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Validité des brevets dans le domaines des Sciences de la vie :

la plausibilité – critère de brevetabilité – ou pas !

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Brevetabilité des anticorps / plausibilité, en EP

- Plausibilité = terme introduit dans les décisions EP depuis plus de 10 ans
- Surtout domaine pharma-biotech
- Surtout Art 56 et Art 83 CBE
- Question « brevet » au congrès

→ Critère de brevetabilité ?

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Plausibilité : Art 83 CBE

- **T1602/10**

Rev 1 : A TIM-3 binding molecule wherein the TIM-3 binding molecule is an antibody specific for TIM-3 or is a fragment of an antibody specific for TIM-3, for use in a treatment of cancer in a subject.

«In view of the above it is considered that the skilled person would not have considered that the disclosure of the application makes it plausible that it would be possible to generate a de novo immune response to cancers where there was no established native response. Moreover, the skilled person would not have believed that substancially all cancer types inherently generate a Th1, TIM-3 mediated immune response and be treatable by administration of anti-TIM-3 antibodies. It is noted that the post-published documents submitted by the appellant support this conclusion, […] » (pt 16)

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Plausibilité : Art 83 CBE

- **T2500/12** **(1/2)**

1. A pharmaceutical preparation containing an immunogen which induces production of antibodies against the animal's autologous APP or Aß, wherein the immunogen incorporates

   a) a polyamino acid which consists of a polyamino acid selected from the group consisting of:
   - amino acid residues 1-12,…. or
   b) is a conjugate …or
   c) is a nucleic acid…..or,
   d) is a non pathogenic microorganism or virus…..,

   for use in the treatment, prevention or amelioration in an animal of Alzheimer disease or other diseases characterized by amyloid deposits.

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Plausibilité : Art 83 CBE

- **T2500/12** **(2/2)**

In the case at hand, the question to be answered is whether or not either the application discloses that an immunogen containing the polyamino acid, defined in the claim, would be suitable (i.e. would plausibly be considered to be useful) for the treatment, prevention or amelioration in an animal, for example a human, patient of Alzheimer's disease or other diseases characterized by amyloid deposits (i.e. for the therapeutic use defined in the claim), or if the skilled person at the priority date would have known this. (pt 2)

Firstly, it was widely accepted in the art that Alzheimer's disease or other diseases characterized by amyloid deposits could be treated by generating an immune response to Aß. It was therefore sufficient that the application made it plausible that such an immune response was generated. The application did this by showing, in a mouse model,…. (pt 3.1)

Even if it were accepted that it is at least plausible that the claimed constructs can elicit an immune response to Aß, the board has seen no evidence in the application, that at the effective date, a direct and unambiguous link, for example, by means of an animal or in vitro model, had been established between the observed effect of eliciting anti-Aß antibodies and the effective treatment of disease. (pt 5)

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Plausibilité : Art 83 CBE

- **T0760/12**

Rev 6 : Use of a substance that inhibits specific binding of HGF ß chain to c-Met in the preparation of a medicament for treating a pathological condition associated with activation of c-Met in a subject, wherein the substance is :

(a) a peptide comprising an amino acid sequence having at least 60 % sequence identity with the sequence VDWVCFRDLGCDWEL,

(b) a monoclonal antibody or a fragment thereof which specifically binds to said activated HGF ß chain; or

(c) a combination thereof, wherein the substance binds to activated HGF ß chain and inhibits specific binding of said activated HGF ß chain to c-met, and wherein the pathological condition is a tumor or angiogenesis-related disorder.

*It thus next has to be examined wether it is made **plausible** in the patent that monoclonal antibodies as defined in the claim are potentially suitable for exerting a therapeutic effect….. »(pt 3.6)*

*It is a priori **plausible** that interference with the HGF/Met signalling pathway may result in a therapeutic effect in those pathological conditions where the activation of this pathway has been shown to play a role.(pt 3.7)*

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Plausibilité : Art 56 CBE

- **T1581/12** (1/2)

1. A protein comprising:
   . amino acid sequence SEQ ID NO:4;
   . an amino acid sequence comprising a fragment of 20 or more consecutive amino acids from SEQ ID NO:4, wherein
   said fragment comprises an epitope from SEQ ID NO:4;
   . acid sequence SEQ ID NO:6;
   . amino an amino acid sequence comprising a fragment of 20 or more consecutive amino acids from SEQ ID NO:6, wherein said fragment comprises an epitope from SEQ ID NO:6.

4. An antibody which specifically binds to amino acid sequence selected from the group consisting of SEQ ID NO:4 and SEQ ID NO:6.

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Plausibilité : Art 56 CBE

- **T1581/12** (2/2)

However, the presence of all the specific structural features listed in point 23 supra, are a reliable sign for a skilled person to identify this lipoprotein as a ***plausible*** *candidate to solve the posed technical problem by having the desired properties, particularly in absence of any evidence to the contrary. With the information provided by the patent, there was no reason for a skilled person to doubt the assumptions made in the patent, sometimes referred to as "educated guesses" in the case law of the Boards of Appeal (…), and which may be confirmed only later by post-published evidence (…). (pt 24)*

……It is the presence of all these specific structural features that render the assumptions made in the patent as regards sequences SEQ ID NO 4, 6 fully ***plausible****. (pt 25)*

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Plausibilité : Art 56 CBE

- **T0716/08**

1. Use of an 48 kD infectious Salmon anaemia virus (ISAV) protein or an immunogenic fragment of said protein, […] at least 70% homologous to the amino acid sequence as depicted in SEQ ID NO: 2, for the manufacturing of a vaccine for combating ISAV infections.

5. Vaccine for combating ISAV infection, characterized in that it comprises a nucleic acid sequence as described in claim 3 or 4, a stretch of nucleotides […], a recombinant DNA molecule comprising […], a live recombinant carrier comprising [….] or such recombinant DNA molecule, a host cell comprising [….] or such recombinant DNA molecule

13. Method for the preparation of a vaccine according to claim 5,

*…..In the decision under appeal the examining division held that it was **not plausible**, on the basis of the disclosure in the application and in particular Examples 4 and 5, that the solution, as then claimed in claims10 to16, solved the problem underlying the application. (pt 13)*

As to the quality of the evidence, "absolute proof" of the achievement of an effect is not required for the effect to be "plausible". Thus, in the case of a vaccine, it is not required that protective immunity is actually demonstrated in the target organism. It suffices that the data indicate that a compound could be a useful candidate for a vaccine (for example decision ….). (pt16)

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Plausibilité : Art 56 CBE

- **T1433/14**

Rev 1 (MR) : An isolated or synthesized H1N1 influenza virus « Replikin » peptide from a hemagglutinin protein wherein said peptide consists of 7 to 50 amino acids comprising (1) at least one lysine résidue located six to ten residues from a second lysine residue; (2) at least one histidine residue; and (3) at least 6% lysine residues.

Rev 1 (Aux Req IV): An antibody that specifically binds to an isolated or synthesized H1N1 influenza virus « Replikin » peptide ……

*However, if it becomes apparent that a purported technical effect is not achieved by all of the claimed subject-matter, for instance because it is **not plausible** that the claimed subject-matter actually achieves the purported effect (see Case Law….), then the problem cannot be considered as having been solved(..). (pt11)*

*The board is not persuaded that the skilled person, when reading these disclosures in the light of the common general knowledge in the art, would consider it **plausible** that the peptide of claim 1 can be used as a vaccine at all and in particular, as a vaccine against H1N1 influenza virus infection. (pt 13)*

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Merci pour votre attention

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