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European Biotech Patent Case Law

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Summary

- T 910/21: New purpose of treating the same disease
- T 209/22: Novelty-sufficiency squeeze based on clinical trial
- T 1255/21: Lack of inventive step in view of clinical trial protocol
- T 1252/20: The definition of “substance or composition” in medical use claims
- T 1920/21: Limits to “diagnostic method” exclusion

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

T 910/21 (N.V. Nutricia) New purpose of treating the same disease

Patient sub-groups

Patient sub-groups case law: **T 19/86**, **T233/96**, **T 1399/04** and others

The criteria for a patient group rendering a previously known therapeutic method novel are that:

I. *The patient group is not disclosed in the relevant prior art.*

II. *The patients belonging to the group can be distinguished from those of the prior art by their **physiological or pathological** status.*

III. *There is a functional relationship between their characterising physiological or pathological status and the therapeutic treatment and thus the selection of the patients is not arbitrary.*

Patient sub-groups T 1399/04 (Schering Corporation)

The use of ribavirin in association with an effective amount of interferon alpha for treating hepatitis C infection :

- administration for a time period of 40-50 weeks
- the patient is an antiviral treatment naive patient
- the patient is one having a HCV genotype type 1 infection
- the patient has a viral load of greater than 2 million copies per ml of serum

Patient sub-groups T 0694/16 (N.V. Nutricia)

Composition comprising (a) one or more of DHA, DPA and EPA, (b) uridine, deoxyuridine, uridine phosphates, uracil or acylated uridine derivatives, and (c) a methyl donor, wherein the composition further includes vitamin B12 and folate

for use in the prevention or delay of the onset of dementia in a person having CSF markers characteristics of a prodromal dementia patient.

Patient sub-groups T 0694/16

- the issue of whether patients displaying the markers of claim 1 were present among a population of previously treated patients and were already "inevitably" or "inherently" treated is irrelevant for assessing novelty in the present case.
- The only thing which counts is that the prior art does not disclose a method whereby a patient or a group of patients displaying the relevant CSF markers but not affected by dementia was purposively and selectively targeted for carrying out the preventive treatment defined in claim 1.

Patient sub-groups T 0694/16

The claimed method can be seen as one which aims at hitting a target which is hidden behind a screen, but the screen reveals a spot which allows the position of the target to be actively aimed at. This allows hitting the target precisely while reducing the risk of hitting other objects present behind that screen.

T 910/21 (N.V. Nutricia): claim 1

1. A composition for use in **improving executive function** of a subject in need thereof, wherein said composition comprises:

   i. one or more of uridine and cytidine, or salts, phosphates, acyl derivatives or esters thereof; and

   ii. a lipid fraction comprising at least one of docosahexaenoic acid (22:6; DHA), eicosapentaenoic acid (20:5; EPA) and docosapentaenoic acid (22:5; DPA), or esters thereof,

wherein said subject suffers from a memory or cognitive disorder, memory decline or cognitive dysfunction, such as Age Associated Memory Impairment (AAMI), **Alzheimer's Disease**, multiple sclerosis, vascular dementia, frontotemporal dementia, semantic dementia or dementia with Lewy bodies, and/or psychiatric and developmental disorders, including obsessive-compulsive disorder, Tourette's syndrome, depression, schizophrenia , attention-deficit/hyperactivity disorder, and autism (asperger).

Background to case

Revoked at opposition as lacking novelty in view of **D6** and **D28**:

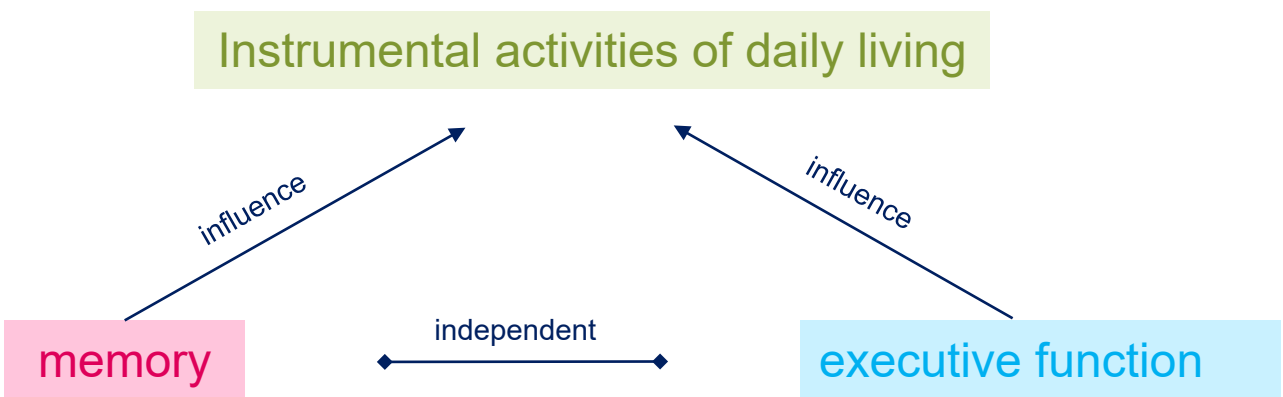
- “which already disclosed the utility of the defined composition for supporting **daily activities** wherein the **executive brain functions** **play an important role**”

Opponent argued

- The defined treatment did **not** involve a **new** group of patients
- The purpose of improving executive function as defined in claim 1 does **not** qualify as a new **therapeutic indication**:
  - D6 and D28 already describe the same compositions for the treatment of Alzheimer's Disease patients
  - any improvement in the activities as described in documents D6 and D28 is nevertheless **inevitably associated** with a positive effect on executive function .
  - Executive function was generally affected in patients with Alzheimer's Disease and could **not be improved in isolation**.

Patentee (appellant) argued

D26 shows that instrumental activities of daily living (IADL) can be affected by memory, executive function **or** both and therefore the improvements in IADL described in documents D6 and D28 **do not directly and unambiguously** reveal an improvement in executive function.



Board's considerations (1)

- D26 explains that changes in memory and executive function are **independently associated** with the rate of change in IADL.
- The benefit of treatment with respect to IADL as described in documents D6 and D28 does therefore **not necessarily imply an improvement** in executive function, because the reported benefit may well have resulted from an improvement in memory.
- D22 indicates that in patients with dementia there is **no parallel decline** in executive function and memory.
- It is evident from D22 that a decline in executive function, and thus also the need for treatment intended to improve executive function, can be **specifically diagnosed** in patients who develop dementia and that the change in executive function over time, and thus also the response to treatment, can be **specifically monitored**.
- As confirmed in D3 the Trail Making Test B (TMT-B) **described in the patent** is commonly known as suitable for this purpose.

Board’s considerations (2)

- The Board therefore considers that the **purpose** of improving executive function defines a **specific clinical situation** which characterizes the therapeutic use as defined in claim 1 as granted.
- Thus, in line with the considerations in T 836/01, the purpose of improving executive function distinguishes the treatment defined in claim 1 as granted from the treatment of patients with Alzheimer's disease as described in documents D6 and D28 **even without the explicit definition of a new patient group**.
- Decision set aside and patent maintained as granted.

Conclusion

- A specific clinical situation that can be **specifically diagnosed** and **specifically monitored** establishes a new patient subgroup.
- Can obtain a claim to a patient subgroup even without the explicit definition of the new patient group in the claim.
- Provision of a test or assay suitable for these purposes may be persuasive.

T 209/22 (Glaxo Group Limited) Novelty-sufficiency squeeze clinical trial

Legal background

- According to the established case law of the Boards of Appeal, where a therapeutic application is claimed in the format provided in Article 54(5) EPC (i.e. a medical use claim), attaining the claimed **therapeutic effect is regarded as a functional technical feature** of the claim that may establish novelty and inventive step

Claim 1

1. A pharmaceutical **combination product for use** in the treatment of chronic obstructive pulmonary disease (COPD) and/or asthma, wherein the product comprises:

    a) Compound I (a salt of **umeclidinium**); and

    b) Compound II (**vilanterol** or a salt thereof);

and further wherein the product is administered once per day.

Prior art

- D1 disclosed a summary of a phase I clinical trial protocol for the drug combination in **healthy volunteers** (that is, **not** patients suffering from COPD or asthma)
- The opponents argued that D21 anticipated the claimed subject-matter and that the clinical trial itself constituted prior public use of the invention
  - D21 did not disclose the chemical structure of the drugs, however the opponents argued that a skilled person could have derived this information by obtaining and analysing the drugs

Board’s considerations: novelty

- The objection fails because the study was performed on healthy volunteers.
- The claim feature that requires **attaining the claimed therapeutic effect** in the treatment of COPD or asthma could not have been anticipated in such a context, simply because the study subjects did not suffer from COPD or asthma.
- Accordingly, neither D21 itself nor the alleged prior use based on D21 provide a basis for denying novelty.

Sufficiency: background

- For the requirement of sufficiency to be met, the claimed efficacy has to be **credible** at the effective date of the patent
  - Assessed on the basis of the information provided in the patent application together with the common general knowledge then available to the skilled person.
- For an opponent to prevail on this ground they must establish **serious doubts substantiated by verifiable facts**

Sufficiency: application as filed

- Vilanterol and umeclidinium are disclosed in documents D3 and D4, respectively, as potential agents for the treatment of respiratory diseases such as, in particular, COPD and asthma. Both documents are referenced in the application as filed.
- The application summarises the results of clinical studies that were performed in relation to umeclidinium or vilanterol **monotherapy** (both compounds provided bronchodilatory action).
- The application also described data from the aforementioned phase I clinical trial in **healthy volunteers**, showing that a combination of the drugs was well tolerated and effective in providing bronchodilation.
  - It could be concluded that the combination was **at least as efficacious** as the monotherapies in providing bronchodilation.
- However, the patent did **not** provide data showing the **efficacy** of the **combination** of drugs in COPD or Asthma **patients**.

Board’s considerations: sufficiency

- Based on the information provided in the application as filed, there is thus a **strong presumption** that dual therapy with umeclidinium/vilanterol would be **effective** in the treatment of asthma or COPD, and that a dosage regimen of once-daily administration would be **feasible**.
- Both aspects would have been regarded as **credible** at the effective date.
- The appellants have **not** established serious doubt in relation to the dual therapy's efficacy in relieving asthma.
- Further corroboration is provided by post-published document D8, which shows that a combination product conforming to claim 1 ("ANORO") was indeed authorised in May 2014 for the treatment of COPD by once-daily administration.

Novelty-sufficiency squeeze

- The opponents argued that if the clinical trial summary did not take away the novelty of the claimed subject-matter, then it followed that the combination study as described in the application as filed could not be regarded as enabling
- The Board did not agree because **different standards apply:**
- To be novelty-destroying, a prior-art disclosure must meet the standard of **direct and unambiguous disclosure** of the claimed subject-matter
  - This criterion was not met by D21 with regard to attaining the **therapeutic effect**
- "The question to be considered under the issue of sufficiency is whether [the therapeutic effect] was **credible** at the effective date"
  - Assessed in view of the disclosure of the patent as a whole and common general knowledge
  - Not always necessary for a claimed technical effect to be disclosed directly and unambiguously in the application as filed

Inventive step

- D3 discloses vilanterol for use in treating COPD. Provides data from *in vitro* tests for onset time and duration of action. Combination with other agents such as a anticholinergic agent are envisaged.
- Umeclidinium is an anticholinergic agent disclosed in D5 to have a very long in vivo duration of bronchodilation in humans.
- Board held:
  - *At the relevant date, both vilanterol and umeclidinium were still in early stages of their pharmaceutical development. While the basis for proceeding with the pharmaceutical development of a compound is favourable preclinical data, this does not necessarily give rise to a well-founded expectation of success, even less in the case of a combination product when neither combination partner has, as yet, progressed to the clinical stage of development.*

T 1255/21 (Targovax Solutions AS)

Lack of inventive step in view of clinical trial protocol

Claim 1

At least one peptide, suitable for eliciting an immune response, wherein the or each peptide corresponds to a fragment of a wild-type RAS protein but has one amino acid substitution thereof, for use in the treatment of cancer

by simultaneous or sequential administration with pyrimidine analogue or a pharmaceutically acceptable salt thereof….

Background

- Appeal stems from opposition division's decision to reject opposition
- OD **only** assessed inventive step starting from document D23, despite acknowledging that the opponent has raised several inventive step attacks (including from D25).
- According to the OD: D25 **does not disclose the sequences of the peptides** and **no results for the trial are shown**, and, thus, D25 is not considered to be a promising springboard for the invention.
- Board of Appeal: According to the established case law of the boards, the assessment of inventive step **should** be done from **all** documents that could represent alternative "**workable routes"** to the invention (CLBA I.D.3.1)

Prior art: D25

- D25 refers to a clinical trial with the title “A Phase I/II Trial of TG01 and Gemcitabine [a pyrimidine analogue] as adjuvant therapy for treating patients with pancreatic cancer”.
- The product code “TG01” is not commonly known
  - It was disputed between the parties whether the skilled person would have been able to determine what the composition identified as “TG01” actually consisted of.
  - The Board’s decision is very detailed on this point (beyond scope of this webinar).
  - It was eventually concluded that the skilled person having common general knowledge in mind would have recognised that the “TG01” composition referred to a peptide as claimed.
- The use of the code-name “TG01” in document D25 does not affect the status of this document as a realistic starting point for assessing inventive step

Difference and technical effect

- The only difference between the disclosure in the patent and the disclosure in document D25 is that the former discloses that the **therapeutic effect** which the trial is set up to test, is actually obtained.
- The objective technical problem can be seen as providing an effective treatment for (pancreatic) cancer.

Obviousness

- Would the skilled person starting from the clinical trial proposal (D25) have **reasonably expected** that putting it into practice **would result in an effective treatment** for pancreatic cancer patients.
- It was common ground that TG-01/GM-CSF had a therapeutic effect (for example, from D6).
- It was undisputed that gemcitabine was a standard treatment of pancreatic cancer (for example, from D7).
- The skilled person therefore knew that each of the two components to be tested in the clinical trial (D25) could separately achieve a therapeutic effect.

Patentee's argument

- Patentee argued the skilled person would **not** have had a reasonable expectation that the clinical trial proposed in document D25 would yield positive results.
- The skilled person would have been dissuaded from implementing said clinical trial proposal because of a possible interference of gemcitabine with TG01/GM-CSF vaccination.
  - The main objective of D25 itself was assessing "the potential for interference of Gemcitabine on immune response to TG01".
  - D31 and D32 reported that clinical trials of a peptide vaccination combined with gemcitabine had been stopped because of a lack of improvement in patient survival.
  - Paragraph [0023] of the patent provided a rationale for why gemcitabine might interfere with peptide vaccination.

Board’s considerations

The board was not convinced:

- The skilled person would have understood the reference to interference in document D25 as a standard indication for any combination therapy, and as such it would not impart to the skilled person any particular prejudice against the proposed clinical trial.
- The passage on interference in the patent itself was not available to the skilled person at the relevant date and appears to reflect general theoretical observations which are not backed up by any specific evidence.
- The appellant-opponent referred to a number of prior art documents which report successful therapy using peptide or protein vaccines in combination with gemcitabine.

Board’s considerations

- The board cannot conclude that there was any **prejudice or teaching away** from combining peptide vaccines with gemcitabine **in the art**, which **would have dissuaded** the skilled person to put the clinical trial proposal of D25 into practice.
- Rather, based on the teaching in the prior art and their common general knowledge, the skilled person is judged to have had a **reasonable expectation of success** when putting the proposal of document D25 into practice.
- Claim 1 lacks inventive step

In line with previous case law

- 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.
  - There may be some cases where a clinical trial itself does not provide a reasonable expectation (T 2963/19).

T 1252/20 (3-D Matrix, Ltd) Definition of “substance or composition” in medical use claims

T 1252/20: background

- EPC allows for purpose-limited product claims for medical uses of format:

  “A substance or composition X for use in the treatment of disease Y”

- In **T 2003/08** (citing **G 5/83**), the Board held that:

  i. medical use form of protection only for those uses in the medical domain which concerned a "substance" or "composition"

  ii. that it was the "substance" or "composition" which achieved the medical effect (i.e. the “**active agent**”)

  iii. the terms "substance" or "composition" referred at least to products which were chemical entities or compositions of chemical entities

T 1252/20: background

- In **T 1758/15** the patent related to a biocompatible, biodegradable, injectable filler material (e.g. collagen or hyaluronic acid) for use in a specific method.
- The board referred to G 5/83 and T 2003/08 which interpreted the term "*substance or composition*" as being "***the active agent or ingredient***" of the particular specific medical use.
- The "**mode of action**" is relevant and the following must be established:
  a) the means by which the therapeutic effect is achieved; and
  b) whether that which achieves the therapeutic effect is a chemical entity or composition of chemical entities.

Case law: not a “substance or composition”

- **T 773/10:** Directed to a new use of a **dialysis membrane** for the treatment of multiple myeloma. The claimed dialysis membrane did not contain any further substance or composition which might constitute an "active" ingredient.
- **T 2136/15:** An **alginate** that was injected into the heart to create 3D structures. It was the shape of these 3D structures, as opposed to the chemical composition of the alginate being injected, that brought about the therapeutic effect (a “viscous device”).
- **T 1345/18:** A **bone adhesive** comprising calcium phosphate. It was not the chemical composition but the macro-structures created by the compound which had the technical effect.

Case law: a “substance or composition”

- **T 2003/08**: the Board allowed a claim directed to a new use of a **column** for an extracorporeal treatment. The medical effect was based was the removal of immunoglobulin. This effect was achieved by the **"specific ligand for human immunoglobulin"**, which was undisputedly a chemical entity. The "column" only served as a carrier for the ligand and was not instrumental in achieving the therapeutic effect.
- **T 0264/17:** A **lubricant** (consisting of at least one perfluoropolyether) for use as a **synovial fluid replacement** for a diseased natural joint of a human or animal body. In the board's view, this effect was achieved as a result of the claimed lubricant's material properties. The lubricating effect of perfluoropolyethers is based on their omniphobic properties.

T 1252/20: claim 1

"A composition for use in reducing or eliminating cancerous cells in a subject by forming at least a partial blockage, lodging, occlusion or embolism in a blood vessel to deprive a tumor in the subject of blood supply, or in the treatment of patent ductus arteriosus (PDA) or major aortopulmonary collateral artery (MAPCA) in a subject, the composition comprising:

a solution comprising an amphiphilic peptide in an effective amount and in an effective concentration to form a hydrogel under physiological conditions to allow at least a partial blockage of the biological vessel to effect embolization or cell necrosis therein,

wherein the peptide has an amino acid sequence of one of RADARADARADARADA (SEQ ID NO: 7), IEIKIEIKIEIKI (SEQ ID NO:8), and IEIKIEIKIEIKIEIKI (SEQ ID NO.9), and

wherein the concentration effective to allow at least partial blockage of the biological vessel comprises a concentration in a range of 0.1 weight per volume (w/v) percent to 3 w/v percent peptide."

T 1252/20: first instance decision

- The examining division based its reasons for the lack of novelty of claim 1 on the Guidelines for Examination, G-VI, 6.1.1 and **T 1758/15**:

  *"***In the present case the mode of action was purely physical and based on the macroscopic 3D-structure; the hydrogel formed in the body obstructed the blood vessel.** *The composition acted thus as a device in the human body and could not be considered a substance or composition in the sense of Articles 54(4) and (5) EPC."*

- The Examining Division held that the "substance or composition" had to be "**the active agent or ingredient**" of the particular specific medical use. Some indirect effects of the compound were **not** sufficient to make the compound the "active principle". It was **not** the chemical composition of the compound, which was primarily the responsible for the therapeutic effect, but the **3D structure**.

T 1252/20: Board’s decision

- This line of case law **imposes restrictions** to what may fall under the definition of "substance or composition" in the sense of Article 54(5) EPC based on its **mode of action**.
- Whereas the materials underlying these cases, collagen fillers, alginates or bone glue, would, in **everyday language**, be seen as **substances or compositions**, they were not considered "substances or compositions" in the sense of Article 54(5) EPC, since once inside the body they acted as a **device**.

T 1252/20: Board’s decision

- The appellant, brought forward various arguments emphasising **the chemical nature** of the peptide solutions defined in the claims.
  - The appellant argued that the embolizing effects were due to the **better adhesion** of the hydrogel formed. The better adhesion, in turn, could be attributed to the **chemical structure** of its components or to the chemical structure of the hydrogel once assembled inside the body of the patient, or even to the self-assembly process.
- **However, the Board was convinced that the peptide solutions defined in the claim must be considered a "substance or composition" in the sense of Article 54(5) EPC already for more fundamental reasons.**

T 1252/20: Board's decision

- The claims do **not** define the material by any technical features which would be characteristic for a **device**, e.g. its **shape**. When administered, the material does not yet have the crucial shape of the plug fitting to the blood vessel, which will in the end result in the therapeutic effect aimed at.
- The claims define a material in a liquid state, a solution containing peptides in specific amounts and concentrations, i.e. a **shapeless** liquid mixture of **chemical entities**. Already for this reason alone, **it is not a device**.
- It is another matter that the peptide solution will, once used as defined in the present claim, **transform** itself into something which may act as if it were a device. However, no good reason to consider the peptide solution defined as the protected object of the claim (i.e. **before** its actual use) as a device.

T 1252/20: Board's decision

The Board found that the use of the **mode of action** as the defining criterion for whether a product is a "substance or composition" (c.f. T 1758/15) was problematic for several reasons:

- The material acting inside the body may **not** be the same as the product to which a patent claim is directed. Claims are generally directed to the **administered product** not necessarily the active (e.g. inactive prodrugs).
- The mechanism of action may not be understood in detail, and may also later turn out to be wrong. **The EPC does not require that the mechanism of action of a substance or composition to be understood**.
- A product may behave in **different** ways according to its **mode of administration**. Odd to classify the very same material as a "substance or composition" or not depending on its way of administration.
- Restriction of the definition of "substance or composition" by way of mode of action "***does not achieve the legislative purpose****, namely to provide at least a complementary form of protection for an otherwise recognisably useful invention in a field*".

T 1252/20: take-home messages

- The question of whether a material or object is a "substance or composition" should be decided on the basis of the claimed material or object as such.
- If this analysis leads to the conclusion that a substance or composition is present, i.e. no “**device-like features**”, this requirement is fulfilled. **No additional restrictions relating to its mode of action are derivable from the EPC.**
- Potentially allows a **broader definition** of the term “*substance or composition*” which are protectable by purpose-limited product claims, but warning that this **cannot be used to circumvent exclusion**.

T 1920/21 (Infai GmbH) Exceptions to patentability (diagnostic methods)

T 1920/21: background

- Diagnostic methods practised on the human or animal body are excluded from patentability.
- Article 53(c) EPC:

  *"European patents shall not be granted in respect of…**diagnostic methods practised on the human or animal body**...."*

T 1920/21: background to G 1/04

- In G 1/04 the Enlarged Board gave the term "diagnostic methods" a **narrow interpretation**.
- Several phases are required to define a diagnostic method:
  - (i) the examination phase involving the collection of data,
  - (ii) the comparison of these data with standard values,
  - (iii) the finding of any significant deviation, i.e. a symptom, during the comparison, and
  - (iv) the deductive phase, i.e. the attribution of the deviation to a particular clinical picture.
- All method steps of a technical nature should satisfy the criterion "**practised on the human or animal body**" i.e. imply an interaction with the human or animal body.

T 1920/21: claim 1

A method for diagnosing a Helicobacter pylori infection in a patient treated with proton-pump-inhibitors (PPIs) comprising the steps of

- administering to the patient a mixture of citric acid, malic acid, tartaric acid in amount of 5 to 7 g, **collecting a first breath sample**,
- administering to the patient ^{13}C-labeled urea, wherein the amount of ^{13}C-labelled urea corresponds to 10 to 100 mg 99% ^{13}C-urea waiting for a time of 10 to 60 minutes, thereafter **collecting a second breath sample** from the patient,
- **measuring the content of ^{13}C in the CO_2 of the first and second sample and determination of a $^{13}C/^{12}C$ ratio by spectroscopy in the respective samples**

characterized in that a difference Deltadelta of the $^{13}C/^{12}C$ ratio of the first breath sample and $^{13}C/^{12}C$ ratio of the second breath sample is calculated and the value of the difference in the range of 2 per mille to 2.9 per mille is used as a cut-off to indicate the presence of a H. pylori infection in the patient, wherein the method requires only a 1 day stop of PPI intake.

T 1920/21: Board of Appeal decision

- The Board agreed that claim 1 included features relating to each of phases (i) to (iv).
- However, two breath samples are collected from the patient and then the content of ^{13}C in the CO_2 of the samples is determined by spectroscopy. **No requirement that the measurement of these two samples also requires the presence of the patient.**
- Suitable devices include those for gas isotope ratio mass spectroscopy or infrared spectrometer and analyse the collected breath samples **without any interaction with the patient** or necessitating its presence**.**

T 1920/21: Board of Appeal decision

- Distinguished from **T 125/02** relating to a method for ascertaining the lung function of a human subject. The **presence of the human subject** and its connection to the device was necessary as the measuring occurred "during one or more exhalation phases".
- Similarly distinguished from **T 1197/02**, **T 143/04** and **T 1016/10** in which **all steps** of a technical nature of phase (i) necessitated the **presence of the human body** and implied an interaction therewith.

T 1920/21: take-home messages

- Diagnostic methods is a **narrow exclusion**.
- To be excluded from patentability:
  - features relating to **each of phases (i) to (iv)** must be present.
  - **each and every one** of the method steps of a technical nature (e.g. in the examination phase) must be "practised on the human or animal body".

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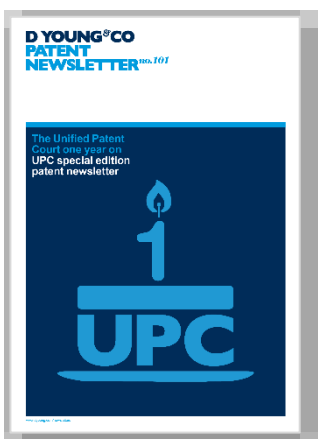

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Any Questions…?

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