A final helping of Esomeprazole?

Kluwer Patent Blog
March 5, 2016

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Please refer to this post as: Anders Valentin, 'A final helping of Esomeprazole?', Kluwer Patent Blog, March 5 2016, http://patentblog.kluweriplaw.com/2016/03/05/a-final-helping-of-esomeprazole/

SH 2016.T-4-13S-SH2016.T.4.13
In continuation of the Europe-wide PI cases a few years back, the Danish Maritime and Commercial Court recently rendered judgment in a patent case between AstraZeneca and Krka. As the reader may recall, AstraZeneca was the holder of patent no. DK/EP 1 020 461 for a magnesium salt of the active substance esomeprazol with an optical purity of ≥ 99,8 % (e.e.), and AstraZeneca had developed the original drug Nexium containing this active substance. The main issue in this case was whether or not the sale and marketing of the generic drug Esomeprazol "Krka", which contained an optical purity of the magnesium salt esomeprazol of ≥ 99,6 % (e.e.), constituted infringement of claim 1 (a method claim) and/or claim 9 (a product claim).

As for claim 9, AstraZeneca argued that the inventive aspect of the patent did not lie in the purity itself. Instead, it was the special pharmacokinetic and metabolic features, which a high optical purity resulted in. AstraZeneca further pointed to Krka's product being bioequivalent to AstraZeneca's product. Finally, AstraZeneca argued that the optically pure esomeprazol magnesium salt was an intermediate product in the process of manufacturing Esomeprazol "Krka" and that the finished product Esomeprazol "Krka" was only a minor modification of the intermediate product.

Krka, on the other hand, argued that it did not sell or market a product on the Danish market containing the magnesium salt of esomeprazol with an optical purity of ≥ 99,8 % (e.e.), and therefore Krka did not make use of any improved pharmacokinetic and metabolic features of exceptionally high purity.

The court held that it must exercise restraint when assessing the protective scope of the patent claim beyond the limitation of ≥ 99,8 % (e.e). The court further held that it was undisputed that Krka's product was bioequivalent to AstraZeneca's product. However, the court found that the protective scope of claim 9 could not be construed as going beyond the wording of the patent claim. Accordingly, Krka's sale and marketing of Esomeprazol "Krka" with an optical purity of magnesium salt of esomeprazol of ≥ 99,6 % (e.e.) did not constitute an infringement of claim 9 (claiming an optical purity of ≥ 99,8 % (e.e.)).

Claim 1 was a method claim concerning the use of the magnesium salt of esomeprazol with an optical purity of 99,8 % (e.e.) to manufacture a medicament. AstraZeneca claimed that due to the fact that the process regarded a use of the optical pure esomeprazol, the patent claim must cover every step of the manufacturing method regarding the use of the optically pure esomeprazol. AstraZeneca further argued that several samples had documented that there existed a solid substance of at least 99,8 % (e.e.) in the reactor when manufacturing Esomeprazol "Krka".

Krka argued that claim 1 only covered the manufacture of the final medicament, i.e. the pharmaceutical manufacturing process and not the chemical process of manufacturing the actual active substance (the magnesium salt of esomeprazol).

The court found that the claim 1 concerned the use of the magnesium salt when manufacturing a medicament and that the suspension in the reactor had contained crystallized esomeprazol magnesium salt with an optical purity of ≥ 99,8 % (e.e.). The optical purity had, however, gradually been reduced to 99,6 % (e.e.). Against this background, the court found that the magnesium salt with an optical purity of ≥ 99,8 % (e.e.) had been used in the manufacturing of Esomeprazol "Krka". Accordingly, it was an infringement of AstraZeneca's claim 1.

In conclusion, the sale and marketing of Esomeprazol "Krka" only constituted an infringement of claim 1 of the patent belonging to AstraZeneca. The court ordered Krka to pay damages and compensation as a result. It is not known whether the decision has been appealed.