

Axinn Obtains Fourth Circuit Victory in Generic Celebrex[®] Case

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December 17, 2014

At the U.S. Court of Appeals for the Fourth Circuit, Axinn obtained a victory that will help its client, Watson Laboratories (now Actavis), speed its generic version of Celebrex[®] to market.

An earlier lower court decision had effectively barred Watson Laboratories and others from bringing their drugs to market until June 2015.

Watson and Mylan Pharmaceuticals initially sued FDA in federal court, challenging an Agency letter decision that concluded that the companies were not eligible for a period of 180-day marketing exclusivity on the launch of their generic versions of Celebrex[®] because a reissued patent, according to FDA, was part of the same “bundle of rights” as an original patent. The U.S. District Court for the Northern District of West Virginia ruled in favor of the Agency, finding that the Agency’s interpretation of the statute regarding exclusivity periods was reasonable and was owed deference.

The Fourth Circuit Court of Appeals reversed and remanded the case, finding in favor of Axinn’s client and holding that FDA’s interpretation was contrary to the unambiguous statute.

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