

PATENTWATCH

You say lactic acid, I say lactide

The US Court of Appeals for the Federal Circuit has affirmed a district court's claim construction that OWL Pharmaceuticals did not infringe patents on polymers in its generic version of the prostate cancer drug leuprolide.

TAP Pharmaceutical Products and Takeda Pharmaceutical Company developed and marketed the cancer treatment under the name of Lupron Depot, which is a sustained-release microcapsule injection of a luteinizing hormone-releasing hormone analogue. The companies claimed that OWL infringed two patents covering polymers and microcapsules in the sustained-release treatment (US Patents 4,728,721 and 4,849,228).

The '721 patent claims biodegradable high-molecular-mass polymers that have good stability and are useful drug excipients. The '228 patent claims microcapsules for use in sustained-release drug formulations in which the biodegradable polymers described in the '721 patent are used as excipients. These

microcapsules allow the injected drug to be delivered at a constant rate over a long period of time because they reduce the concentration of low-molecular-mass compounds.

Infringement of the '721 and '228 patent claims depended on claim construction of the term "copolymer of lactic acid and glycolic acid". OWL argued that the copolymers would have to be made by direct polymerization from lactic acid and glycolic acid. However, the district court construed the claim more broadly to include such copolymers produced by any method, including the ring-opening method, in which lactic acid and glycolic acid are first converted into cyclic dimers lactide and glycolide. The appellate court affirmed that the copolymers can be made by either method, as a person of ordinary skill in the art would consider the term 'copolymer of lactic acid and glycolic acid' to be synonymous with 'copolymer of lactide and glycolide'.

TAP *et al.* versus OWL *et al.*:

<http://www.fedcir.gov/opinions/03-1634.pdf>

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