
Kluwer Patent Blog

No more pemetrexed?

Alexa von Uexküll, Oswin Ridderbusch (Vossius & Partner) · Wednesday, November 21st, 2018

Over the past few years the pan-European and parallel national patent litigation based on Eli Lilly's pemetrexed patent has attracted considerable attention, as it has resulted in a number of diverse land mark decisions in relation to the doctrine of equivalence, as evidenced by the various posts on the Kluwer Patent Blog.

By way of reminder, Lilly's patent claims a vitamin B12 regime mitigating the toxic side effects of the anti-cancer drug pemetrexed, which in the course of prosecution had been limited to its disodium salt.

Generic competitors have filed declaratory actions for non-infringement with respect to pemetrexed products, other than the disodium salt.

In the UK the Supreme Court in its [judgment of 12 July 2017 \(\[2017\] UKSC 48\)](#) ruled that the Lilly patent is not limited to the disodium salt of pemetrexed, and that Actavis' diacid form and other salts of pemetrexed, representing immaterial variants of the claimed invention, directly infringe the patent.

In other jurisdictions, including Germany ([Federal Supreme Court X ZR 29/15 of 14 June 2016](#)), Switzerland ([Federal Supreme Court 4A_208/2017 of 20 October 2017](#)) and Italy ([Court of Milan Case No. 45209/2017 of 15 October 2018](#)), the courts also acknowledged infringement under the doctrine of equivalence.

In the UK cross-border case, the claimant Actavis was irrevocably bound to its undertaking not to challenge the validity of the Lilly patent.

The Lilly patent had survived EPO opposition proceedings, but in Germany its validity was again challenged by third party generics.

On 17 July 2018 the Federal Patent Court handed down its decision in the joined cases 3 Ni 23/16 and 3 Ni 19/17 ([an English translation of the decision can be found here](#)). The court sided with the generics and revoked the patent for lack of inventive step. Thus, the court held that the technical problem underlying the invention was overt and that one of skill in the art, taking into account his expert knowledge would have had ample pointers and motivation to arrive at the invention, in view of the well documented biochemical processes involved.

The court also emphasized that their conclusion should not be viewed as being in contradiction

with the [decision of the opposition division](#), as here other prior art had been considered.

Dr. Alexa von Uexküll and Oswin Ridderbusch, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the new handbook “European SPCs Unravelling: A Practitioner’s Guide to Supplementary Protection Certificates in Europe” published by Wolters Kluwer.

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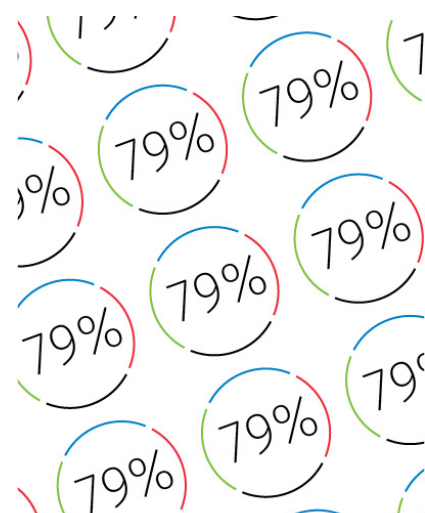
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