

**EIP**

# Interpreting Swiss claims: Ranbaxy (UK) Limited and AstraZeneca AB

This case raised the question of the proper interpretation of a medical use ("Swiss") claim, and confirmed that they will generally be interpreted in the same way as a "specific use" second medical use claim.

The patentee, AstraZeneca, held a patent directed at magnesium esomeprazole with an optical purity of  $\geq 99.8\%$  e.e. The patent claimed the magnesium esomeprazole as a product per se; as a medical use (i.e. magnesium esomeprazole with an optical purity of  $\geq 99.8\%$  e.e. for use in therapy); as a specific medical use (magnesium esomeprazole with an optical purity of  $\geq 99.8\%$  e.e. for use in the treatment of a gastric acid-related disease) and as a Swiss form claim (the use of magnesium esomeprazole with an optical purity of  $\geq 99.8\%$  e.e. for the manufacture of a medicament for the inhibition of gastric acid secretion).

Ranbaxy wished to import a medicament made by a process which began with magnesium esomeprazole with an optical purity of  $\geq 99.8\%$  e.e. but added a quantity of omeprazole racemate such that the finished product no longer contained magnesium esomeprazole of that optical purity.

AstraZeneca accepted that there was no infringement of the product per se claim, nor of the medical use or specific medical use claim. This left only the Swiss form claim, and AstraZeneca contended that this was infringed because Ranbaxy's medicament was the direct product of a process in which magnesium esomeprazole with an optical purity of  $\geq 99.8\%$  e.e. is used to make a medicament for the inhibition of gastric acid secretion.

The Court referred to *KirinAmgen v Hoechst Marion Roussel* [2004] UKHL 46 and said the question to be decided is what the skilled person would have understood the claim to

mean. The words of the claim are to be construed having regard to the patentee's purpose as set out in the rest of the specification. The skilled person would consult a patent attorney about the conventions of drafting patents, and would understand the nature of a Swiss form claim.

In light of this, the court held that it was inherent that the skilled person would generally understand a Swiss form claim to mean that the medicament must contain the active ingredient for which the new and inventive use has been found. The court did not go so far as to suggest that a claim cast in Swiss form must always be construed in this way, as the proper meaning of the claim must be determined having regard to the words of the claim when construed purposively in the light of the specification and the common general knowledge. However, this would normally be how a claim was construed.

The Court discussed Article 52(4) EPC and referring to EISA (G5/83 OJ EPO 64) noted "...it is legitimate in principle to allow claims directed to the use of a substance ... for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture ... does not differ from known processes using the same active ingredient."

In the present case, the court observed that "..... there is no suggestion anywhere in ...(AstraZeneca's)... specification of the provision or use of any analogue or derivative of magnesium esomeprazole or, indeed, of any other active ingredient for the treatment of gastrointestinal disorders or any other condition. ... The whole teaching of the specification is about the production of optically pure magnesium esomeprazole and its use in particular therapies ..."

The Court concluded that "Recognising the teaching of the specification that magnesium esomeprazole with an optical purity of  $\geq 99.8\%$  e.e. is new, the skilled person would understand claim 1 to be directed to the use of such magnesium esomeprazole to manufacture a medicament which contains that active ingredient."

Thus Ranbaxy did not infringe.

The EPO will no longer allow Swiss claim formats, and this ruling would seem to confirm the understanding that because specific medical use claims are now allowed, the prohibition on Swiss claims does not prejudice patentees in that the claims will generally be interpreted in the same way.