SECOND MEDICAL USE CLAIMS

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Mari Korsten
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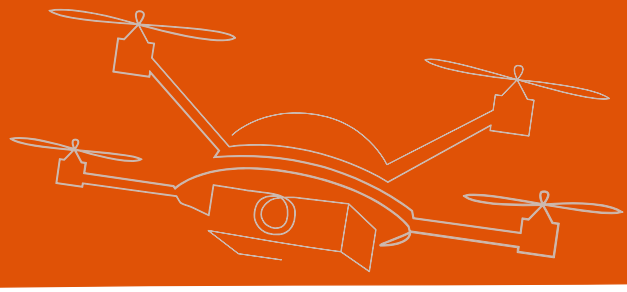

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Second medical use claims (EPO perspective)

- Background of medical use claims;
- Legal basis of medical use claims
- Novelty and Inventive step of medical use claims;
- Sufficiency of disclosure of medical use claims
- Questions

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Second medical use claims (background)

- Pharmaceuticals are biologically active products and interfere in biological processes.
- Most pharmaceuticals have an intended use, but also have side effects.
- Sometimes, the side effect may be favorable and a possible new use of the known compound is envisaged.
- Developing a known compound for a new use is beneficial for pharmaceutical companies for reasons that they already have experience with the compound (e.g. toxicity data, stability data, allowed dossier etc.).
- Another incentive is to use "*medical use claims*" as a life cycle management tool.
- Hence, a need exists for protecting a new use of an already known medical product, i.e. a second medical use.
- If a known compound is used for the first time as a medical product, it is referred to as a first medical use.

Second medical use claims

Aclasta - osteoporosis

Zometa - bone cancer

Revatio – pulmonary hypertension

Viagra – erectile dysfunction

Second medical use claims (legal basis)

- In order for a patent to be granted the EPC requires that:

  "*Art.52(1) European patents shall be granted for any inventions, in all fields of technology, provided they are new, involve an inventive step and are susceptible of industrial application*"

- Patenting a new and inventive medical use of a known compound, would (intuitively) be in the form of a "*method of treatment*" or "*use of the know compound in the treatment of a disease*" (such as with second non-medical uses)
- However, the EPC explicitly excludes method of treatment claims:

  "*Art 53 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 practiced on the human body or animal body;"

- The EPC1973 also excluded method of treatment claims:

  "*Art 52(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1"*

Second medical use claims (legal basis)

- In G5/83 it was confirmed that claims directed to the "*use of a known substance for the treatment of the human / animal body*" are in direct conflict with Art 52(4) EPC(1973).
- Nevertheless, the Board stated that:

  "No intention to exclude second (and further) medical indications generally from patent protection can be deduced from the terms of the European Patent Convention; nor can it be deduced from the legislative history of the articles in question."

- In order to be able to claim a second medical use the EBA followed the practice of the Swiss patent office (hence, these types of claims were called Swiss-type claims.

  "For these reasons the Enlarged Board considers that it is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient."

- Swiss-type claims are process claims (i.e. the manufacture of a medicament) and are therefore referred to as "*purpose limited process claims*".
- However, legal uncertainty remained in the national Courts about the validity and scope of these types of claims.

Second medical use claims (legal basis)

- In order to solve this legal uncertainty a new Art. 54(5) EPC was introduced in EPC2000:

  "*Art 54(5) 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.*"

- Hence, with EPC2000 so called "*purpose limited product claims*" were introduced for known medicinal substances or composition which are intended to be used in the treatment of the human or animal body

- Specific claim language is now required to distinguish said claims from "*suitable for*" language:

Substance X *or* *Composition comprising X*	*for use*	*in a method for the treatment of Y* *in the therapy of Y* *in a method of therapy of Y* *as a medicament defined by its function* *(e.g. as an anti-inflamatory medicament)*

Second medical use claims (possible medical uses)

- In Art. 54(5) it is mentioned that *any specific use* may be claimed and be used to delimit a claim from the prior art.
- However, the EPC does not define the nature of the further therapeutic use.
- Hence, the question remained if it was only allowed to claim another diseases or if all other uses were in fact allowable.
- In G2/08 this question was answered:

  "*5.9.1.1 […] It would be at odds with the principle of good faith required by Article 31(1) of the Vienna Convention to give the term "any specific use" a limitative meaning contrary to its ordinary on" .*

  5.10.3 […] Thus, the new use within the meaning of Article 54(5) EPC need not be the treatment of another disease"

  6.1 Article 54(5) EPC may be used in cases of the treatment of the same illness, the "specific use" in the sense of that provision may reside in something else than the treatment of a different illness."

- Thus, in principle any use may be claimed, such as dosage regimens, different administration modes, patient selections etc.
- However, said specific uses need to fulfill all substantive requirements of the EPC (novelty, inventive step and sufficiency)

Second medical use claims (novelty & inventive step of medical uses)

Dosage regimes:

- Relates to the amount and frequency of dosing a medicament to a patient:

  - "*Substance X for use in the treatment of disease Y, whereby X is administered by the dosage regimen Z.*"

  - "*Compound X for use in the treatment of Y, wherein Y is administered for X days, then discontinued for between A to B days and then again administered for X days.*"

- In G2/08 it was specifically mentioned that these types of claims are allowable if:

  "*In particular, the claimed definition of the dosage regime must therefore not only be verbally different from what was described in the state of the art but also reflect a different technical teaching*"

  "*a new technical effect caused by said feature shall be considered when examining inventive step*"

- If the dosing regime claimed is a selection from a broader range, the existing case law with respect to selection inventions applies!

  "*assuming for the sake of argument that the claimed modalities of the dosage regime would only consist in a mere selection within the teaching of a broader prior disclosure in the state of the art, then novelty can only be acknowledged if the criteria developed in the jurisprudence of the boards of appeal with respect to selection inventions would be fulfilled*"

Second medical use claims (novelty & inventive step of medical uses)

Special patient groups:

- The selection of a new group of patients to be treated can confer novelty and inventive step to a second medical use claim:

  "*the use of the same compound in the treatment of of the same disease for a particular group of subjects, can nevertheless constitute a novel therapeutic application, provided that it is carried out on a new group of subjects which is distinguished from the former by its physiological or pathological status (T19/86, T893/90, T1399/04, T734/12)*"

- However, the new patient group should not overlap with the group of prior art patients

  "*controlling bleeding in non-hemophilic patients*" vs. "*controlling bleeding in hemophilic patients*" (T0893/90);

  "*patients unable or unwilling to exercise*" vs. "*general population*" (T0233/96)

- The new patient group should not have been made arbitrarily, i.e. a special technical effect within the group claimed has to be observed

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Second medical use claims (novelty & inventive step of medical uses)

Special technical effect or mechanism leading to a novel clinical situation:

- In T290/86 it was decided that:

  "*When a prior art document and a claimed invention are both concerned with a similar treatment of the human body for the same therapeutic purpose, the claimed invention represents a further medical indication […] if it is based on a different technical effect which is both new and inventive over the disclosure of the prior document.*"

- In for example T836/01 it was decided that:

  the use of IL-6 to directly influence tumor growth and differentiation was novel over the use of IL-6 to indirectly treat cancer by activating T-cells

  The BoA considered here that a new technical effect resided in the medical indication of the treatment of cancer vs enhancement of the immune system

- This appears to be comparable to a second non-medical use situation wherein the 'mere' discovery is made that in stead of lubricating an engine a composition also has an anti-corrosive effect (i.e. a different technical effect was observed)
- However, in T254/93 it was decided that the mere discovery of a working mechanism did not confer novelty (no new technical effect was observed)

Second medical use claims (novelty & inventive step of medical uses)

Modes of administration:

- In T51/93 it was held that also the mode of administration could provide novelty to a second medical use claim

  "*intramuscular injection" vs. "subcutaneous injection"*

Medical devices and systems

- According to established case law (e.g. T1096/11 and T227/91) it is not possible to claim a medical use of a device or system
- In the decision T773/10 the BoA stated that:

  "*Based on these considerations, the Board comes to the conclusion that the scope of the term "substance or composition" in Article 54(5) EPC does not extend to all products for a specific use in a method referred to in Article 53(c) EPC.*"

- However, if the device comprises a coating it may exceptionally be available for second medical use protection. In T773/10 it was stated:

  "*The claimed dialysis membrane does not contain any further substance or compsition which may constitute an "active" ingredient according to decision T2003/08*"

Second medical use claims (sufficiency of medical uses)

- Article 83 EPC requires that:

  "*The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.*"

- In G2/93 the EBA stated that the requirement of Art. 83 EPC must be met at the date of filing of the patent application.

- It cannot be cured without offending against Art. 123(2) EPC, which provides that the subject-matter content of an application as filed may not be extended.

- In T1164/11 the BoA stated in this regard that:

  "*It is not the purpose of the patent system to grant a monopoly for technical speculations that cannot be realised at the time of filing*"

Second medical use claims (sufficiency of medical uses)

- In T609/02 the BoA stated in relation to medical use claims that (par. 8):

  "*Sufficiency of disclosure must be satisfied at the effective date of the patent, ie on the basis of the information in the patent application together with the common general knowledge then available to skilled person.*"

  Clearly, also for medical use claims it is required that evidence of the claimed medical use has to be provided at the filing date of the patent application

- The Board further stated that the medical use is a technical feature of the claim:

  "*Where a therapeutic application is claimed in the form allowed by the Enlarged Board of Appeal in its decision G5/83, ie in the form of the use of a substance or composition for the manufacture of a medicament for a defined therapeutic application* [i.e. a second medical use], *attaining the claimed therapeutic effect is a functional technical feature of the claim.*"

- Consequently, the application as filed must disclose the suitability of the product claimed for the therapeutic application

  "*As a consequence, under Article 83 EPC, unless this is already known to the skilled person at the priority date, the application must disclose the suitability of the product to be manufactured for the claimed therapeutic application*."

Second medical use claims (sufficiency of medical uses)

- With respect to the suitability of the product for the claimed therapeutic application the BoA stated the following:

  "*It is a well-known fact that proving the suitability of a given compound as an active ingredient in a pharmaceutical composition might require several years and very high development costs…The patent system takes account of the intrinsic difficulties for a compound to be officially certified as a drug by not requiring an absolute proof that the compound is approved as a drug before it may be claimed as such.*"

- In this regard the BoA explicitly mentioned that it is not always necessary that results of applying the claimed compounds in clinical trials or in animal data are reported.

- According to the Board showing the pharmaceutical effect in vitro may be sufficient if for the skilled person this observed effect directly and unambiguously reflects such a therapeutic application

  "or, as decision T158/96 also put it, if there is a "clear and accepted established relationship" between the shown physiological activitities and the disease"

- This is a major issue in the daily practice of protecting medicinal products. At the intended time of filing often only preliminary data is available (affinity data/ cell growth / enzym inhibition). However, a clear and accepted relationship (in the scientific literature) between such tests and the therapeutic application (i.e. the disease) claimed is often not available.

Second medical use claims

- Second medical use claims are a fantastic life cycle management tool

- However, their usefulness depends on how well they can be enforced

  - off-label use / skinny labelling

- and, what type and level of data is required by the different courts to proof the second or further medical use

  - in vitro data vs. in vivo data?
  - data in animals vs data in humans?
  - special requirements with respect to (extremely) broad claims?

Second medical use claims

Questions?