

**Presentation
to Fordham University on 28 April 2011
on some aspects of the EBA Decision G02/08 (dosage regime)**

**by
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Abstract:

- The treatment of a disease with a substance or composition which is already known to be used for treating said disease and which differs from the known treatment in a dosage regime is a specific further medical use within the meaning of Article 54(5) EPC.

Reasons for the referral of decision T1319/04 to the Enlarged Board of Appeal

"The use of nicotinic acid ... for the manufacture of a sustained release medicament for use in a treatment **by oral administration once per day prior to sleep**, of hyperlipidaemia characterized in that ..."

The only feature which was not known from the prior art was the dosage regimen.

It was not clear, whether this feature could establish novelty, because in previous decisions (T317/95, T 56/97, T584/97) the Boards of Appeal had taken different views on the issue of whether the prescribing and modification of a drug regimen for known medical treatments represents a further medical indication from which novelty could be derived.

Questions referred to the Enlarged Board of Appeal

(1) 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?

(2) 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?

EPC 2000 provisions for first and further medical use

Article 53(c) EPC

European patents shall not be granted in respect of methods for the treatment of the human or animal body by surgery, 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.**

Article 54(5) EPC

This Article explicitly allows further patent protection of substances or compositions already known as medicines provided their use in a method under Article 53(c) EPC be **specific** and not comprised in the state of the art.

Answer to the referred questions :

(1) Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness.

(2) Such patenting is also not excluded where a dosage regime is the only novel feature claimed which is not comprised in the state of the art.

- The dosage regime must not only be verbally different from what is described in the state of the art but must also reflect **a different technical teaching** which involves an inventive step.
- Novelty and inventive step of the claimed subject-matter must be determined according to established case law.

Issues in opposition and litigation

- Is the prescription of doctors or recommendation of pharmacies on how to apply a known medicament, which describe the dosage regimen feature in a claim, novelty destroying ?
- What will constitute a prior use?
- Who can be an infringer of a claim for a dosage regimen? The pharmacies when specifying the modality of the use of a known medicament as claimed?