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DC Circuit Upholds Shire's Five-Year NCE Marketing Exclusivity For Vyvanse®

The DC Court of Appeals for the District of Columbia ("DC Circuit") has upheld the FDA's grant of the five-year New Chemical Entity ("NCE") marketing exclusivity to Shire for its attention deficit hyperactivity disorder (ADHD), drug Vyvanse® (lisdexamfetamine dimesylate). The decision will keep Actavis' generic version of the drug off the market at least through February 23, 2010. Vyvanse® is also protected by patents, which presently begin to expire in June 2023.

Actavis submitted an ANDA for Vyvanse in January 2009, arguing that Vyvanse did not deserve the five-year NCE exclusivity because lisdexamfetamine converted to a previously FDA-approved compound (dextroamphetamine) after it enters the body. The FDA rejected Actavis' ANDA, precipitating the lawsuit by Actavis against the FDA, wherein Actavis argued that its ANDA should be accepted because the "active ingredient" is the drug as converted inside the body (dextroamphetamine), and not the pre-cursor molecule (lisdexamfetamine dimesylate) that enters the body.

The District Court, as well as the DC Circuit, ruled in the FDA's favor, affirming the FDA's definition of the term "active ingredient" to include, at least for certain types of products, the entire pre-ingestion drug molecule, which can include its metabolism, excretion, or toxicity. Thus, FDA properly treated the lisdexamfetamine as the "active moiety."

The DC Circuit discounted Actavis' fears that such a ruling would lead to unending cycles of five-year exclusivities by filing minor variations to the drug, indicating that, in the almost 20 years since the inception of the current FDA regulations, no such case has occurred.

Otsuka Prevails In Suit Preventing Generic Abilify® From Entering Market Until 2015

The United States District Court for the District of New Jersey recently found in favor of Otsuka Pharmaceutical in its suits against several companies seeking to make generic versions of its blockbuster antipsychotic Abilify®, which is used to treat various conditions including schizophrenia, bipolar mania disorder, and major depressive disorder. The generic manufacturers, including Sandoz, Teva, Sun, and Synthon, had claimed that Otsuka's US Patent No. 5,006,528 ("the '528 patent"), directed to Abilify's® active ingredient aripiprazole, was invalid due to obviousness, and that the '528 patent was not enforceable due to inequitable conduct.

The District Court ruled that the '528 patent was valid and enforceable, relying in large part on Otsuka's expert witness, noting that "Otsuka's witness, Mr. Jarosz, an expert in economics and intellectual property valuation, credibly testified at trial to the extraordinary commercial success of Abilify, the commercial embodiment of the compound and methods claimed in Claim 12, Claim 17, and Claim 23 of the '528 Patent, aripiprazole." The District Court also enjoined the multiple generic defendants from marketing generic versions of Abilify® until at least April 20, 2015.