

Construction of “Swiss” medical use claims

In *Ranbaxy (UK) Ltd v AstraZeneca AB*, the England and Wales High Court considered the scope of “Swiss” medical use claims. This important decision clarifies how these types of claims can be infringed.

Background: “Swiss” Claims

The European Patent Convention (EPC) expressly excludes methods of treatment from being patentable. The reason for this is that healthcare professionals should not be prevented by patents from treating patients. This exclusion is a major difference between the European and U.S. patent systems.

New and inventive pharmaceuticals are patentable, provided they are novel and inventive in their own right. Under the original EPC, the *first* medical use of a known compound is also patentable, using a claim worded “Compound X for use in therapy.”. However the original EPC only included the *first* medical use under this provision.

An early decision (G5/83) of the Enlarged Board of Appeal of the European Patent Office (EPO) considered the claim form that might protect a further inventive therapeutic use of a compound. It decided that the wording “Compound X for the manufacture of a medicament for [the therapy]” would be valid. This is known as a “Swiss” claim, and under the original EPC was used to patent a second medical use of a known pharmaceutical.

The Claims

AstraZeneca owned a patent (EP1020461) which contained a “Swiss” claim to the use of high purity magnesium esomeprazole for the inhibition of gastric acid secretion.

Proposed Importation

AstraZeneca was the only supplier of esomeprazole in the UK. Ranbaxy sought a declaration that their generic product for the inhibition of gastric acid secretion would not infringe the patent.

Ranbaxy’s product was to be imported into the UK. Neither side disputed that one of the *starting* materials for the product was magnesium omeprazole with the claimed purity, or that Ranbaxy’s final product (which it wanted to import into the UK) did *not* have the claimed purity.

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The court considered whether, either:

- Ranbaxy infringed, because their product was the direct product of a process which used high purity
- magnesium esomeprazole to make a medicament; or,
- Ranbaxy did not infringe, because their product did not contain magnesium esomeprazole of the claimed purity.

The UK courts construe a patent claim by asking what meaning a skilled person would have given to the terms in the claim, in the context of the patent.

The High Court judge decided that the teaching of the whole specification was to the production of pure esomeprazole and its' use in the inhibiting gastric acid secretion. As a result, the judge interpreted the "Swiss" of claim as directed to the use of the pure magnesium esomeprazole in the manufacture of a medicament, which medicament contains the active ingredient at that level of purity.

The High Court declared that Ranbaxy would not infringe the "Swiss" claim, because the product it intended to import did not have the claimed purity.

This case provides interesting guidance on the scope of "Swiss" medical use claims in the UK. The courts will construe these claims as covering a medicament, containing the claimed active ingredient, packaged for use in the claimed therapy.

The EPC 2000 came into force in 2007. This updated European Patent Convention allows the previous "first medical use" claim form to protect any subsequent medical uses of a known pharmaceutical. We recently reported an EPO decision (G2/08), which stated that "Swiss" claims are redundant under EPC 2000. We wait to see if the UK court interprets "Swiss" claims and the new "medical use" claims as having the same scope.