

## PATENT WATCH

## Court clears the way for Nexium alternative

A US court has ruled that an alternative salt form of Nexium does not infringe on patents that protect AstraZeneca's version of the drug. This means that Hanmi Pharmaceutical's form of the proton pump inhibitor, which is used to treat gastroesophageal reflux disease, can remain on the US market.

AstraZeneca's Nexium is the magnesium salt of the (S)-enantiomer of omeprazole. When the company originally applied for patent protection in 1995, it claimed particular salt forms — namely, sodium, magnesium, lithium, potassium, calcium or ammonium salts — of single enantiomers of omeprazole. Later, the company amended its patents to focus on the (S)-enantiomer (known as esomeprazole) and also changed the wording of the claims. In particular, reference to specific salt forms in the claims was removed, being replaced instead by the term "alkaline salts". However, the written description — the part of the patent that describes the invention — still contained information about the six salt forms.

Hanmi's product — known as Esoomezol — is the strontium salt of esomeprazole. Because this salt was not listed in the written description and in other parts of AstraZeneca's patents, Hanmi asserted that its product did not infringe on the patents. Conversely, AstraZeneca argued that the written description only provided examples of alkaline salts and that its patents covered a broader range of salts, including Hanmi's strontium salt of esomeprazole.

The court's analysis noted that the everyday meaning of the term 'alkaline salt' would normally encompass a strontium salt, but the particular wording that AstraZeneca had used in the written description negated this meaning. Rather, the court decided that AstraZeneca's written description "clearly defined" Nexium as sodium, magnesium, lithium, potassium, calcium or ammonium salts, and that other members of the class of alkaline salts, including strontium salts, were not covered by the patents.

Nexium is a big earner for AstraZeneca; in 2012, it had worldwide sales of US\$3.94 billion. Esoomezol was launched onto the US market just before the current decision, but it remains to be seen how much Nexium's sales will be eroded. AstraZeneca notes that Esoomezol is not classed as being bioequivalent to Nexium, meaning that doctors will have to specifically prescribe Esoomezol. The company's Nexium patents (US 5714504 and US 5877192) that were litigated in this case expire late this year and in 2015, but an agreement with generics manufacturers Teva and Rambaxy means that a generic can hit the US market in May.

**AstraZeneca versus Hanmi:** <http://www.cafc.uscourts.gov/images/stories/opinions-orders/13-1490.Opinion.12-17-2013.1.PDF>

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