size is of **crucial importance** for the administration of a medicinal product by inhalation. As evidence of **common knowledge**, the respondent referred to documents D1, D16a, D16b and D17.”
- Post-filed data related to storage stability compared with closest prior art was admitted.

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T 1847/23: relationship **not** known from CGK

- Claim related to a pharmaceutical composition comprising maropitant, cyclodextrin, and **7-18 mg/ml** benzyl alcohol.
- Data in the patent showed **improved injection site tolerance** and meets antimicrobial requirements.
- D1 differed in that composition comprised **20 mg/ml** benzyl alcohol.
- Annex 3 was post-filed to demonstrate **improved stability of claimed composition** **at low temperatures over several freeze/thaw cycles**.

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T 1847/23: relationship not known from CGK

The board did not admit post-filed data in Annex 3:

- The application as filed **does not contain any observation in relation to the stability** of the claimed compositions, even less at specific low or very low temperatures or after freeze/thaw cycles.
- The preparation and/or storage of a drug composition at low or very low temperatures is **neither systematic nor widely practiced**. There is no indication in the application as filed or in the prior art that the compositions comprising maropitant have to be prepared and/or stored under these conditions (c.f. D10).
- **Consequently, the behaviour of compositions comprising maropitant under low or very low temperatures cannot be considered as a common problem as argued by the OD.**

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1. Is a relationship between the claimed matter and effect known?

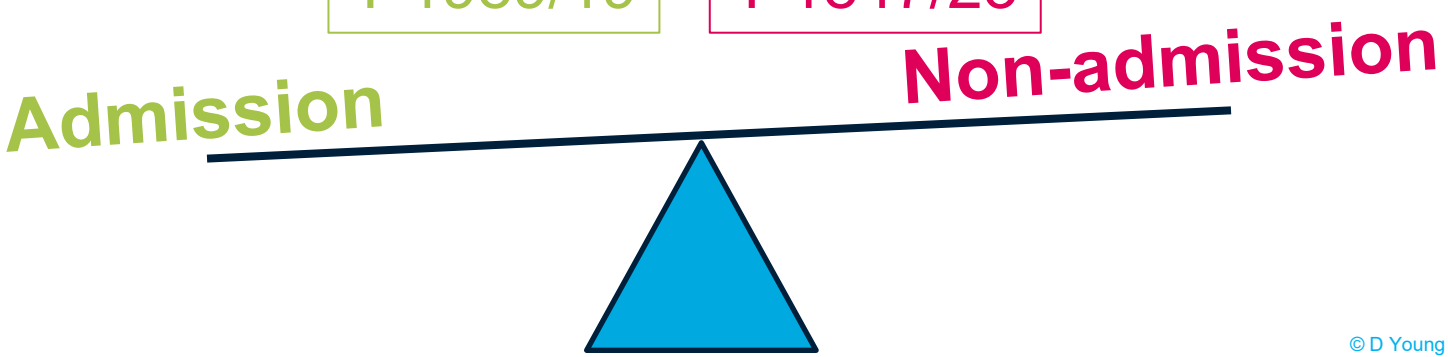
Relationship disclosed in patent

Is relationship common general knowledge?

Relationship previously unknown

T 1989/19

T 1847/23



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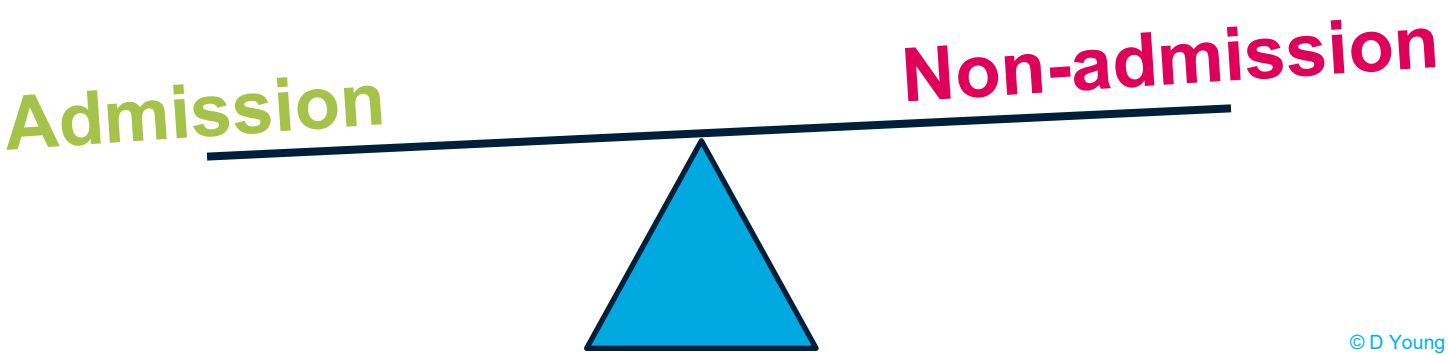
2. Are there any reasons to doubt the effect?

Closely related data in patent

Legitimate doubts



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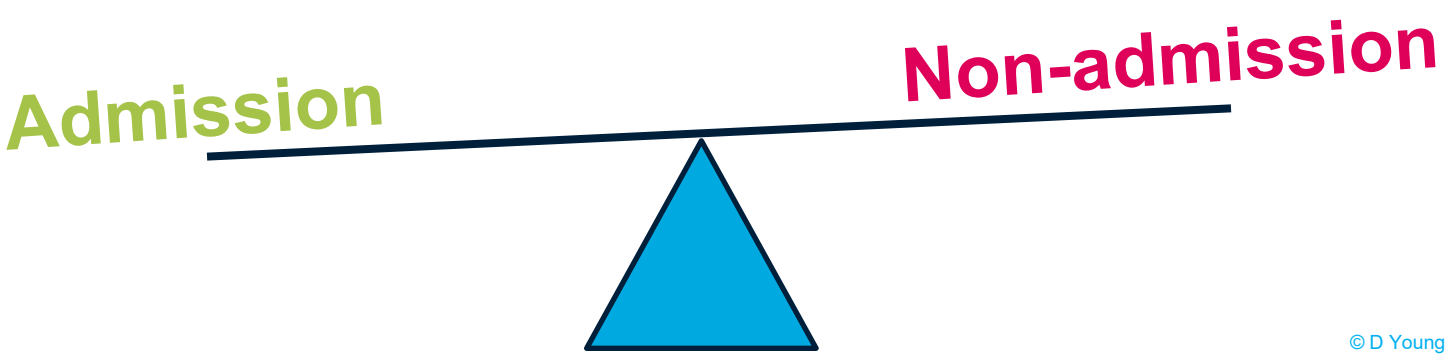
2. Are there any reasons to doubt the effect?

Closely related data in patent

Effect unproven but no reason to doubt?

Legitimate doubts



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T 2046/21: no reason to doubt effect

- Claim related to a preservative free bimatoprost and timolol composition for use in lowering intraocular pressure (i.e. no benzalkonium chloride (BAK))
- Patent **did not provide any experimental data** regarding its use in lowering intraocular pressure.
- Post-filed data to substantiate an **improved/maintained efficacy for the BAK-free composition** compared to prior art composition comprising BAK.

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T 2046/21: no reason to doubt effect

- An IOP lowering effect of the claimed combination **would have been expected** at the filing date. It was CGK that both active ingredients were used to reduce IOP.
- No consensus existed in the cited prior art on the potential effect of preservative BAK on improving the efficacy of the composition in lowering IOP. There was therefore **no legitimate reason to doubt a priori** that the effect mentioned in the application as originally filed could be achieved.
- Post-filed data related to improved/maintained efficacy for the BAK-free composition was admitted.

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T 1385/23: the effect is unproven

- Claim related to a multi-layer liquid absorption and distribution fleece for hygiene products.
- Proprietor argued that the technical effect was **to improve the liquid absorption capacity** of comparable materials for a given distribution effect.
- The Proprietor offered to carry out comparative tests to establish this **across the whole scope** of the claim.

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T 1385/23: the effect is unproven

- Board held that it can not only be regarded as **unproven**, but must also be regarded as **not covered by the technical teaching** of the patent that an improvement in the liquid absorption capacity would be achieved across whole scope covered by claim 1 for a given distributive effect. Based on the information in the patent, **a skilled person would not expect this**.
- In such a case, a patent proprietor cannot rely on this effect to prove inventive step…to prevent patents from being granted on inventions that had not been completed at the filing date. This is particularly true for inventions **where the existence of a technical effect or the generalization to broader parameter ranges is speculative**.
- Therefore, even if the board had given the respondent the opportunity to provide new comparative tests, they would not be admitted.

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2. Are there any reasons to doubt the effect?

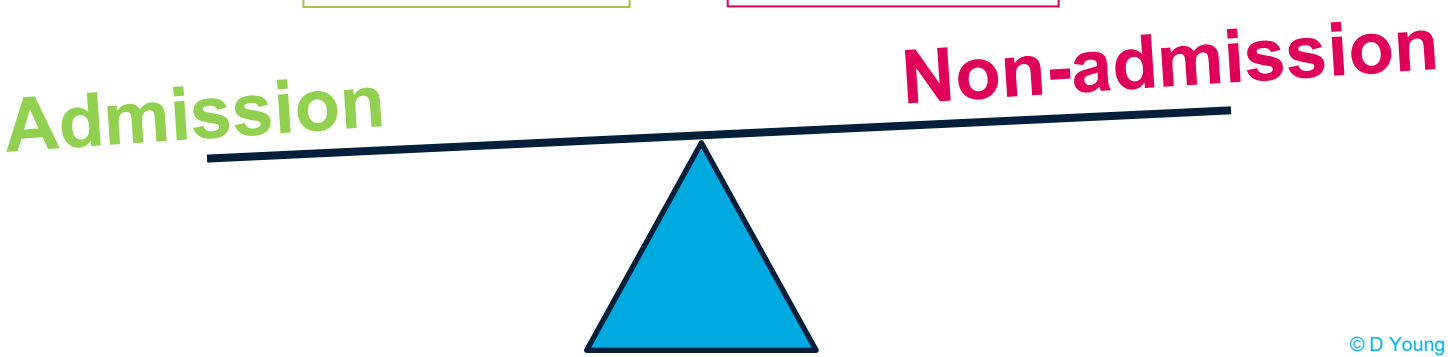
Closely related data in patent

Effect unproven but no reason to doubt?

Legitimate doubts

T 2046/21

T 1385/23



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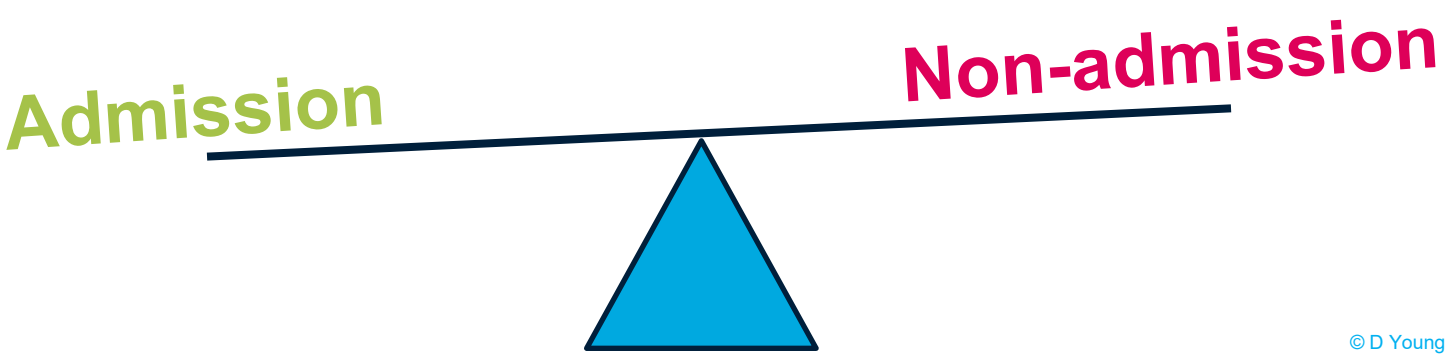
3. Is the selected embodiment preferred?

Most preferred embodiment

From a list of equally preferred embodiments



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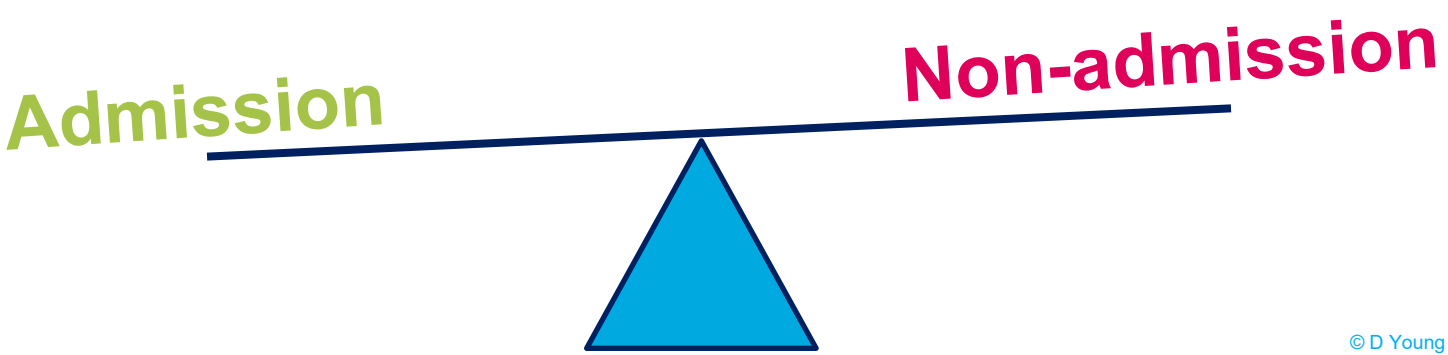
3. Is the selected embodiment preferred?

Most preferred embodiment

One of several preferred embodiments?

From a list of equally preferred embodiments



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T 0840/22: two preferred embodiments

- Claim related to a multilayer coated metal substrate
- **Two equivalent embodiments** disclosed: (1) the corrosion-inhibiting components being the **same**; (2) the corrosion-inhibiting components **differing** from each other.
- The board admitted post-filed data showing that embodiment (2) has **improved corrosion resistance** compared to embodiment (1)

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T 0840/22: two preferred embodiments

- "The fact to which the appellant took offence, **namely that one of several embodiments disclosed in the application as filed turns out to be better…does not change this conclusion…this scenario is precisely what regularly occurs in patents/patent applications in the field of chemistry,** where claimed subject-matter must be limited at the expense of subject-matter disclosed in the application as filed as part of the invention, because the effect relied on for inventive step over the closest prior art is not achieved across the entire breadth of the claimed subject-matter"

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T 0314/20: three preferred embodiments

- Claim related to the combination of empagliflozin and linagliptin.
- Post-filed data to show that claimed combination increased the plasma level of active GLP-1 in patients with diabetic diseases in a **stronger and more prolonged manner** than the **other two combinations** described in the application.
- The board did not admit the post-filed data.

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T 0314/20: three preferred embodiments

- The application disclosed that the other combinations had the **same level of preference** and achieve the **same increase** in plasma levels of active GLP-1 in patients as the claimed combination.
- “the skilled person, would **not** derive the increase in plasma levels of active GLP-1 relied on by the respondent as being encompassed by the technical teaching of the claimed invention and embodied by the same originally disclosed invention”

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3. Is the selected embodiment preferred?

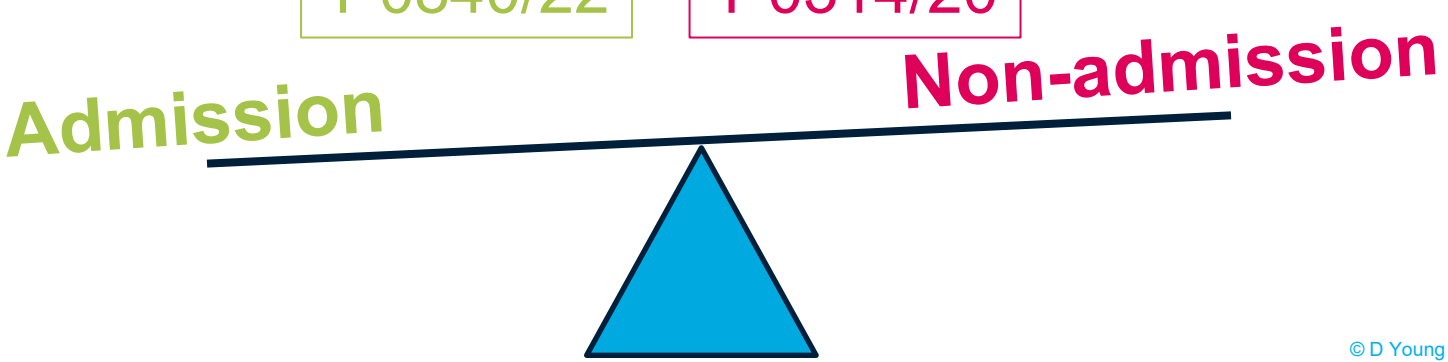
Most preferred embodiment

One of several preferred embodiments?

From a list of equally preferred embodiments

T 0840/22

T 0314/20



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Summary of G 2/21 factors

1. Is a **relationship** between the claimed matter and effect known?
   - Is the effect crucial importance in the field (T 1989/19) or not a common problem (T 1847/23)?
2. Are there any **reasons to doubt** the effect?
   - Is there no reason to doubt the effect can be achieved (T 2046/21) or is the effect merely speculative (T 1385/23)?
3. Is the selected embodiment **preferred** in any way?
   - Is it one of two preferred embodiments (T 0840/22) or three preferred embodiments (T 0314/20)?

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T 0738/23
Lack of novelty of medical use claims reciting a “composition for use in…”

T 0738/23: background

- Article 54(5) EPC allows for purpose-limited product claims of format:

“Product X for use in treating and/or preventing disease Y”

- Such a claim is patentable provided that the recited use of product X is novel and inventive.
- But Article 54(5) EPC distinguishes between a **substance or composition.**

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T 0738/23: granted claims

- **Claim 1:** **A MCFA [medium chain fatty acid] for use in** treating and/or preventing anxiety wherein, the MCFA is decanoic acid or octanoic acid and wherein, the MCFA is in the form of a medium chain triglyceride (MCT).
- **Claim 3:** **A composition** comprising a MCFA as defined in any one of claims 1 to 2 **for use in** treating and/or preventing anxiety.

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T 0738/23: cited prior art

- D21 disclosed that the consumption of lipids from **goat milk** resulted in a reduction of anxiety of rats.
- The presence of **triglycerides of octanoic acid and decanoic acid** is **implicit**, because D22 shows that they are present in goat milk.
- D21 therefore discloses the use of **a composition** comprising octanoic acid and decanoic acid in the form of triglycerides for the prevention or treatment of anxiety.

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T 0738/23: board's decision

- "Whereas claim 1 relates specifically to decanoic or octanoic acid in the form of MCT for the treatment of anxiety, claim 3 **more broadly encompasses any composition** comprising the same compounds as in claim 1, **potentially along with additional substances**, for the same therapeutic application."
- "…claim 3 does **not** relate to the therapeutic use of a **substance** but rather to the therapeutic use of **any composition** comprising specific substances."
- Claim 3 lacks novelty over D21 but claim 1 novel and inventive.

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T 0738/23: take-aways

- Under EPO practice there is a difference in claim scope for novelty/inventive step between:
  - "**Substance X** for use in treating disease Y"
  - "**A composition comprising substance X** for use in treating disease Y"
- Take great care that claims do not read on to "accidental" disclosures.

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Webinar invitation

UPC case law, observations and analysis
1pm BST, Wednesday 17 June 2026

An analysis of the Unified Patent Court's decisions, with D Young & Co's observations and analysis.

Registration and further information:
dycip.com/webinar-upc-jun2026

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Questions

Simon O’Brien
Partner, Patent Attorney
swo@dyoung.com

Nathaniel Wand
Senior Associate, Patent Attorney
now@dyoung.com

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