Second Medical Use Claims in the EPO

Post G2/08

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Second Medical Use Claims
– How did we get here?
  – Background case law and how the referral happened.
– What does G2/08 say?
  – The reasoning of the decision and how the Board arrived at it.
– What are the implications?
  – New and Existing applications: possible strategies
Prohibition on Claims to Methods of Treatment

- Art. 53 EPC2000 (corresponding to Art 52(4) EPC1973)

- “European patents shall not be granted in respect of:....

(c) methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced 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.”
First Medical Use Claims

- Art 54(4) EPC 2000 (corresponding to Art.54(5) EPC1973)

“Paragraphs 2 and 3 [defining the state of the art] shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.”

- Thus, where a compound is known, but has no previously known medical use, a First Medical Use claim is permitted
  - “Compound X for use in therapy”
“Swiss” Second Medical Use Claim Format

– No statutory basis for second medical use claims in EPC 1973.

– Permitted following G5/83 – “A European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application.”

– Thus, where a compound is known and has a known medical use, a new and inventive therapeutic application may be claimed in the so-called Swiss format –
  – “Use of X in the manufacture of a medicament for the treatment of Y”
EPC 2000 Changes

- Art 54(4) EPC 2000
  “Paragraphs 2 and 3 [defining the state of the art] shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.”

- Art 54(5) EPC 2000
  “Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.”
Art 54(5) EPC 2000 Second Medical Use Claim Format

1. X for use in a method of treating Y
2. X according to claim 1, wherein ....
   Or
2. X for use according to claim 1, wherein....
What if the same compound has been used to treat the same disease in the prior art?

- Novelty and inventive step can be established on a variety of features

- Eg
  - Patient subclass
  - Mode of administration
  - Combination therapy
  - Dosage regimen?
New patient subclass

– T19/86 “Duphar Pigs II”

  Allowed claim:
  
  “Use of live attenuated Aujeszky-virus for the manufacture of a vaccine for intranasally protecting maternally immune pigs against Aujeszky's disease.”

– Similarly T893/90.

  Allowed claim:
  
  “A method of producing a pharmaceutical composition for controlling bleeding in non-hemophilic mammals characterized by forming a mixture of phospholipid vesicles and mammalian blood Factor Xa in a form suitable for administration, the phospholipid and Factor Xa being present in amounts and in proportions just sufficient to arrest bleeding, said mixture excluding other physiologically-active materials.”
New mode of administration

– Classic case is “HCG/SERONO” – T51/93.

  Allowed claim:

  “Use of HCG for the manufacture of a non-depot medicament for use in the treatment by subcutaneous administration of infertility or male sexual disorders.”

– Similarly T143/94.

  Allowed claim:

  “Use of trigonelline for the production of an encapsulated agent which is to be administered perorally for reviving, and for stimulating and enhancing hair growth in living creatures.”
Combination Therapy

- Compound A for use in the manufacture of a medicament for treating Y, wherein compound A is administered simultaneously, separately or sequentially with compound B.

- Compound B for use in the manufacture of a medicament for treating Y, wherein compound B is administered simultaneously, separately or sequentially with compound A.

- Compound A for use in treating Y, wherein compound A is administered simultaneously, separately or sequentially with compound B.

- Compound B for use in treating Y, wherein compound B is administered simultaneously, separately or sequentially with compound A.

- A product containing compound A and compound B as a combined preparation for simultaneous, separate or sequential use in treating Y. (see T9/81 Asta-Werke)
New Dosage Regimen

– For some time, it was unclear whether dosage/treatment regimen features could establish patentability, based on *obiter* in T317/95 and T56/97, T584/97, T485/99 etc.

– Then T1020/03 came along and allowed the following claim:

> Use of insulin-like growth factor-I (IGF-I) in the preparation of a medicament for administering to a mammal so as to sustain its biological response in the treatment of a chronic disorder in the mammal wherein the administration pattern of the medicament comprises administering a therapeutically effective amount of IGF-I to the mammal to provide an exposure to IGF-I that is continuous or at least once a day consecutively over a period of days that provides the maximum biological response in the mammal, then discontinuing said administration by means of a continual lack of treatment or a lack of treatment for consecutive days over a period of days equal to or less than the number of days during which the IGF-I was previously administered, then administering [...]
G2/08 – The Referral
How did we get here?

- Referral from Board 3.3.2 (T1319/04 - Oswald – Apr-2008) concerning an appeal from a refusal by the ED on the claim:
  - The use of nicotinic acid ... for the manufacture of a sustained release medicament for use in the treatment by oral administration once per day prior to sleep, of hyperlipidaemia ...

- Referring to T317/95 and T584/97, ED held that the claim lacked novelty because the regime once per day prior to sleep reflected an excluded medical activity which could not be considered a further medical indication.
G2/08 – The Referral
The questions referred:

- (Q1) Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness?
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- (Q2) If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?
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– (Q2) If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?

– (Q3) Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?
The answers (Q1)

– **Q1** - can a known medicament be patented ... for use in a different, new and inventive treatment by therapy of the same illness?

– The Board noted:

  – The answer hinges on the meaning of Article 54(5) EPC 2000, which provides that any substance or composition ... *for any specific use* in a method of treatment by surgery or therapy may be patentable, provided the use is not known (r. 5.9.1)
The answers (Q1)

– It would be contrary to the rules of interpretation of the Vienna convention to give the term *any specific use* a limitative meaning contrary to its ordinary one

– It was unable to find any basis in the wording of G5/83 that that ruling was restricted to a new indication in the sense of a new disease (r. 5.10.5).

– It noted a well-established trend in the case law acknowledging the patentability of substances and compositions known in the prior art for the treatment of a particular disease, even if that disease is known (e.g. novel group of subjects; new route or mode of administration; different technical effect and truly new application) (r. 5.10.7)

– It was unable to find any intention by the legislator to limit the scope of the phrase *for any specific use*. On the contrary, it was the declared intention of the legislator to maintain the status quo of protection evolved under G5/83 (r. 5.10.8-9).
The answers (Q1)

– Therefore, the Board decided that the words *any specific use* were not limited to a new indication.

– The Board *explicitly* endorsed T1020/03.

– Answer: *yes*. A known medicament can be patented ... for use in a different, new and inventive treatment by therapy of the same illness.
The answers (Q2)

- Q2 – is patenting possible where the only novel feature of the treatment is a new and inventive dosage regime?

- The Board noted:
  - that there was no reason to give a dosage regime of a known medicament any different treatment from other specific uses (for instance specific patient sub-populations or new routes of administration).

- Answer: yes. Dosage regimes can be patented.
The answers (Q3)

Q3 – are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?

The Board noted:

- the loophole addressed by G5/83 has now been closed by Article 54(5) EPC.
  
- when the reason of the law ceases, the law ceases.

Answer: yes.

Goodbye G5/83 and Swiss-style claims – make way for Article 54(5) EPC.
EPO Notice dated 20th September 2010

- European patents may not be granted in respect of European or international patent applications having a filing date or earliest priority date of 29th January 2011 or later if they contain Swiss-type claims.

- If any such application contains Swiss-type claims, the applicant will be invited to correct this deficiency.

- The relevant date for divisional applications is the date of filing or earliest priority date of the patent application.
Life After G2/08

- The Board clearly does not intend for dosage regimes to be a walk in the park:
  - To keep EU Commission happy?

6.3 The Enlarged Board of Appeal does not ignore the concerns with respect to undue prolongations of patent rights potentially resulting from patent protection for claims purporting to derive their novelty and inventive step only from a not hitherto so defined dosage regime for treatment by therapy of an illness already treated by the same drug. Therefore, it is important to stress that, beyond the legal fiction of Article 54(5) EPC, for the assessment of novelty and inventive step of a claim in which the only novel feature would be the dosage regime, the whole body of jurisprudence relating to the assessment of novelty and inventive step generally also applies.
Board’s examples of the application of that law

– Selection invention case law applies when mere selection of a broader dosage regime disclosure.

– New dosage regime must lead to a new technical effect.
  – Technical effect must be identified in the application (T1329/04 etc.)

– Case law as to whether or not a new technical effect not previously recognised in the state of the art can confer novelty still applies.
  – Still no mechanism of action patents?
Existing Cases

– Decision to abolish Swiss-style claims has no retroactive effect
  – For all cases relating to a specific use (not just dosage regimes) – Swiss style claims remain possible.

– Is it worth pursing both style of claims?
  – Almost certainly, yes.
  – Board has recognised that EPC 2000 claims could be broader in protection that Swiss style claims (r. 6.5).
  – Now on a better legal footing for litigation with EPC 2000 claims?
  – But care with Article 123(3) EPC in opposition.
  – Double patenting objection if pursued in a divisional?
New Applications – Dosage regimen claim wording?

- T1319/04 - OK: use in the treatment by oral administration once per day prior to sleep, of hyperlipidaemia.

- T1020/03 - OK: very complex dosage regime based on cyclic dosing over many days:
New Applications – Dosage regimen claim wording?

– T1319/04 - OK: use in the treatment by oral administration once per day prior to sleep, of hyperlipidaemia.

– T1020/03 - OK: very complex dosage regime based on cyclic dosing over many days:

See next slide
Use of insulin-like growth factor-I (IGF-I) in the preparation of a medicament for administering to a mammal so as to sustain its biological response in the treatment of a chronic disorder in the mammal wherein the administration pattern of the medicament comprises administering a therapeutically effective amount of IGF—I to the mammal to provide an exposure to IGF-I that is continuous or at least once a day consecutively over a period of days that provides the maximum biological response in the mammal, then discontinuing said administration by means of a continual lack of treatment or a lack of treatment for consecutive days over a period of days equal to or less than the number of days during which the IGF-I was previously administered, then administering a therapeutically effective amount of IGF-I to the mammal to provide an exposure to IGF—I that is continuous or at least once a day consecutively over a period of days that provides the maximum biological response in the mammal, then discontinuing said administration by means of a continual lack of treatment or a lack of treatment or consecutive days over a period of days equal to or less than the number of days during which the IGF—I was just previously administered, and repeating this pattern of administration and discontinuance of administration for as long as necessary to achieve or maintain sustained biological response in the mammal.
Other Examples

- T36/04 – OK: *wherein the animal is first* exposed to the DNA damaging compound *and then* contacted with a p53 protein or gene.

- T1074/06 – OK: *wherein the medicament is for administration at a dose in the range of from 300 to 600 IU on every third day of the first six days of the stimulation phase.*

- T230/01 – OK: said medicament to be administered in an amount *sufficient to provide from 0.1 mg to less than 10 mg per day* of DCL or pharmaceutically acceptable salt thereof to a human.

- T584/97 – previously not OK, but probably now OK: *Use of nicotine for the manufacture of a kit containing separate units of nicotine of varying concentration, such that at least one unit contains a sub-therapeutic dose of nicotine and at least one unit contains a therapeutic dose of nicotine for the treatment of a condition susceptible to nicotine therapy involving the separate or sequential administration of increasing doses of nicotine.*
What else?

– Some ideas:
  – wherein the initial dose is a therapeutically effective dose.
  – wherein the initial dose is at least 50% or more of the final dose.
  – wherein the patient has not been previously treated with X for a period of at least two weeks.
  – administering 2-5 mg of X per kg patient weight.
  – wherein the treatment comprises weighing the patient and administering 2-5 mg of X per kg of patient’s measured weight.
  – wherein the treatment is administered to the patient standing.
  – wherein the patient does not lie down within one hour of administration.
Beyond Dosage Regimens?

- The Board’s reliance upon
  - previously established case law relating to other specific uses, *e.g.* patient sub-populations and new routes of administration; and
  - *any* specific use in Article 54(5) EPC.

appears to open the door to a variety of acceptable specific uses, not just dosage regimes (which is deliberately undefined in G2/08).

- Appears to be extremely generous to applicants.
  - Routes now available for claiming pharmaceutical inventions using limitations and distinctions which were not previously open to applicants at the EPO?
  - Limit appears to be the imagination of the applicant.
Questions?

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