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PANEL 8

Second Use Patents in the Medical Area: ANVISA Issues and Recent Treatments of Swiss Claims

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Legal background (I): Patentability of substances for medical treatment

- Methods of medical treatment are excluded from patent protection (Art. 52(4) EPC 1973, Art. 53(c) EPC 2000)

*EPC: European Patent Convention (In-force since Oct 5, 1973, and revised on Nov 29, 2000)

Legal background (I)

- However, there is a specific derogation from this requirement of absolute novelty in Art. 52(4) EPC 1973, 53 (c) EPC 2000:

"...; this provision shall not apply to products, in particular substances or compositions, **for use** in any of these methods."

-Substances used in treating patients remained patentable notwhithstanding the medical treatment exclusion.

Legal background (II): Novelty

Products or processes already known in the art are not patentable (Art. 54 (1) EPC* 1973, 2000)

¿Is it possible to protect a substance that is already known for a medical treatment, just because it has been found that it serves for a new (second or further) medical treatment?

Legal background (III): Discoveries vs Inventions

- Discovery: Gaining knowledge of or ascertaining the existence of something previously unknown or unrecognized (No technical effect).
- Invention: Making or creating something which did not exist before it was made or invented (Technical effect)

Legal background (III):

Discoveries vs Inventions

Discoveries as such have no technical effect and therefore they are not considered as inventions within the meaning of Art. 52 (1) EPC. If, however, the invention consist in the finding of a new practical use of something already known, then this constitutes an invention which may be patentable. (Guidelines for Examination in the EPO, Part C, Chapter IV, 2)

Problems to be solved

- Initially, the EPO was reluctant to grant patents for second (or further) medical uses based on a literal reading of the relevant Articles

- Research in the pharmaceutical industry tends not to stop at one pharmaceutical activity (e.g. Aspirin)

*EPO: European Patent Office

Problems to be solved

- Without the benefit of patent protection, new research into further uses of known drugs has less incentive.

- An inventor who has found out a new therapeutic use of a known compound "should be rewarded with a purpose-limited substance claim" (TBA [1979-1985] EPOR B591)

*TBA: Technical Board of Appeal

Sildenafil (Viagra®) case

- Sometimes the second use of a medicament is more important that the first medical use.
- Sildenafil was initially studied for use in hypertension and angina pectoris. The first clinical trials suggested that the drug had little effect on angina, but that it could induce marked penile erections. Pfizer therefore decided to market it for erectile dysfunction, rather than for angina.

Question to be answer by the EBA*

Can a patent be granted for the use of a sustance or composition for the treatment of the human or animal body by therapy?

*EBA: Enlarged Board of Appeal

Answer of EBA (G 05/83*)

- "Use claims" were acceptable (including second and further medical uses)
- But must not be directed at one of the excluded methods in Art. 52(4) EPC 1973.
- Claims directed to the use of a substance or composition for the treatment of the animal or human body by therapy were excluded from patent protection.

*G 05/83, *EISAI/Second medical indication,* [1979-85] EPOR B241

Answer of EBA (G 05/83)

The EBA accepted the practice of the Swiss Federal Intellectual Property, which had sanctioned claims directed to the "use of a substance or composition for the manufacture of a medicament for a specified therapeutic application*"

*[1984] OJEPO 581

Swiss-type claim structure

(Use) of a (substance or composition) in the manufacture of a (medicament/composition) for the (new therapeutic application)

Novelty of a Swiss-type claim

The novelty of such claims is derived not in the *substance* or its *use* but in the *new purpose* that it was put to.

Requirements of the swiss-type claim

a) The manufacture of a medicament

b) New therapeutic application

Both have the functions of identifying novelty and defining the scope of the claim

Scope of the swiss-type claim

- It is a product claim limited to an specific therapeutical application.
- Also protect a manufacturing process and not merely to the taking of the active ingredient and converting it into a special medicament (Monsanto vs Merck, British Court of Appeal, [2000] RPC 709).

Swiss claims vs Methods of treatment

- The element of the Swiss claim which gives it novelty and inventive step is the new method of treatment.

- However, the methods of treatment are still excluded from patentability according to the EPC.

Reform of the EPC

- A new provision was added in the new 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 Art. 53(c), provided that such use is not comprised in the state of the art."

Decision G 02/08 (19 Feb, 2010)

- Q1: Art 54(5) EPC does not exclude the use of a known medicament in a different treatment by therapy of the same illness.

- Q2: Even if the dosage regime is the only feature claimed which is not comprised in the state of the art.

- Q3: Where the subject-matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by the decision G 05/83.

New claim format

(Use) of a (substance or composition) for the (new therapeutical application)

Conclusions

- The EPO has interpreted the EPC in light of the needs of the pharmaceutical industry.

- Patentees are provided with incentive to justify continued research and development in finding new and further uses of known substances and compositions.

Conclusions

- The new Art. 54(5) EPC 2000 means that there is now a statutory basis for second (and further) medical uses under the EPC.

- It will no longer be necessary to resort to the Swiss form of claims.

Practical applications

- Change of the scope of protection?
- Change direct infringement into contributory infringement?
- How will Courts treat this new claims? Wait and see?