

Enforcement of 2nd Medical Use Claims

The Dutch Perspective

Rian Kalden
Court of Appeal The Hague*

*personal suggestions only!

Problem and Solution I

- Novelty: the active ingredient is not new
- The exclusion from patentability in art. 53(c) EPC of methods of medical treatment
- Solution I: Swiss type claim (prior to EPC 2000)
 - use of compound X for the manufacture of a medicament Y for the treatment of indication Z
- Generally regarded as purpose limited *process* claim

Swiss Type claims

- Clearly a fiction: in reality it concerns a new form of medical treatment; the manufacture is neither new nor inventive;
- The 'manufacture' element is added to circumvent art. 53(c) EPC
- The real invention (and novelty) only lies in the new use of the known compound (G 5/83).

Solution II: EPC 2000 claim

- Art. 54 (5) EPC 2000 explicitly allows a claim:
 - ‘compound X for the treatment of indication Z’
- Purpose limited *product* claim

Claim Construction

- If ST claim is (construed as) process claim;
 - Who is considered manufacturer?
 - What is ‘manufacturing’ (also packaging, advertising?)
 - If manufacturer intends patented use, but the pharmacy is not dispensing for patented use – still infringement (64(2) EPC)?
 - If the manufacturer only intends free use and the pharmacy knowingly dispenses for patented use, is it not an infringement (as he is not manufacturing)?
- Indirect infringement problematic: no manufacturing downstream

T 1780/12

- Context of the decision: double patenting (Swiss Type parent and EPC 2000 divisional)
- ED: “they concern the same invention claimed in different format”
- TBA: “It is generally accepted as a principle underlying the EPC that a claim to a particular physical *activity* (e.g. method, process, use) confers less protection than a claim to the physical *entity per se*”

G 2/08

- [G 5/83 Eisai] ruling found its cause in the fact that a claim directed to the use of the substance or composition for the treatment of the human body by therapy (...) was forbidden. (...) only the first medical indication of a known composition in the form of a medicament was (...) entitled to be drafted in the form of a purpose-related product claim. And since the **intention of the legislator was clearly not to exclude second therapeutic indications of a known medicament from the field of patentability** the so-called Swiss-type claim constituted the adequate but exceptional solution.

G 2/08

- Article 54(5) EPC now permits purpose-related product protection for any further specific use of a known medicament in a method of therapy. Therefore, as mentioned in the preparatory document (MR/24/00, point 139) the loophole existing in the provisions of the EPC 1973 was closed.

G 2/08

- Swiss-type claims could be (and have been) considered objectionable as regards the question as to whether they fulfil the patentability requirements, due to the **absence of any functional relationship of the features (belonging to therapy) conferring novelty and inventiveness, if any, and the claimed manufacturing process.**

Preparatory document EPC 2000

- preparatory document MR/18/00, point 4: "The new Article 54(5) EPC **eliminates any legal uncertainty** on the patentability of further medical uses. It **unambiguously permits purpose—related product protection** for each further new medical use of a substance or composition already known as a medicine. This **protection is equivalent**, as far as the further uses are concerned, to that offered by the 'Swiss type claim'. In contrast to previous Article 54(5), now Article 54(4) EPC, providing broad (generic) protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) is expressly limited to a specific use. This limitation is **intended to match as closely as possible the scope of protection** to the scope provided by a 'Swiss type claim'."

Proper Claim Construction

- There is strong argument to *construe* a Swiss type claim effectively as a purpose related product claim
- This strikes the right balance between the legitimate interests of the patentee and legal certainty of third parties under art. 69 EPC:
 - The actual purpose provides novelty and inventive step, so that element should be determining
 - It is generally known to be a legal construct

Direct infringement

Proceeding from this claim construction:

- There is an act of direct infringement by the manufacturer or distributor if at the time of manufacture or further distribution, he himself designates the medicament for use (further down the chain) for the patented indication, e.g. by prescribing the suitability for that indication in the patient information leaflet, etc.

Indirect infringement

- There is an act of indirect infringement if the manufacturer / distributor knows or should reasonably foresee, that the medicament is (going to be) used for the patented indication (further down the chain) and he nevertheless continues to manufacture and deliver the medicament, without taking any measures to prevent that use for the patented indication

Thank you for your attention!