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European biotech patent law update

12 November 2019

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Slides and a recording of this webinar will be emailed to you later this week. Email us direct after the webinar with any follow up questions.

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Webinar agenda

- Patient sub-groups – T 0694/16 (N.V. Nutricia) and T 0787/14 (GlaxoSmithKline Biologicals SA)
- T 1731/12 – medical devices
- Rules of Procedure of the Boards of Appeal

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Patient sub-groups

- Pharmaceutical companies are investing heavily in the potential benefits of targeted medicine.
  - delivering certain specific treatments to smaller specific patient populations whose profile may indicate that they would be more receptive to particular treatments.
- Biomarkers may be used to identify new patient population, e.g., patients that respond particularly well to a drug.
- Is it possible to patent the use of drugs to treat a ‘new’ patient population?

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Patient sub-groups - T 233/96 (Medco Research Inc)

T 233/96

> The use of adenosine in the preparation of a diagnostic agent for detecting the presence of vascular disease of coronary arteries by parenteral administration to a **human who is unable to exercise adequately,** in conjunction with radioimaging of coronary arteries.

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Patient sub-groups - T 233/96

Set out conditions for a claim that is directed to a new patient group.

- The treatment or diagnosis of the same disease with the same compound must be carried out on a new group of subjects which is distinguished from the former by its physiological or pathological status.
- Chosen subject group must not overlap with the group previously treated.
- Chosen subjects group must not be arbitrary i.e., where no functional relationship exists between the particular physiological or pathological status of the group of subjects and the therapeutic or pharmacological effect achieved.

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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:

- to eradicate detectable HCV-RNA.
- 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.

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Patient sub-groups T 1399/04

Previous document (D8) discloses the use of ribavirin and interferon alpha for treating chronic HCV infections.

No mention of specific genotypes and does not mention the virus load of patients.

Appellant argued that at least 50% of HCV infections were genotype 1 infections, which were known to be associated with high virus load.

Appellant argued that the subject-matter was the selection of a specific patient group, which for a big part, overlapped with the patient group of D8.

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Patient sub-groups T 1399/04

Board dismissed reasoning of T 233/96 – held that can have novelty if new group overlaps with the group previously treated.

- Board held that patient group should distinguished by its physiological and pathological status – (viral genotype/viral load).
- "*The patent in suit contains studies which convincingly show that it is exactly the patient group according to claims 1 to 3, namely antiviral treatment naïve chronic HCV genotype 1 patients with a virus load greater than 2 million copies per ml serum, which profits most from an extension of the combination therapy from 24 weeks to 48 weeks (see tables 6, 14 16 and 17 of the patent)*."
- Therefore, held claims are novel over D8.

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

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 characteristics of a prodromal dementia patient.

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Patient sub-groups T 0694/16

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 characteristics of a prodromal dementia patient, wherein said characteristics comprise at least:

- a level of more than 350 ng Total-tau per litre cerebrospinal fluid (CSF); and
- a weight ratio of abeta-42/Phospho-tau-181 of less than 6.5 in CSF."

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Patient sub-groups T 0694/16

- Prior art (D1 and D3) disclosed not only treatment but prevention of dementia with the claimed composition.
- Argued that subjects not yet affected by clinical dementia but displaying relevant CSF markers had necessarily been treated.
- The decisive issue for deciding novelty is the construction of the feature "for use in the prevention or delay of dementia in a person having characteristics of a prodromal dementia patient, wherein said characteristics comprise...".

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Patient sub-groups T 0694/16

- Claim 1 is a “purpose-limited product claim”.
- The perspective of the skilled person who works in the relevant field and understands that purpose must also be considered.
- In the present case this is a person working in the field of personalised medicine. Their goal is to move away from the "one-size-fits-all approach" of traditional medicine and to provide a treatment tailored to specific groups of patients who best profit from the treatment.
- The purpose of the treatment is to target selectively prodromal patients identified by the CSF markers, rather than other subjects that do not display the markers.

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Patient sub-groups T 0694/16

- "...a line must be drawn between what is in fact made available and what remains hidden or otherwise has not been made available...". Thus, the relevant issue is what has been made available, and not "...what may have been inherent in what was made available..." (G 2/88, points 10-10.1).
- The board is of the opinion that this principle applies also to claims drafted under Article 54(5) EPC.
- It is also supported by the statement in G 2/88 that "... the question of "inherency" does not arise under Article 54 EPC" (i.e. in relation to all aspects relating to novelty).

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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 D1 and D3 do 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.

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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. No such a method is disclosed in D1 and D13.
- Claim deemed novel by the Board.

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T 0787/14 (GlaxoSmithKline Biologicals SA)

- One embodiment falling within claim 1 of all the claim requests is:
- A composition that comprises conjugates of four capsular saccharides of *N. meningitidis* and CRM197 as the carrier protein,
- wherein the conjugates are mixed to give a 2:1:1:1 ratio…
- the meningococcal conjugates comprise an adipic acid linker,
- for use in a method for immunising a human patient against a disease caused by N. meningitidis comprising the step of administering the composition to the human patient, wherein the patient was preimmunised at least six months previously and within 1 year of the patient's birth with a conjugate of a capsular saccharide of an organism other than N. meningitidis and a diphtheria toxoid or CRM197.

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T 0787/14

- Patent disclosed results of a clinical trail and concluded that “no evidence of carrier suppression was seen in the trial”.
- Proprietor also argued that the patent showed that the ratio of 2:1:1:1 was particularly effective and that this was confirmed in post-dated filing, and that linker provided additional advantages.
- However, the Board noted that the patent is silent on the pre-immunisation status of the patients enrolled in the clinical trial i.e. that they represented the subgroup of patients to be treated according to the embodiment under consideration.
- The verification of whether the claimed subject-matter actually provides the desired effect, must be based on the data in the application in order to avoid that an invention is based on knowledge available after the effective date only.
- Post-published evidence to support that the claimed subject-matter solves the underlying technical problem can only be taken into account if it is already credible from the disclosure in the patent that the problem is indeed solved.

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Lessons

- The EPO is relatively patentee friendly with respect to claims directed to a patient subgroup.
- It is important to clearly characterise the subgroup (e.g. with relevant biomarkers) in the claim.
- Include data in application for treatment of subgroup – do not rely solely on later filed data.
- Must show selection is purposive and not arbitrary.
- Inherency of prior art not terminal with respect to novelty.

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T 1731/12

- Medical device – product claim reciting functional features
- Exceptions to patentability – Article 53(c) EPC
- “A device defined by a feature which can only be produced by a surgical or therapeutic step is excluded from patentability under Article 53(c) EPC”

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T 1731/12 – Background

- EP1613394 – Device for the desynchronisation of neuronal brain activity.
- Filed 8 April 2004.
- Appeal of opponent against OD’s decision to reject opposition.

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T 1731/12 – Background

- Patent opposed on the grounds of lack of novelty and inventive step, and added subject matter.
- OD introduced ground of exception to patentability of its own motion.
- OD rejected opposition – Patent maintained as granted.

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T 1731/12 – Background

- Article 53(c) EPC:

  European patents shall not be granted in respect of:

  […]

  (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

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T 1731/12 – Background

- Article 53(c) EPC – G 1/07:

  “medical and veterinary practitioners' freedom to use the best available treatments to the benefit of their patients, uninhibited by any worry that some treatment might be covered by a patent, should be protected by excluding these activities from patentability”

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T 1731/12 – Background

- Patent:
  - Device for treatment of Parkinson’s disease and similar conditions.
  - Diseases related by unwanted synchronisation of activities of pathological areas of the brain.
  - Device desynchronises these areas.

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T 1731/12

- Main Request – Claim 1:

  Device for the desynchronization of activity of pathologically active brain areas comprising means for stimulating brain regions, characterized in that it comprises the following components:

  - at least two electrodes (2); and
  - control means which are designed such that, during operation, they control the at least two electrodes (2) such that the at least two electrodes (2) emit stimuli to in each case one of at least two subpopulations of a neuron population to be desynchronized, with the stimuli emitted from different electrodes (2) being offset in time, and the stimuli causing the neural activity of the at least two subpopulations to be phase-reset, such that the at least two subpopulations have different neural-activity phases after the phase resets produced by the stimuli.

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T 1731/12 - Decision

- Cited T 775/97:
  - That case related to claim to a product made from two known parts by a surgical step in the human body

"No European patent can be granted with claims directed to a new and even possibly inventive way of using materials or devices, in particular endoprotheses, involving a treatment by surgery. This is equally true for product claims defined by a construction which is only arrived at in the human or animal body following a surgical method step."

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T 1731/12 - Decision

- Functional feature can only be met after implantation:

  “On the one hand, it is stated in many places in the description that the control means are adapted to the conditions after the implantation in order that the intended method of the phase reset of subpopulations can be carried out.”

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T 1731/12 - Decision

- Functional feature can only be met after implantation:

  “For example, it is described that the stimulation period T is adjusted as a function of the activity of downstream areas (B1: [0052]) and that the timing is also demand-controlled (B1: [0053]). A key reason for this adjustment of the control means, so that they actually work as desired after implantation, as shown in the description is that the stimulation parameters are crucially dependent on the positioning of the electrodes.”

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T 1731/12 - Decision

"It is also pointed out that the duration of the stimuli must be taken into account for the control (B1: page 6, lines 36-51). From this information, it follows that the control means for realizing the feature "the at least two subpopulations have different neural-activity phases after the phase resets produced by the stimuli" must take into account the position of the implanted electrodes. However, this position can also be determined only after the implantation, so that the control means before the implantation cannot yet be designed so that the feature is fulfilled."

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T 1731/12 - Decision

- Excluded from patentability under Article 53(c) EPC:

> “The claimed device is therefore defined by at least one feature which can only be produced by the implantation, i.e. a surgical step.”

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T 1731/12 - Summary

- Particular facts of this type of device?

- Include description of approaches for testing and calibrating devices outside of the body, if possible.

- Disclaimers?

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Revision of the Rules of Procedure of the Boards of Appeal

- New rules come into force on 01 January 2020.
- Significant changes: more challenging to have new requests, facts, objections or arguments admitted into proceedings at the appeal stage.

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Key points

- Procedural efficiency.
- Remittal.
- Basis of appeal proceedings.
- Convergent approach – amendment to a party’s case.
- Abridged decision.

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Procedural efficiency

- Advance publication of a list of cases for each Board (New Article 1(2))
- Acceleration:
  - New Article 10(3) – Board may accelerate appeal proceedings on the request of a party (reasons and supporting evidence must be provided).
  - New Article 10(4) – A court can request acceleration of proceedings.
  - New Article 10(5) – Board may also accelerate proceedings of its own motion.

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Remittal

- Current Article 11:

  A Board shall remit a case to the department of first instance if fundamental deficiencies are apparent in the first instance proceedings, unless special reasons present themselves for doing otherwise.

- New Article 11:

  The Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. As a rule, fundamental deficiencies which are apparent in the proceedings before that department constitute such special reasons.

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Basis of appeal proceedings

- Article 12(1):

  Appeal proceedings shall be based on

  (a) the decision under appeal and minutes of any oral proceedings before the department having issued that decision;

  […]

  (e) minutes of any video or telephone conference with the party or parties sent by the Board.

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Judicial review

- New Article 12(2):

  In view of the primary object of the appeal proceedings to review the decision under appeal in a judicial manner, a party's appeal case shall be directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based.

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Convergent approach

- First level: beginning of appeal proceedings – statement of grounds of appeal / responses.
- Second level: before expiry of period set in an invitation to file observations / before summons to OPs notified.
- Third level: after expiry of period set in an invitation to file observations / after summons to OPs notified.

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Convergent approach – first level

- New Article 12(4):

  Any part of a party's appeal case which does not meet the requirements in paragraph 2 is to be regarded as an amendment, unless the party demonstrates that this part was admissibly raised and maintained in the proceedings leading to the decision under appeal. Any such amendment may be admitted only at the discretion of the Board.

  The party shall clearly identify each amendment and provide reasons for submitting it in the appeal proceedings. In the case of an amendment to a patent application or patent, the party shall also indicate the basis for the amendment in the application as filed and provide reasons why the amendment overcomes the objections raised.

  The Board shall exercise its discretion in view of, inter alia, the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal, and the need for procedural economy.

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Convergent approach – second level

- New Article 13(1):

  Any amendment to a party's appeal case after it has filed its grounds of appeal or reply is subject to the party's justification for its amendment and may be admitted only at the discretion of the Board.

  Article 12, paragraphs 4 to 6, shall apply mutatis mutandis.

  The party shall provide reasons for submitting the amendment at this stage of the appeal proceedings.

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Convergent approach – second level

[…]

The Board shall exercise its discretion in view of, inter alia, the current state of the proceedings, the suitability of the amendment to resolve the issues which were admissibly raised by another party in the appeal proceedings or which were raised by the Board, whether the amendment is detrimental to procedural economy, and, in the case of an amendment to a patent application or patent, whether the party has demonstrated that any such amendment, prima facie, overcomes the issues raised by another party in the appeal proceedings or by the Board and does not give rise to new objections.

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Convergent approach – third level

- New Article 13(2):

  Any amendment to a party's appeal case made after the expiry of a period specified by the Board in a communication under Rule 100, paragraph 2, EPC or, where such a communication is not issued, after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

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Abridged decisions

- New Article 15:

  (7) Where the decision on the appeal has been announced orally in accordance with paragraph 6, the reasons for the decision, or parts thereof, may, with the explicit consent of the parties, be put in writing in abridged form. However, where it has been indicated to the Board that a third party or a court has, in the particular case, a legitimate interest in the reasons for the decision not being in abridged form, they shall not be abridged. Where appropriate, the reasons for the decision in abridged form may already be included in the minutes of the oral proceedings.

  (8) If the Board agrees with the finding of the department which issued the decision under appeal, on one or more issues, and with the reasons given for it in the decision under appeal, the Board may put the reasons for its decision in abridged form in respect of that issue.

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Transitional provisions

- New articles apply to all appeals pending on 01 January 2020.
- Except:
  - New Articles 12(4) to (6) – not applicable to any grounds of appeal or response thereto filed before 01 January 2020.
  - New Article 13(2) – not applicable if the summons or invitation notified before 01 January 2020.

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Summary

- File complete case at first instance including all reasonable claim requests, evidence and arguments.
- If filing documents late in first instance – take time to set out all arguments for admissibility.
- Review minutes of oral proceedings – request correction if necessary.
- Review pending opposition / appeal cases now – consider whether any additional claim requests, data, citations etc. can be filed before 01 January 2020.
- File new appeals before 01 January 2020 if possible.

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Summary

- Justify all amendments to the case – why was it not possible to submit earlier; why they address outstanding issues; why they do not give rise to new objections.
- Convergent approach – the later in an appeal an amendment to the case is submitted the less likely it is to be admitted – look at requirements for admittance at each stage – provide appropriate level of justification.

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