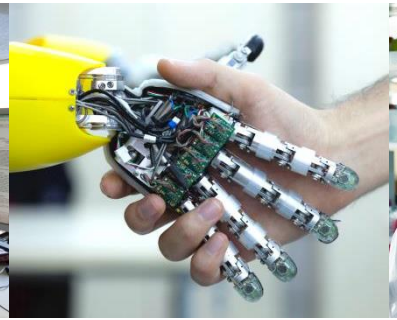
Europäisches Patentamt
European Patent Office
Office européen des brevets

Examination Matters – webinar series in the medical field

Experimental data: Impact on patentability in medical applications





Elsie Cielen
Britta Kley

Examiner, Second Medical Applications
Lawyer

5 December 2018

Presenting today

The presenter(s)

Elsie Cielen

- Examiner Search/Examination/Opposition
- Expert Patent Procedures Management
- Sector HBC – 2nd Medical Applications
- PhD Chemistry, KU Leuven, BE

Britta Kley

- Litigator for an international law firm, 2001-2004
- Lawyer at the EPO since 2004
- Lawyer in Directorate Patent Law since 2012
- Doctorate Degree in Law, University of Trier, DE

Experimental data: Impact on patentability in medical applications

Objectives

- Understanding under which conditions an objection of insufficiency of disclosure or lack of inventive step can be overcome by submitting post-published evidence
- Becoming aware of the impact enhanced publication requirements for clinical trail data may have on further medical use claims
- Gaining awareness of the role of clinical trials as prior art in relation to novelty and inventive step, and the importance of the presence of experimental data in the application as filed

Experimental data: Impact on patentability in medical applications

Agenda

- Experimental data and sufficiency of disclosure / inventive step
  - Background
  - Practical case
  - Conclusion
- Clinical trials and novelty / inventive step
  - Background
  - Publication requirements for clinical trial data
  - Practical case
  - Conclusion
- Questions

Experimental data: Impact on patentability in medical applications

Agenda

- Experimental data and sufficiency of disclosure / inventive step
  - Background
  - Practical case
  - Conclusion
- Clinical trials and novelty / inventive step
  - Background
  - Publication requirements for clinical trial data
  - Practical case
  - Conclusion
- Questions

Experimental data and sufficiency of disclosure / inventive step

§§ Article 56 vs Article 83

G 1/03

GL F-III, 12

Claimed invention lacks reproducibility (non-working examples):

- If the technical effect expressed in the claim is not achieved: Art. 83
  Technical effect is part of the proposed solution, hence it cannot be part of the problem
- If the effect is not expressed in the claim but is part of the problem to be solved: Art. 56

Can insufficiency of disclosure or lack of inventive step be solved by submitting post-published evidence?

Experimental data and sufficiency of disclosure / inventive step

Late filed evidence: of avail

GL H-V, 2.2
Art. 56 EPC
Art. 83 EPC
Art. 123(2) EPC

Later filed examples or new effects may be taken into account in support of patentability, e.g.:

- 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

GL F-IV, 6.3

- a new effect in support of inventive step, provided that it is implied by or at least related to an effect disclosed in the application as filed

GL G-VII, 11

Experimental data and sufficiency of disclosure / inventive step

Art. 83 EPC

Late filed evidence of no avail: T 609/02

Claim	Use of a steroid hormone which fails to promote transcriptional activation of glucocorticoid receptor- or retinoic acid receptor- responsive genes, for the preparation of a pharmaceutical for the treatment of AP-1 stimulated tumour formation, arthritis, asthma, allergies and rashes, said hormone being identified by the method according to the previous claims

Experimental data and sufficiency of disclosure / inventive step

Art. 83 EPC

Late filed evidence of no avail: T 609/02 (2)

- Second medical use claim: therapeutic effect is functional technical feature of the claim
- Unless known at priority date, application must disclose suitability of the product for the claimed therapy
- Simple verbal statement in application is not enough
- For sufficient disclosure of a therapeutic application, results in clinical trials/animals not always necessary

Experimental data and sufficiency of disclosure / inventive step

Art. 83 EPC

Late filed evidence of no avail: T 609/02 (3)

- Patent must provide information, e.g. tests, to show that claimed compound has direct effect on mechanism involved in the disease, this mechanism being known from prior art or demonstrated in patent
- Showing pharmaceutical effect in vitro sufficient if for skilled person this effect directly and unambiguously reflects therapeutic application, i.e. if there is a "clear and accepted established relationship" between shown physiological activities and disease

Experimental data and sufficiency of disclosure / inventive step

Late filed evidence of no avail: T 609/02 (4)

- Once this evidence is available from application, post-published evidence may be taken into account,
  - but only to back-up findings in the patent application in relation to the use of the ingredient as a pharmaceutical,
  - not to establish sufficiency of disclosure on their own[1]

Art. 83 EPC

1 Case Law of the Boards of Appeal of the EPO, 8th edition 2016, section II.C.6.2

Experimental data and sufficiency of disclosure / inventive step

Late filed evidence of no avail: T 609/02 (4)

- Once this evidence is available from application, post-published evidence may be taken into account,
  - but only to back-up findings in the patent application in relation to the use of the ingredient as a pharmaceutical,
  - not to establish sufficiency of disclosure on their own[1]

- **T 801/06:** r. 28: claimed therapeutic effect may be proven by any kind of data, as long as they clearly and unambiguously reflect the therapeutic effect

Art. 83 EPC

1 Case Law of the Boards of Appeal of the EPO, 8th edition 2016, section II.C.6.2

Experimental data and sufficiency of disclosure / inventive step

Art. 56 EPC

Late filed evidence of no avail: T 1329/04

Claim	A polynucleotide encoding a polypeptide having GDF-9 activity selected from the group consisting of: (a) a polynucleotide having the nucleic acid sequence of SEQ ID NO:3; (b) a polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO:4; ...

Experimental data and sufficiency of disclosure / inventive step

Art. 56 EPC

Late filed evidence of no avail: T 1329/04 (2)

- The definition of an invention as being a contribution to the art requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve
- Supplementary post-published evidence may in the proper circumstances also be taken into consideration,

BUT

it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve

Experimental data: Impact on patentability in medical applications

Agenda

- Experimental data and sufficiency of disclosure / inventive step
  - Background
  - Practical case
  - Conclusion
- Clinical trials and novelty / inventive step
  - Background
  - Publication requirements for clinical trial data
  - Practical case
  - Conclusion
- Questions

Experimental data and sufficiency of disclosure / inventive step

Case 1 (1)

Claim	A compound of formula (1) for use in the treatment of a CNS disorder associated with the dopamine D2 receptor, which is bipolar disorder.

Experimental data and sufficiency of disclosure / inventive step

Case 1 (1)

Claim	A compound of formula (1) for use in the treatment of a CNS disorder associated with the dopamine D2 receptor, which is bipolar disorder.
Disclosure	▪ data show that compound is D2 receptor antagonist ▪ "The potent D2 receptor antagonist in the present invention is useful for various disorders of the CNS associated with the dopamine D2 receptor that induces bipolar disorders."

Experimental data and sufficiency of disclosure / inventive step

Case 1 (1)

Claim	A compound of formula (1) for use in the treatment of a CNS disorder associated with the dopamine D2 receptor, which is bipolar disorder.
Disclosure	▪ data show that compound is D2 receptor antagonist ▪ "The potent D2 receptor antagonist in the present invention is useful for various disorders of the CNS associated with the dopamine D2 receptor that induces bipolar disorders."

Do you think that the information in the application is sufficient?

Experimental data and sufficiency of disclosure / inventive step

Case 1 (1)

Claim	A compound of formula (1) for use in the treatment of a CNS disorder associated with the dopamine D2 receptor, which is bipolar disorder.
Disclosure	▪ data show that compound is D2 receptor antagonist ▪ "The potent D2 receptor antagonist in the present invention is useful for various disorders of the CNS associated with the dopamine D2 receptor that induces bipolar disorders."

Do you think that the information in the application is sufficient?

→ ☑ yes ☒ no

Experimental data and sufficiency of disclosure / inventive step

Case 1 (1)

Claim	A compound of formula (1) for use in the treatment of a CNS disorder associated with the dopamine D2 receptor, which is bipolar disorder.
Disclosure	▪ data show that compound is D2 receptor antagonist ▪ "The potent D2 receptor antagonist in the present invention is useful for various disorders of the CNS associated with the dopamine D2 receptor that induces bipolar disorders."

Do you think that the information in the application is sufficient?

→ ☑ yes ☒ no

→ **Not sufficient.**
The patent does not disclose a clear relationship between D2 antagonism and the suitability of a drug against bipolar disorders.

Experimental data and sufficiency of disclosure / inventive step

Case 1 (2)

Prior art	D6, D7 and D8 (in time) show direct relationship between D2 antagonism and the suitability for the treatment of bipolar disorders ▪ D6 is a patent application ▪ D7 is a postgraduate medicine special report ▪ D8 is an article published in a scientific journal

Experimental data and sufficiency of disclosure / inventive step

Case 1 (2)

Prior art	D6, D7 and D8 (in time) show direct relationship between D2 antagonism and the suitability for the treatment of bipolar disorders ▪ D6 is a patent application ▪ D7 is a postgraduate medicine special report ▪ D8 is an article published in a scientific journal

Do you think that these documents can be used in support of the statement in the description?

Experimental data and sufficiency of disclosure / inventive step

Case 1 (2)

Prior art	D6, D7 and D8 (in time) show direct relationship between D2 antagonism and the suitability for the treatment of bipolar disorders ▪ D6 is a patent application ▪ D7 is a postgraduate medicine special report ▪ D8 is an article published in a scientific journal

Do you think that these documents can be used in support of the statement in the description?

→ ☑ yes ☒ no

Experimental data and sufficiency of disclosure / inventive step

Case 1 (2)

Prior art	D6, D7 and D8 (in time) show direct relationship between D2 antagonism and the suitability for the treatment of bipolar disorders ▪ D6 is a patent application ▪ D7 is a postgraduate medicine special report ▪ D8 is an article published in a scientific journal

Do you think that these documents can be used in support of the statement in the description?

→ ☑ yes ☒ no

→ **Documents cannot support the description.**
They do not represent common general knowledge, because the field is not so new that common general knowledge is solely reflected in patent documents and scientific articles (GL, G-VII, 3.1).

Experimental data and sufficiency of disclosure / inventive step

Case 1 (3)

Post-published evidence	Additional data provided in several documents and in a letter by the Proprietor with conclusive evidence

Experimental data and sufficiency of disclosure / inventive step

Case 1 (3)

Post-published evidence	Additional data provided in several documents and in a letter by the Proprietor with conclusive evidence

Can the applicant's post-published evidence be taken into account?

Experimental data and sufficiency of disclosure / inventive step

Case 1 (3)

Post-published evidence	Additional data provided in several documents and in a letter by the Proprietor with conclusive evidence

Can the applicant's post-published evidence be taken into account?

→ ☑ yes ☒ no

Experimental data and sufficiency of disclosure / inventive step

Case 1 (3)

Post-published evidence	Additional data provided in several documents and in a letter by the Proprietor with conclusive evidence

Can the applicant's post-published evidence be taken into account?

→ ☑ yes ☒ no

→ **Post-published evidence cannot be taken into account.**

- The application as filed does not disclose the suitability of a compound of formula (1) for the treatment of bipolar disorder, and there is no common general knowledge to provide the missing link.
- In such a case, post-published evidence cannot cure the deficiency of disclosure of the patent.

Experimental data and sufficiency of disclosure / inventive step

T 2059/13

Aspects relevant for Art. 83 assessment

- to what extent does the original application reveal the suitability of compounds for the claimed therapeutic use?
- to what extent can the skilled person supplement this disclosure with its common general knowledge?
- to what extent are pre-published documents to be considered as common general knowledge?, and
- can any alleged deficiency of the disclosure of the patent / application be cured by post-published evidence?

Experimental data: Impact on patentability in medical applications

Agenda

- Experimental data and sufficiency of disclosure / inventive step
  - Background
  - Practical case
  - Conclusion
- Clinical trials and novelty / inventive step
  - Background
  - Publication requirements for clinical trial data
  - Practical case
  - Conclusion
- Questions

Experimental data and sufficiency of disclosure / inventive step

Conclusion: post-published evidence

Article 83 or 56?	+	–
The nature of the objection can be anticipated based on the criteria set out in GL, F-III, 12 and G 1/03: ▪ Effect in claim: Art. 83 ▪ Effect not in claim: Art. 56	**Post-published evidence can only be taken into account for the assessment of Art. 83 or 56 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,** **nor serve as the sole basis to establish that the application solves indeed the underlying problem**

Experimental data and sufficiency of disclosure / inventive step

Conclusion: post-published evidence

Article 83 or 56?	+	–
The nature of the objection can be anticipated based on the criteria set out in GL, F-III, 12 and G 1/03: ▪ Effect in claim: Art. 83 ▪ Effect not in claim: Art. 56	**Post-published evidence can only be taken into account for the assessment of Art. 83 or 56 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,** **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**

Experimental data: Impact on patentability in medical applications

Agenda

- ✓ Experimental data and sufficiency of disclosure / inventive step
  - Background
  - Practical case
  - Conclusion
- Clinical trials and novelty / inventive step
  - Background
  - Publication requirements for clinical trial data
  - Practical case
  - Conclusion
- Questions

Clinical trials and novelty / inventive step

Clinical trial phases

Phase I

- Testing of drug for dose-ranging
- 20-100 healthy volunteers
- determines whether drug is safe to check for efficacy
- no efficacy studied

Phase II

- Testing of drug on patients to assess efficacy and side effects
- 100–300 patients with specific diseases
- determines whether drug can have any efficacy; at this point, the drug is not presumed to have any therapeutic effect

Phase III

- Testing of drug on patients to assess efficacy, effectiveness and safety
- 300–3 000 patients with specific diseases
- determines a drug's therapeutic effect; at this point, the drug is presumed to have some effect

Clinical trials and novelty / inventive step

Clinical trials: T 158/96

Claim	The use of sertraline or a pharmaceutically acceptable salt thereof for the manufacture of a medicament to treat or prevent obsessive-compulsive disorder (OCD).

Clinical trials and novelty / inventive step

Clinical trials: T 158/96

Claim	The use of sertraline or a pharmaceutically acceptable salt thereof for the manufacture of a medicament to treat or prevent obsessive-compulsive disorder (OCD).
Prior art	Sertraline is undergoing phase II clinical trials

Clinical trials and novelty / inventive step

Clinical trials: T 158/96 (2)

Same therapeutic effect shown in the prior art?

- no prediction of therapeutic activity (no +/- results)
  - many drugs fail to proceed to phase III
  - OCD is complex
  - no consensus how to study OCD (heterogeneous populations)
  - no animal model for OCD
  - no reliable preclinical evaluation of utility of sertraline in OCD

Clinical trials and novelty / inventive step

Clinical trials: T 158/96 (2)

Same therapeutic effect shown in the prior art?

- no prediction of therapeutic activity (no +/- results)
  - many drugs fail to proceed to phase III
  - OCD is complex
  - no consensus how to study OCD (heterogeneous populations)
  - no animal model for OCD
  - no reliable preclinical evaluation of utility of sertraline in OCD
- the case was remitted to the first instance

Clinical trials and novelty / inventive step

Clinical trials: T 158/96 (3)

"The information in a citation that a medicament is undergoing a clinical phase evaluation for a specific therapeutic application is not prejudicial to the novelty of a claim directed to the same therapeutic application of the same medicament

- if such information is plausibly contradicted by the circumstances and
- if the content of said citation does not allow any conclusion to be drawn with regard to the actual existence of a therapeutic effect or any pharmacological effect which directly and unambiguously underlies the claimed therapeutic application"

Experimental data: Impact on patentability in medical applications

Agenda

- Experimental data and sufficiency of disclosure / inventive step
  - Background
  - Practical case
  - Conclusion
- Clinical trials and novelty / inventive step
  - Background
  - Publication requirements for clinical trial data
  - Practical case
  - Conclusion
- Questions

Clinical trials and novelty / inventive step

§§ Legal Framework

- European Medicines Agency policy on publication of clinical data for medicinal products for human use

  applicable as from 1 January 2015

- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use

  expected to apply as from 2020.

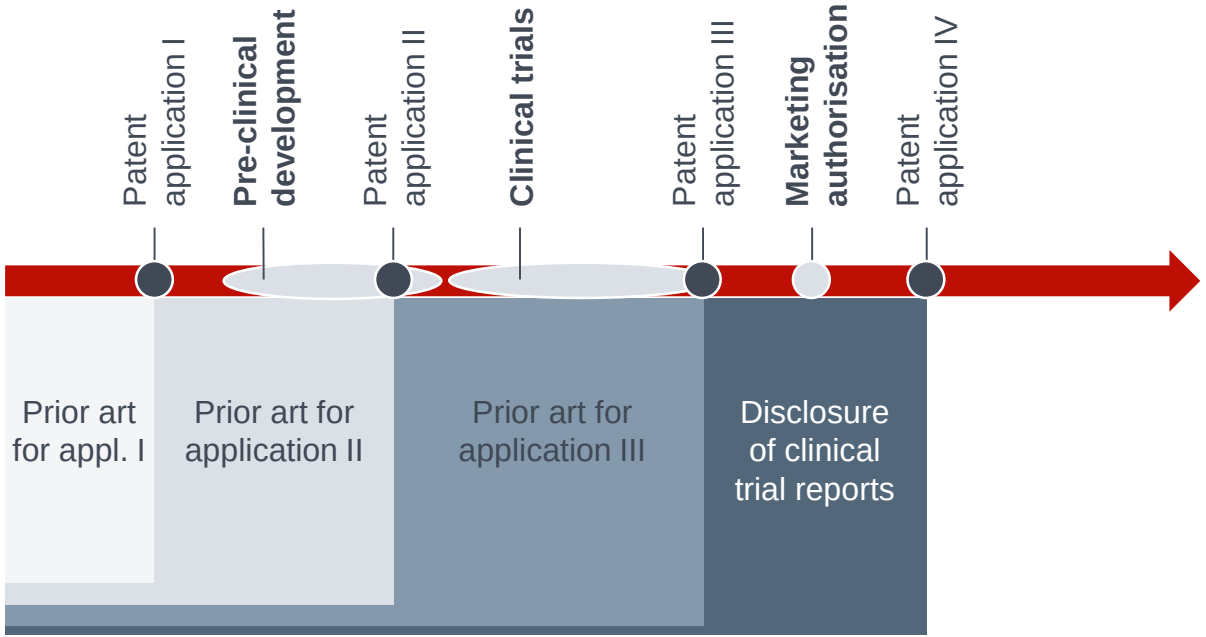
Clinical trials and novelty / inventive step

§§ Legal Framework

	Clinical data publication policy	Clinical Trial Regulation
Medicinal products covered	Centrally authorised products only	All investigational medicinal products
Clinical studies covered	Clinical studies submitted to the EMA in the context of a MAA	Clinical trials conducted in and outside the EU
Documents published	Clinical overview, clinical summarises and clinical study reports	All clinical trial-related information (e.g. protocol, decision on trail conduct, summary of trial results, study reports, etc.)
Publication from	October 2016	Expected in 2020

Clinical trials and novelty / inventive step

Legal Framework



Clinical trials and novelty / inventive step

§§ CCI can remain unpublished upon request

- **Art. 81(4)(a) Regulation (EU) No. 536/2014:**
  All data submitted shall be publicly accessible unless confidentiality is justified to protect commercially confidential information (CCI), if there is no overriding public interest in disclosure.
- **Sec. 4.2.2 EMA policy on publication:**
  Information contained in clinical reports should not be considered CCI. However, the EMA acknowledges that in limited circumstances clinical reports can contain CCI.

Experimental data: Impact on patentability in medical applications

Agenda

- Experimental data and sufficiency of disclosure / inventive step
  - Background
  - Practical case
  - Conclusion
- Clinical trials and novelty / inventive step
  - Background
  - Publication requirements for clinical trial data
  - Practical case
  - Conclusion
- Questions

Clinical trials and novelty / inventive step

Case 2 (1)

Claim 1	Medicament comprising a combination of compound X and compound Y for use in treating cancer.

Clinical trials and novelty / inventive step

Case 2 (1)

Claim 1	Medicament comprising a combination of compound X and compound Y for use in treating cancer.
Prior art	▪ D1: Compound X and Y are each effective for breast cancer in monotherapy ▪ D2: Phase I clinical trial of X and Y against cancer ongoing at the filing date; no data

Clinical trials and novelty / inventive step

Case 2 (1)

Claim 1	Medicament comprising a combination of compound X and compound Y for use in treating cancer.
Prior art	▪ D1: Compound X and Y are each effective for breast cancer in monotherapy ▪ D2: Phase I clinical trial of X and Y against cancer ongoing at the filing date; no data

Is D2 prejudicial to the novelty of claim 1?

Clinical trials and novelty / inventive step

Case 2 (1)

Claim 1	Medicament comprising a combination of compound X and compound Y for use in treating cancer.
Prior art	▪ D1: Compound X and Y are each effective for breast cancer in monotherapy ▪ D2: Phase I clinical trial of X and Y against cancer ongoing at the filing date; no data

Is D2 prejudicial to the novelty of claim 1?

→ ☑ yes ☒ no

Clinical trials and novelty / inventive step

Case 2 (1)

Claim 1	Medicament comprising a combination of compound X and compound Y for use in treating cancer.
Prior art	▪ D1: Compound X and Y are each effective for breast cancer in monotherapy ▪ D2: Phase I clinical trial of X and Y against cancer ongoing at the filing date; no data

Is D2 prejudicial to the novelty of claim 1?

→ ☑ yes ☒ no

→ **Not prejudicial.**
The knowledge that clinical trials were on-going does not anticipate the claimed matter, because the results of said trials were not yet available.

Clinical trials and novelty / inventive step

Case 2 (1)

Claim 1	Medicament comprising a combination of compound X and compound Y for use in treating cancer.
Prior art	▪ D1: Compound X and Y are each effective for breast cancer in monotherapy ▪ D2: Phase I clinical trial of X and Y against cancer ongoing at the filing date; no data

Is D2 prejudicial to the novelty of claim 1?

→ ☑ yes ☒ no

→ **Not prejudicial.**
The knowledge that clinical trials were on-going does not anticipate the claimed matter, because the results of said trials were not yet available.

Do you find the opponent's argument that since the two mono-therapies were known to be effective from D1, the combination was also inevitably effective, convincing?

Clinical trials and novelty / inventive step

Case 2 (1)

Claim 1	Medicament comprising a combination of compound X and compound Y for use in treating cancer.
Prior art	▪ D1: Compound X and Y are each effective for breast cancer in monotherapy ▪ D2: Phase I clinical trial of X and Y against cancer ongoing at the filing date; no data

Is D2 prejudicial to the novelty of claim 1?

→ ☑ yes ☒ no

→ **Not prejudicial.**
The knowledge that clinical trials were on-going does not anticipate the claimed matter, because the results of said trials were not yet available.

Do you find the opponent's argument that since the two mono-therapies were known to be effective from D1, the combination was also inevitably effective, convincing?

→ ☑ yes ☒ no

Clinical trials and novelty / inventive step

Case 2 (1)

Claim 1	Medicament comprising a combination of compound X and compound Y for use in treating cancer.
Prior art	▪ D1: Compound X and Y are each effective for breast cancer in monotherapy ▪ D2: Phase I clinical trial of X and Y against cancer ongoing at the filing date; no data

Is D2 prejudicial to the novelty of claim 1?

→ ☑ yes ☒ no

→ **Not prejudicial.**
The knowledge that clinical trials were on-going does not anticipate the claimed matter, because the results of said trials were not yet available.

Do you find the opponent's argument that since the two mono-therapies were known to be effective from D1, the combination was also inevitably effective, convincing?

→ ☑ yes ☒ no

→ **Not convincing.**
There is no evidence in the prior art that the combination is safe; the interaction between the drugs may result in toxicity.

Clinical trials and novelty / inventive step

Case 2 (2)

Disclosure

Example 1:
= results of a phase I study
MTD (maximum tolerated dose) of X in combination with Y
at this dose, the combination treatment is safe
dose finding study found partial response in some patients

Clinical trials and novelty / inventive step

Case 2 (2)

Disclosure

Example 1:
= results of a phase I study
MTD (maximum tolerated dose) of X in combination with Y
at this dose, the combination treatment is safe
dose finding study found partial response in some patients

Which document is the closest prior art? D1 (each alone effective) or D2 (combination, but no data)?

Clinical trials and novelty / inventive step

Case 2 (2)

Disclosure

Example 1:
= results of a phase I study
MTD (maximum tolerated dose) of X in combination with Y
at this dose, the combination treatment is safe
dose finding study found partial response in some patients

Which document is the closest prior art? D1 (each alone effective) or D2 (combination, but no data)?

→ ☑ **D1** ☒ **D2**

Clinical trials and novelty / inventive step

Case 2 (2)

Disclosure

Example 1:
= results of a phase I study
MTD (maximum tolerated dose) of X in combination with Y
at this dose, the combination treatment is safe
dose finding study found partial response in some patients

Which document is the closest prior art? D1 (each alone effective) or D2 (combination, but no data)?

→ ☑ **D1** ☒ **D2**

→ D1, disclosing the monotherapies, is closest prior art, since it contains data.

Clinical trials and novelty / inventive step

Case 2 (2)

Disclosure

Example 1:
= results of a phase I study
MTD (maximum tolerated dose) of X in combination with Y
at this dose, the combination treatment is safe
dose finding study found partial response in some patients

Which document is the closest prior art? D1 (each alone effective) or D2 (combination, but no data)?

→ ☑ **D1** ☒ **D2**

→ D1, disclosing the monotherapies, is closest prior art, since it contains data.

In view of the data in the application, the problem is the provision of a safe and effective combination for treating cancer. Is the solution obvious?

Clinical trials and novelty / inventive step

Case 2 (2)

Disclosure

Example 1:
= results of a phase I study
MTD (maximum tolerated dose) of X in combination with Y
at this dose, the combination treatment is safe
dose finding study found partial response in some patients

Which document is the closest prior art? D1 (each alone effective) or D2 (combination, but no data)?

→ ☑ **D1** ☒ **D2**

→ D1, disclosing the monotherapies, is closest prior art, since it contains data.

In view of the data in the application, the problem is the provision of a safe and effective combination for treating cancer. Is the solution obvious?

→ ☑ **yes** ☒ **no**

Clinical trials and novelty / inventive step

Case 2 (2)

Disclosure

Example 1:
= results of a phase I study
MTD (maximum tolerated dose) of X in combination with Y
at this dose, the combination treatment is safe
dose finding study found partial response in some patients

Which document is the closest prior art? D1 (each alone effective) or D2 (combination, but no data)?

→ ☑ **D1** ☒ **D2**

→ D1, disclosing the monotherapies, is closest prior art, since it contains data.

In view of the data in the application, the problem is the provision of a safe and effective combination for treating cancer. Is the solution obvious?

→ ☑ **yes** ☒ **no**

→ Obvious according to the BoA in the "real" case T2506/12.

Clinical trials and novelty / inventive step

T 2506/12

Case 2 (3)

- The 2 drugs were known as effective in mono-therapy for the same cancer types
- No evidence on file that there was no "reasonable expectation of success".
- D2 proved that pharmaceutical researchers considered the expectation of success of the combination treatment sufficient to justify a clinical trial.
- Such trials were not initiated based on a general "try and see attitude", but on the base of existing favourable results, for ethical and economic reasons. They were not a mere "screening exercise".

Experimental data: Impact on patentability in medical applications

Agenda

- Experimental data and sufficiency of disclosure / inventive step
  - Background
  - Practical case
  - Conclusion
- Clinical trials and novelty / inventive step
  - Background
  - Publication requirements for clinical trial data
  - Practical case
  - Conclusion
- Questions

Clinical trials and novelty / inventive step

Conclusion: Clinical trials

Novelty

Ongoing clinical trial is not prejudicial to the novelty if:

- information is plausibly contradicted by the circumstances,

and

- no conclusion can be drawn about actual existence of effect

Novelty

If the prior art provides no technical

evidence

that the combination treatment is safe,

an "effective treatment"

is not disclosed in the prior art

Inventive step

If prior art discloses **effectiveness** of **each** drug **individually**, and that **clinical trials** are **ongoing**,

in the absence of evidence to the contrary,

there is **reasonable expectation** that the **combination** treatment will be **successful**

Clinical trials and novelty / inventive step

Conclusion: Clinical trials

Novelty	Novelty	Inventive step
Ongoing clinical trial is not prejudicial to the novelty if: ▪ information is plausibly contradicted by the circumstances, and ▪ no conclusion can be drawn about actual existence of effect	**If the prior art provides no technical** **evidence** **that the combination treatment is safe,** **an "effective treatment"** **is not disclosed in the prior art**	If prior art discloses **effectiveness** of **each** drug **individually**, and that **clinical trials** are **ongoing**, in the absence of evidence to the contrary, there is **reasonable expectation** that the **combination** treatment will be **successful**

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

Clinical trials and novelty / inventive step

Cited decisions

- **Landmark decisions:**
  T 609/02, T 1329/04, T 158/96
- **Other decisions:**
  T 801/06
- **Decisions underlying practical cases:**
  T 2059/13, T 2506/12 (see also T 0239/16)

Experimental data: Impact on patentability in medical applications

Agenda

- ✓ Experimental data and sufficiency of disclosure / inventive step
  - Background
  - Practical case
  - Conclusion
- ✓ Clinical trials and novelty / inventive step
  - Background
  - Publication requirements for clinical trial data
  - Practical case
  - Conclusion
- Questions

Questions

Questions

now	via chat to "All participants"
later	via mail ➔ academy@epo.org