
Cephalon Victorious in ANDA Litigation

2013-02-20

Last week, the Federal Circuit issued a favorable decision on behalf of Cephalon, Inc., an international biopharmaceutical company and WilmerHale client, in its case against Watson Pharmaceuticals (now Actavis), a generic drug manufacturer. The ruling reversed a district court decision that invalidated two patents that cover Cephalon's cancer pain medication FENTORA®.

This action arose out of the filing of an Abbreviated New Drug Application (ANDA) by Watson Pharmaceuticals, Inc. for a generic version of FENTORA®. In response to Watson's ANDA filing, Cephalon instituted a patent infringement suit at the U.S. District Court for the District of Delaware asserting U.S. Patent Nos. 6,200,604 and 6,974,590, covering novel methods for delivering pain medication through oral transmucosal absorption (of which FENTORA® is a commercial embodiment). After a bench trial that concluded on May 17, 2010, the district court found that Watson's ANDA products did not infringe and held the asserted patents invalid for lack of enablement. On February 14, 2013, the Federal Circuit reversed that decision on the issue of enablement because "Watson failed as a matter of law to show with clear and convincing evidence that Cephalon's patents require undue experimentation to practice the invention." The Court also held that there is no burden-shifting framework when addressing

the issue of enablement.

Senior Associate [Carolyn Chachkin](#) argued the appeal before the Federal Circuit on behalf of Cephalon, and was supported by a team that included Partners [Bill Lee](#), [Bill McElwain](#), [Mark Fleming](#) and Counsel [Jake Oyloe](#).