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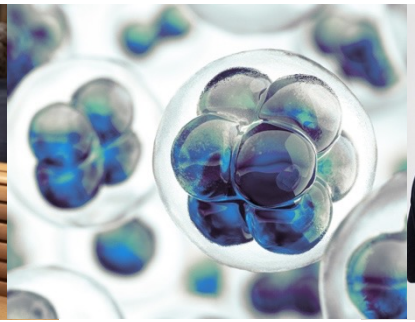
# Examination Matters reloaded

## Sufficiency of disclosure and enablement in pharmaceuticals


Miren Langer | Shiri Burema

Examiners | Healthcare, Biotechnology and Chemistry

17-19 May 2021

# Presenter

## Miren Langer

- PhD in Pharmacology
- Project manager, Medical Dept., Pharmaceutical Industry (3 years)
- Examiner at the EPO (15 years)
- Chairman in examination, chairman and first member in opposition (Opposition dir.)
- EQE (2011 and 2012)

# Presenter

## Shiri Burema

- PhD in Chemistry
- Dutch and European patent attorney, private practice (~6 years)
- Examiner at the EPO (2 years)
- Patent attorney experience with oppositions/appeals; Opposition Division experience as second member
- Dutch patent attorney exams (2017)
- EQE (2017)

# Outline

- Art. 83 EPC
  - Requirement of Suitability
  - Art. 83 EPC vs Art. 56 EPC
  - Late filed evidence
  - Case Law
- Enablement of the Prior Art
  - Requirement of Enablement
  - Clinical trials
  - Case Law
- Questions = ✓ (yes) or ✗ (no)

# Article 83 EPC for medical use claims – the requirement of suitability

# Article 83 EPC - refresher

Article 83 EPC: Disclosure of the invention

The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

# Article 83 EPC - Warm up question

**Application as filed:**

- Simple verbal assertion: XYZ treats disease A
- Experiments: *only* very detailed synthetic pathways for making XYZ

**Claim 1:** A compound of formula XYZ.

**Question:** Is claim 1 sufficiently disclosed?
Please answer ✓ (yes) or ✗ (no)

# Article 83 EPC - Warm up question

**Application as filed:**

- Simple verbal assertion: XYZ treats disease A
- Experiments: *only* very detailed synthetic pathways for making XYZ

**Claim 1:** A compound of formula XYZ for use in treating A.

**Question:** Is claim 1 sufficiently disclosed?
Please answer ✓ (yes) or ✗ (no)

# Article 83 EPC - Requirement of Suitability

It is established case law of the boards of appeal for a medical use claim to fulfil the requirements of Art. 83 EPC, …that the patent has to disclose the suitability of the product to be manufactured for the claimed therapeutic application. A claimed therapeutic application may be proven by any kind of evidence as long as it reflects the therapeutic effect on which the therapeutic application relies.

The disclosure of experimental results in the application is not always required to establish sufficiency, in particular if the application discloses a **plausible** technical concept and there are no substantiated doubts that the claimed concept can be put into practice
(**T 950/13** citing **T 578/06**).

*(Case Law of the EPO's Boards of Appeal - part II-C-7.2*
*(9th Edition, 2019))*

# T 609/02

- Second medical use claim: therapeutic effect is a functional technical feature of the claim
- the application must disclose the suitability of the product for the claimed therapeutic use (Art. 83 EPC)
- it is not always necessary that results of clinical trials or efficacy studies in animal models are reported
- Simple verbal assertion in the application is not enough
- Effect needs to be plausible at filing date (priority date)

**Conclusion: technical contribution to the art needs to be plausible => no speculative patents should be granted**

# Article 83 EPC vs Article 56 EPC

# Article 56 EPC vs Article 83 EPC: Warm up question

**Application as filed:**

- Simple verbal assertion: XYZ treats disease A
- Experiments: very detailed synthetic pathways for making XYZ and *in vitro* assays demonstrating the efficacy of a compound X for treating disease A

**Claim 1:** A compound of formula XYZ.

**Question:** Should claim 1 be objected to under **Article 83 EPC**?
Please answer ✓ (yes) or ✗ (no)

# Article 56 EPC vs Article 83 EPC: Warm up question

**Application as filed:**

- Simple verbal assertion: XYZ treats disease A
- Experiments: very detailed synthetic pathways for making XYZ and *in vitro* assays demonstrating the efficacy of a compound X for treating disease A

**Claim 1:** A compound of formula XYZ for use in treating A.

**Question:** Should claim 1 be objected to under **Article 83 EPC**?
Please answer ✓ (yes) or ✗ (no)

# Article 56 EPC vs Article 83 EPC: Warm up question

**Application as filed:**

- Simple verbal assertion: XYZ treats disease A
- Experiments: very detailed synthetic pathways for making XYZ

and *in vitro* assays demonstrating the efficacy of a compound X for treating disease A

**Claim 1:** A compound of formula XYZ

**Question:** Should claim 1 be objected to under **Article 56 EPC**?
Please answer ✓ (yes) or × (no)

# Article 56 EPC vs Article 83 EPC: Guidelines F-III, 12

- Claimed invention lacks reproducibility (non-working examples or not credible/plausibly solved for all embodiments)

  ▶ issue of sufficiency of disclosure **or** of inventive step

- Technical effect expressed in the claim (e.g. 2nd medical use claim) not achieved/or not made **plausible**: Art. 83 EPC objection
  Since the technical effect is part of the solution proposed in the claim, it cannot be part of the problem underlying the application

- Effect is not expressed in the claim (e.g. product claim) but is part of the problem to be solved: Art. 56 EPC objection: problem not solved over the whole scope of the claim – not **credible**
  (G 1/03, reasons 2.5.2, T 1079/08, T 1019/10, T 5/06 and T 380/05)

# Article 56 EPC vs Article 83 EPC

A compound of formula XYZ.

- Technical effect is not a feature of the claim.
- Is it **credible** that all compounds are a solution to the problem addressed?
- Art. 56 EPC objection with reference to the CPA and, if necessary, reformulation of the objective problem

A compound of formula XYZ for use in treating A.

- Technical effect is a feature of the claims.
- Is it **plausible** that all compounds can be used successfully for treating A?
- Art. 83 EPC objection

# Can insufficiency of disclosure be solved by submitting post-published evidence?

# Late filed evidence

## Guidelines H-V, 2.2

- Of avail: an additional example, as evidence that the invention can be applied, on the basis of the information in the application as filed, over the whole field claimed (F-IV, 6.3)
- Of no avail: If effect is not made at least plausible in the application as filed (T 609/02)

# Late filed evidence – Warm up question

**Application as filed:**

- Simple verbal assertion: XYZ treats disease A
- Experiments: very detailed synthetic pathways for making XYZ

and a hypothetical example: “experiments may be performed using protocol B”, “effects may be observed for treating disease A” (no data)

**Claim 1:** A compound of formula XYZ for use in treating A.

**Question:** Is claim 1 sufficiently disclosed?
Please answer ✓ (yes) or ✗ (no)

# T 1868/16 –illustrative case law: plausibility (Art. 83 EPC), common general knowledge and post-published evidence

# T 1868/16: Article 83 EPC – 2nd medical use (1/5)

**Claim 1:**
2nd medical use of everolimus for the treatment of pancreatic tumour

- **Data in Application:**
  - reference to hypothetical clinical trial projects ("may be performed")
  - prophetic statements "effects that may be observed“
  - in vitro/in vivo experiments:
    - inhibition of S6K1 activity/reduction of chromogranin A (hypothetical)
    - Statement that synergistic effects were observed

**Post-published evidence:**
D6, D19, D56 disclose the use of everolimus for treating pancreatic tumour

**Question:** Are the requirements of Article 83 EPC fulfilled?
Please answer ✓ (yes) or ✗ (no)

# T 1868/16: Article 83 EPC – 2nd medical use (2/5)

**Opposition Division:**

**Requirements of Article 83 EPC are fulfilled because:**

- In the absence of any concrete evidence to the contrary it is plausible that the intended effect can be achieved.
- Post-published evidence D6, D19, D56 confirm the therapeutic activity
- Synergistic effect mentioned in the application as filed (in vitro data) implies that each active ingredient used in the combination exhibits some activity.

# T 1868/16: Article 83 EPC – 2nd medical use (3/5)

**BoA:**

**Requirements of Article 83 EPC are not fulfilled because:**

- the application must disclose the suitability for the claimed therapeutic use: clinical data is not always necessary, however a mere verbal statement is not enough
- no results of the clinical trials, no statement that a clinical trial was ongoing, only hypothetical statements "may be performed"
- synergistic effect – only mere statement
- in vitro data: inhibition of S6K1 activity and reduction of chromogranin A

**no relation established regarding efficacy in treating pancreatic tumour**

# T 1868/16: Article 83 EPC – 2nd medical use (4/5)

Is it plausible from the application as filed that everolimus can be used for the treatment of pancreatic tumour **taking into account the common general knowledge of the person skilled in art?**

**BoA:**

- In vitro data: no established relationship between the biological activity observed and the successful treatment of PNET
- D56 proves a link of reduction of chromogranin A and treatment of PNET but is post-published

**Thus the gap could not be filled by common general knowledge**

# T 1868/16: Article 83 EPC – 2nd medical use (5/5)

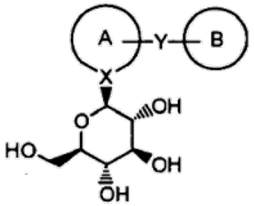
**Conclusion:**

- **hypothetical statements** that studies may be performed and effects may be observed can not establish the suitability of a compound for the treatment of a disease
- observed reduction/inhibition of biomarkers (in vitro data) can not be used as a proof for a therapeutic activity **if the link to the successful treatment is not established in the application as filed. Common general knowledge might fill in the gap** and establish the link**.**
- **if the suitability of the product is not demonstrated in the application as filed post-published data can not remedy said deficiency.** It was not made plausible in the application as filed that everolimus is effective in treating pancreatic tumour. Thus the post-published data presented additional information.

# T 0184/16 – All in one illustrative case law: plausibility (Art. 83 EPC), obviousness (Art. 56 EPC) and post-published evidence

# T 0184/16 – The case

- **Claim 14 (simplified):** A compound according to formula (I) for use in treating diabetes mellitus




(I)

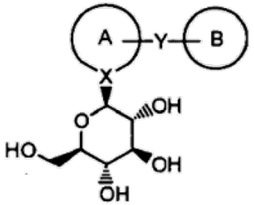
- **Application as filed:**
  - No examples showing that compounds of claim 1 can treat diabetes
  - Reference to prior art D7, which shows that other compounds (with same tricyclic core structure but different R groups) are inhibitors of SGLT2 and therefore anti-diabetic.

- **D4 (post-published evidence):**
  Compounds according to claim 1 are SGLT2 inhibitors, even better than example 26 of D2 (CPA)

**Question:** Is the medical use plausible (Art. 83 EPC) at the time of filing?
Please answer ✓ (yes) or × (no)

# T 0184/16 – The case

- **Claim 14 (simplified):** A compound according to formula (I) for use in treating diabetes mellitus

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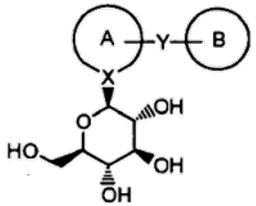
- **D4 (post-published evidence):**
  Compounds according to claim 1 are SGLT2 inhibitors, even better than example 26 of D2 (CPA)

**Question:** Is the medical use plausible (Art. 83 EPC) at the time of filing?
Please answer ✓ (yes) or × (no)

BoA: ✓ (yes) because the claimed compounds are related to those of prior art D7

# T 0184/16 – The case

- **Claim 14 (simplified):** A compound according to formula (I) for use in treating diabetes mellitus

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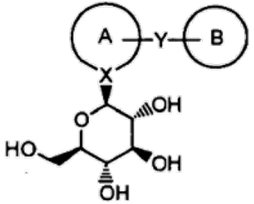
- **D4 (post-published evidence):**
  Compounds according to claim 1 are SGLT2 inhibitors, even better than example 26 of D2 (CPA)

**Question:** Should **D4** be admitted?
Please answer ✓ (yes) or × (no)

# T 0184/16 – The case

- **Claim 14 (simplified):** A compound according to formula (I) for use in treating diabetes mellitus

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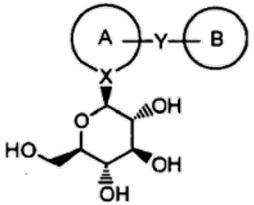
- **D4 (post-published evidence):**
  Compounds according to claim 1 are SGLT2 inhibitors, even better than example 26 of D2 (CPA)

**Question:** Should **D4** be admitted?
Please answer ✓ (yes) or × (no)

BoA: ✓ (yes) because the medical use was plausible at the time of filing

# T 0184/16 – The case

- **Claim 14 (simplified):** A compound according to formula (I) for use in treating diabetes mellitus

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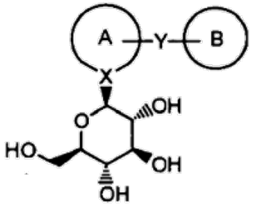
- **D4 (post-published evidence):**
  Compounds according to claim 1 are SGLT2 inhibitors, even better than example 26 of D2 (CPA)

**Question:** Is the claimed medical use obvious (Art. 56 EPC)?
Please answer ✓ (yes) or × (no)

# T 0184/16 – The case

- **Claim 14 (simplified):** A compound according to formula (I) for use in treating diabetes mellitus

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- **D4 (post-published evidence):**
  Compounds according to claim 1 are SGLT2 inhibitors, even better than example 26 of D2 (CPA)

**Question:** Is the claimed medical use obvious (Art. 56 EPC)?
Please answer ✓ (yes) or × (no)

BoA: × (no) because D4 shows an unexpected effect (better SGLT2 inhibition than D2 (CPA))

# T 0184/16 – Conclusions

No contradiction between acknowledging plausibility (Art. 83 EPC) and non-obviousness (Art. 56 EPC), because criteria differ:

| Plausibility (Art. 83 EPC) | Obviousness (Art. 56 EPC) |
|---|---|
| No **prima facie** serious doubt (T108/09)<br><br>No **a priori** reason why it can't work (T1760/11)<br><br>No indication in **common general knowledge** that it can't work (T919/15) | Framework of the problem-solution approach<br><br>"Is the claimed solution suggested by the prior art?" |

# T 2015/20 – landmark, Art. 83 EPC medical use, data requirement

# T2015/20: Article 83 EPC – 2nd medical use

Claim 1: **Aclidinium** in the form of a dry powder… for use **by inhalation** in the treatment of **asthma**."

- Experimental data:
  - trial showing the bronchodilatory effect of aclidinium in COPD
  - no data relating to asthma

- Common general knowledge:
  - anticholinergic effect of aclidinium for treatment of respiratory diseases
  - mechanism of airways obstruction in COPD and asthma different

**Question:** Are the requirements of Article 83 EPC fulfilled?
Is the use of aclidinium for treating asthma made plausible?
Please answer ✓ (yes) or × (no)

# T2015/20: Article 83 EPC – 2nd medical use

**Opposition Division concludes:**

The requirements of Article 83 EPC are not fulfilled:

- D5: mechanism of airway obstruction different in COPD and asthma. anticholinergic drugs are potent bronchodilators in COPD, whereas the same beneficial effect is not observed in asthma, in which cholinergic mechanisms are of **less** importance

- Experimental results obtained for COPD can thus not be extrapolated to asthma.

- It was not made plausible in the application as filed that aclidinium can be successfully used for treating asthma.

# T2015/20: Article 83 EPC – 2nd medical use

**BoA concludes:**

The requirements of Article 83 EPC are fulfilled:

- Bronchodilatory effect of aclidinium in COPD shown in examples
- D5 confirms, that asthma is influenced by cholinergic mechanisms, be it to a lesser extent than COPD.
- Common general knowledge (bronchodilation and anticholinergic effect play a role in asthma) in combination with experimental data – make it plausible
- **Absence of serious doubts substantiated by verifiable facts with respect to the defined utility**

# Conclusion: post-published evidence and Art. 83/56 EPC

| Article 83 or 56 EPC? | + | – |
|---|---|---|
| The nature of the objection can be anticipated based on the criteria set out in GL, F-III, 12 and G 1/03:<br>▪ Effect in claim: Art. 83 EPC<br>▪ Effect not in claim: Art. 56 EPC | Post-published evidence can only be taken into account for the assessment of Art. 83 or 56 EPC if the suitability of a compound for a claimed use is plausible from the application as filed | Post-published evidence cannot establish sufficiency of disclosure on its own,<br>nor serve as the sole basis to establish that the application solves indeed the underlying problem |

**Each case has to be judged on its own merits, depending on the specific circumstances of the case**

# Outline

- Art. 83 EPC
  - Requirement of Suitability
  - Art. 83 EPC vs Art. 56 EPC
  - Late filed evidence
  - Case Law
- Enablement of the Prior Art
  - Requirement of Enablement
  - Clinical trials
  - Case Law

# Enablement of the Prior Art: Warm-up question

**Prior Art - D1:**

- Simple verbal assertion: XYZ treats disease A
- No experiments in **D1**
- No other prior art or common knowledge available on possible treatments of disease A

**Application as filed:**

Very detailed *in vivo* studies with extensive data demonstrating that XYZ treats disease A

**Claim 1:** A compound of formula XYZ for use in treating A.

**Question:** Does claim 1 lack novelty in view of **D1**?
Please answer ✓ (yes) or ✗ (no)

# Enablement of the Prior Art

**Guidelines, G-VI. Novelty 4:**

Subject-matter described in a document can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1) EPC, if the information given therein is sufficient to enable the skilled person, at the relevant date of the document (see G-VI, 3), to practise the technical teaching which is the subject of the document, taking into account also the **general knowledge at that time** in the field (see T 26/85, T 206/83 and T 491/99).

# Enablement and Art. 83 EPC: Same standard to be applied

**Case law book: I-C Novelty 4.11**

In T 1437/07 the board pointed out that a disclosure in a prior art document is novelty-destroying only if the teaching it contains is reproducible. This need for an enabling disclosure is in conformity with the principle expressed in Art. 83 EPC. Thus, the requirements of sufficiency of disclosure are identical for a prior art document and a patent. The board followed the principles developed by the case law in the framework of the evaluation of the requirements of Art. 83 EPC in the case of a medical use, i.e. that the skilled person should not only be able to carry out the teaching of the prior art document, but it should also be credible that the effect at issue – here, relief of pain – has been achieved (see also T 491/08).

# Aspects relevant for Art. 54 EPC assessment

**1. Data presented in the prior art document:**

- Is the effect disclosed or is it credible that the effect can be reached? Is the document thus enabled?
- Is the report of an ongoing clinical trial novelty destroying?

**2. Comparison of disclosure in the prior art and disclosure in the patent application**

- Does the patent application provide a "new element" vis-à-vis the teaching of a prior art document?
- Is the level of technical teaching the same?

# Relevance of the category and the outcome of experimental tests for the assessment of novelty of medical use claims (1/2)

**1. Category of experimental data:**

- in vitro
- in vivo (animal models –PK/PD, safety)
- clinical data (phase I, II, III, IV, post-marketing, case report)

# Relevance of the category and the outcome of experimental tests for the assessment of novelty of medical use claims (2/2)

**2. Different phases of drug testing before marketing authorisation/approval of a medicament:**

2.1 Preclinical phase:

- screening of compounds
- pharmacology: animal models, cell culture and tissue, computer models
  → pharmacological activity, mechanism of action, therapeutic potential
- toxicology and safety: acute, sub-acute and chronic toxicity, mutagenesis, safety
- pharmacokinetics (animal study)

2.2 Clinical phase:

# Clinical trial phases

| Phase I | Phase II | Phase III |
| --- | --- | --- |
| ▪ 20-100 healthy volunteers (or patients e.g. cancer)<br>▪ evaluation of pharmacodynamic, pharmacokinetic,dose-finding, safety<br>▪ if possible early evidence on effectiveness | ▪ Testing of drug on patients to assess efficacy and side effects<br>▪ 100-300 patients with specific diseases | ▪ Testing of drug on patients to assess efficacy, effectiveness and safety<br>▪ 300–3000 patients with specific diseases<br>▪ often multicentre, controlled trials, comparison with standard therapy |

# T 1031/00

**Claim:** 2nd medical use of (-) amlodipine for treating hypertension

**Data in Application:** In vitro data ((inhibition of calcium ion influx into rat aorta tissue by (-)amlodipine)

**Prior Art:** In vitro data (inhibition of calcium ion influx into rat aorta tissue by (-)amlodipine) − disclosure of ongoing phase III clinical trials for amlodipine for treating hypertension.

**BoA:** refusal lack of novelty:
- absence of any data providing an additional technical information in relation to the actual treatment of hypertension in humans compared with the disclosure in the prior art document
- prior art discloses the same "therapeutic application" as the application

**same level of technical teaching**

# T 1859/08 (1/2)

**Claim (simplified):** Use of an anti-ErbB2 antibody in combination with a taxoid for the treatment of malignant breast cancer

**Data in Application:** In vivo data, humans

**Prior Art:** D1 describes the design of a phase III randomized multicenter study involving malignant breast cancer patients and using a treatment schema involving an anti-ErbB2 antibody in combination with paclitaxel (i.e. a taxoid).

**Question:** Is the claimed subject-matter novel?
Please answer ✓ (yes) or ✗ (no)

# T 1859/08 (2/2)

**Ex Div:** Refusal − lack of novelty − D1 describes the design of multinational phase III studies, so this means that a therapeutic effect must have been achieved, because the results of a phase II study must have been encouraging enough to start designing phase III.

**BoA:** Novel − it cannot be directly and unambiguously derived from the planned or ongoing phase III trial that a therapeutic effect is obtained (point 21 of the Decision)

- Information that a medicament is undergoing a clinical trial is not prejudicial to novelty if the content of said citation does not allow any conclusion to be drawn with the regard of the existence of a therapeutic effect.

# T 0158/96 (1/2)

**Claim:** Use of sertraline for treating obsessive-compulsive disorder (OCD)

**Data in application:** no data

**Prior Art (D2):** sertraline underwent clinical phase II trials for obsessive-compulsive disorder

**Question:** Is the claimed subject-matter novel?
Please answer ✓ (yes) or × (no)

# T 0158/96 (2/2)

**Ex Div:** Refusal − lack of novelty − phase II clinical trial commonly accepted as indicator for potential therapeutic utility, preceded by various proofs of activity in vitro and in vivo (in preclinical phase)

**BoA:** Novel − D2 lacks any anticipation of a preliminary positive outcome of phase II trials

- Information that a medicament is undergoing a clinical trial is not prejudicial to novelty if the content of said citation does not allow any conclusion to be drawn with the regard of the existence of a therapeutic effect.
- OCD – no animal models – no certainty that efficacy was shown in phase I clinical trials – thus D2 no proof of efficacy

# Enablement: clinical trial as prior art (1/2)

**Conclusion:**

The disclosure of an ongoing clinical trial is not prejudicial to novelty if the results are not disclosed

- phase III clinical trial (T 1859/08 – indication: cancer)
- phase II clinical trial (T 0158/96 – indication: obsessive-compulsive disorder)
- phase I clinical trial (T 0385/07 – indication: cancer)

Case law book I-C.4.1

# Enablement: clinical trial as prior art (2/2)

**Could the efficacy not be derived from preclinical data or phase I study?**

- if the skilled person was in a position to conclude with the required certainty that the pharmacological effect had already been shown or proven during phase I trials or during the pre-clinical experimentation (T 0158/96)
- permission to start a clinical trial in humans is usually given by the ethical commission only if the pharmacological efficacy has been proven in animals (pre-clinical). This data is quite often not published.

# Conclusion: enablement

| Clinical trial | Technical teaching | New element |
| --- | --- | --- |
| **Ongoing clinical trial is not prejudicial to the novelty:**<br>phase I, II and III clinical trials<br>- if the results are not disclosed in the prior art document and<br>- if the skilled person can not derive the therapeutic effect from preclinical tests. | In the absence of any data in the application compared with the disclosure in the prior art, the prior art discloses the same "therapeutic application" as the application<br><br>=> same level of technical teaching | Failure by a patent application to provide a "new element" vis-à-vis the teaching of a prior art document may lead to a lack of novelty of a claimed medical use; i.e.<br>"the subject-matter is not developed further" |

**Each case has to be judged on its own merits, depending on the specific circumstances of the case**

# Conclusions

- Requirement of plausibility for the claimed use must be met at the date of filing
- Common general knowledge can be used to fill the gap between what is claimed and what is demonstrated
- Post-published data can usually not be taken into account for Art. 83 EPC
- Post-published data can be useful for demonstrating an additional technical effect (Art. 56 EPC)
- Same criteria must be used for sufficiency of disclosure and for enablement of the prior art
- The level of technical teaching in the application/patent must be compared with that of the prior art

# Conclusions

- Avoid hypothetical statements (may be performed etc)
- All experimental evidence available at the date of filing should be included in the application
- If only in vitro data is available – make the link to the actual treatment in the application using common general knowledge (review articles)
  - ➢ **sufficiency of disclosure is established at the date of filing**
- Check whether the available prior art documents actually are *enabling disclosures* (i.e. render achieving the effect credible)
- Demonstrate in the application a “new element” / different level of technical teaching vis-à-vis the teaching of the prior art
  - ➢ **sufficiency of disclosure criteria also apply for enablement of the prior art**

# Further questions

Now

via chat to "All Panelists"

Later

via e-mail to mirenlanger@epo.org

sburema@epo.org