Keywords: **claim construction; intrinsic evidence; inequitable conduct; generic drugs**

General: **Claims for a polymer comprising a copolymer of lactic acid and glycolic acid do not require that polymer be made from direct polymerization of lactic acid and glycolic acid starting materials.**

TAP Pharmaceutical Products Inc. v. OWL Pharmaceuticals LLC
76 U.S.P.Q.2d 1126 (Fed. Cir. 2005)
Decided August 18, 2005

I. Facts

OWL Pharmaceuticals LLC (OWL) sought to market a generic version of leuprolide, patented by TAP Pharmaceutical Products (TAP). Leoprolide is a sustained-release formulation of a prostate cancer therapeutic. Upon OWL's filing of an Abbreviated New Drug Application for leoprolide, TAP filed suit against OWL alleging infringement of several patents owned by TAP. On motion for summary judgment, the district court held that OWL infringed claim 1 of U.S. Patent No. 4,728,721 (the '721 patent) and claims 1-4 of U.S. Patent No. 4,849,228 (the '228 patent). At trial, a jury found that the '721 and '228 patents were not invalid and that OWL's infringement was not willful.

The claims at issue dealt with sustained-release pharmaceutical preparation. Claim 1 of the '721 patent reads:

> 1. A biodegradable high molecular polymer useful as an excipient in producing a pharmaceutical preparation comprising a copolymer or homopolymer of about 50-100 mole percent of lactic acid and about 50-0 mole percent of glycolic acid having a weight average molecular weight of about 2,000 to 50,000 and wherein the content of water-soluble low molecular compounds, as calculated on the assumption that each of said compounds is a monobasic acid, is less than 0.01 mole per 100 grams of said high molecular polymer.

The district court found that the claims at issue should not be limited in scope to copolymers made from direct polymerization of lactic acid or glycolic acid.

Following trial, the district court rejected OWL's claim that the '721 and '228 patents were unenforceable due to inequitable conduct based on the failure to cite two prior art references to the PTO during the prosecution of the patents.

II. Issues

A. Did the district court correctly construe the term "copolymer…of lactic acid and…glycolic acid"?

B. Did the failure to disclose a reference cited in foreign prosecution constitute inequitable conduct?

III. Discussion

A. Yes. The Federal Circuit upheld the district court's claim construction.

On appeal, OWL argued that the claim language "comprising a copolymer . . . of lactic acid and . . . of glycolic acid" required that the copolymers be made directly from lactic acid and glycolic acid as starting materials, rather than copolymers composed of lactic acid and

glycolic acid monomers produced by any other method (including the use of lactide and glycolide).

The Federal Circuit noted that neither the language of the claims nor the specification of either patent explicitly set forth the starting materials for making the copolymers, nor did the claims or the specification require that the copolymers be produced by direct polymerization. Importantly for the Federal Circuit, the specification explicitly provided that that the biodegradable high molecular polymer that serves as the starting material for performing the method of the invention "may be produced by any method." Even treatises relied upon by the district court confirmed that copolymers of lactic acid and glycolic acid could be made either by direct polymerization or by ring opening. Further, OWL's own expert testified that one with ordinary skill in the art would understand that the terms "lactic acid" and "glycolic acid" could be used interchangeably with "lactide" and "glycolide." Because the intrinsic evidence supported this interpretation, the judgment of infringement was affirmed.

OWL also argued that TAP disclaimed an interpretation that included polymers made from lactide and glycolide starting materials during foreign prosection. However, the Federal Circuit gave little weight to statements made by TAP to an Examiner in the European Patent Office that the invention did not include compounds made from lactide or glycolide. The European Examiner had rejected the claims after this argument was made, finding that the compounds which the patentee had attempted to disclaim were not different from those made from lactic and glycolic acid. Therefore, because the European claims were later allowed on other grounds, and because the patentee had not made this argument before the USPTO, the patentee must have "receded from that characterization of the claims," and thus these statements should be given little weight in the process of claim construction.

B. No. The Federal Circuit upheld the district court's finding of no inequitable conduct.

OWL argued that the '721 and the '228 patent were unenforceable based on (1) the submission of a reference after a notice of allowance in the prosecution of the '721 patent and (2) the misrepresentation of the materiality of the same reference. The Federal Circuit held that the timeline of the reference submission did not constitute inequitable conduct, as the EP Search Report was submitted to the PTO within a month of TAP's attorney having received it. Further, the Eurpoean Search Report characterized the Kent application as "merely technological background" and thus "not material to patentability," and the evidence showed the Kent application to be cumulative of references already before the PTO examiner.