



Intellectual Property Today: Brian Trinque and Giulio DeConti on Lead Compound Analysis

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In 1997, the generic pharmaceutical company Danbury filed for Paragraph IV certification seeking market entry for the antacid Pepcid® prior to expiration of the U.S. patent covering this drug. Their application, and subsequent legal battle with the pharmaceutical company Yamanouchi, was settled by the U.S. Court of Appeals for the Federal Circuit (CAFC) in *Yamanouchi v. Danbury* (2000). During trial, Danbury took the position that the structure of Pepcid was obvious under 35 U.S.C 103, especially in view of the similarly-structured compound tiotidine, as well as a prior art compound referred to as “example 44.”