CUMBERLAND PHARMACEUTICALS INC. v. MYLAN INSTITUTIONAL LLC, Appeal Nos. 2016-1155, -1259 (Fed. Cir. January 26, 2017). Before Moore, Reyna, and Taranto. Appealed from N.D. Ill. (Judge Pallmeyer).

Background:

Cumberland owns a patent (the 455 patent) covering its chelating-agent-free formulation of Acetadote®. Prior to filing the application leading to the 455 patent, Cumberland sought FDA approval for an acetylcysteine composition that included edetate, which is a chelating agent that stabilizes the composition. The FDA requested justification for the inclusion of edetate. Cumberland suggested a study to determine stability of both decreasing and completely removing edetate from the composition. Cumberland tested the Acetadote® formulation containing no edetate or any other chelating agent, which is claimed in the 455 patent.

After Mylan filed an abbreviated new drug application to market its own formulation of acetylcysteine, Cumberland sued for infringement. Mylan stipulated to infringement but asserted that the 455 patent is invalid on the grounds of (1) derivation, and (2) obviousness. The district court found in favor of Cumberland.

Issues/Holdings:

Did the district court err in finding that Mylan did not prove Cumberland's patent was invalid for derivation or obviousness? No, affirmed.

Discussion:

Regarding derivation, Mylan must show that there was a prior conception of the claimed subject matter by an FDA representative and communication of the conception to Cumberland. The Federal Circuit found that the FDA's request for justification as to the inclusion of edetate in the acetylcysteine composition does not rise to the level of conception required for derivation. Instead, the required complete conception had to include the specific idea to remove edetate from the composition and not add another chelating agent.

Mylan alleged that the 455 patent was obvious over Cumberland's edetate-containing acetylcysteine composition in view of several references that allegedly disclosed removal of edetate from acetylcysteine formulations. However, the references did not disclose that the removal of adetate would lead to a stable composition, which was expressly claimed in the 455 patent. In fact, the prior art taught that edetate or another chelating agent was necessary to stabilize the formulation. Thus, the Federal Circuit found that the hypothetical relevant skilled artisan would not have reasonably expected a chelating-agent-free acetylcysteine composition to be stable. The Federal Circuit therefore affirmed the district court's finding that the 455 patent was nonobvious because the prior art did not provide either a motivation to remove edetate or a reasonable expectation of success.