

# Antidote for Acetaminophen Overdoses Not Invalid as Either Derived From Another or Obvious Over the Prior Art

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[\*CUMBERLAND PHARMS. INC. v. MYLAN INSTITUTIONAL LLC\*](#): Jan. 26, 2017. Before Moore, Reyna, and Taranto.

## Takeaway:

- To prove that a claimed invention was derived from another, a defendant must show that the specific invention was previously conceived by someone else and then communicated to the named inventor.
- There is no reasonable expectation of success in combining two prior-art references, and patent claims are not obvious, when the combination would exclude an element that was understood in the prior art to be necessary to the claimed invention.

## Procedural Posture:

After the defendant stipulated to infringement and the court held a bench trial on invalidity, the N.D. Ill. ruled that the asserted claims of plaintiff Cumberland's '445 patent-in-suit were not invalid either for derivation or obviousness. The CAFC affirmed.

## Synopsis:

- **Inventorship-Derivation:** Acetylcysteine was known in the prior art before the priority date of Cumberland's '445 patent-in-suit as an antidote for acetaminophen overdoses. Because acetylcysteine was also known to have a stability problem, prior-art acetylcysteine formulations included edetate disodium (EDTA), a chelating agent that prevents degradation. The '445 patent describes and claims as its advance over the prior art acetylcysteine compositions that are substantially free of chelating agents. The CAFC affirmed that Mylan failed to show that this invention was derived from another because it was previously conceived by someone else and then communicated to the named inventor, a Cumberland

employee. Prior communications between the FDA and Cumberland did not show that an FDA employee had conceived of the specific idea of the invention, or communicated it to the named inventor, because the communications merely referred to removing EDTA from Cumberland's prior acetylcysteine formulations, and did not show that an FDA employee conceived of the idea of not replacing the EDTA with another chelating agent.

- **Obviousness:** The district court also correctly held that Mylan failed to prove that the claims were obvious over the combination of Cumberland's prior-art acetylcysteine formulations and other cited prior art. The evidence supported the district court's holding that a person of ordinary skill in the art would not have had a reasonable expectation of success in removing EDTA from Cumberland's prior-art acetylcysteine formulations, as required by the combination, because the prior art taught that EDTA or another chelating agent was necessary to create a stable formulation, as described in the '445 patent claims.

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