

Shire's Vyvanse likely to retain NCE status; court likely to support FDA - attorneys

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*by Jacqueline Kwong in New York*

Actavis' lawsuit against the FDA for granting Shire's (NASDAQ:SHPGY) Vyvanse NCE exclusivity is likely to result in the FDA standing by its original decision, attorneys said. The majority of sources interviewed also noted that the district court would likely support the FDA's decision.

Actavis filed a complaint against the FDA on 24 February 2009, challenging the agency's decision to grant Shire's Vyvanse new chemical entity (NCE) status, which prevents a generic drug company from submitting an abbreviated new drug application for five years. On 13 April 2009, the US District Court for the District of Columbia agreed to stay the proceedings until the FDA made a decision by 24 September 2009. The FDA then requested an extension for 23 October 2009, which was granted by the court.

In the complaint, Actavis stated its belief that the FDA incorrectly granted NCE status to Vyvanse, as the active ingredient of the drug, dextroamphetamine, was already approved by the FDA. Vyvanse is a prodrug to dextroamphetamine and is converted to its active ingredient in the gastrointestinal tract.

Both Shire and Actavis declined to comment.

The FDA will likely stand by its original decision because the innovators will be very vocal, said Rahsaan Thompson, of counsel at Quarles & Brady. Although representatives of generic drug companies will also be heard, the FDA will be hesitant to side with Actavis because major policy changes will be required, and the agency will face immense "push back" from innovators, he added.

An attorney, who wished to remain anonymous, noted that the FDA generally prefers to side with generic drug companies, but in this situation, the agency might not favor Actavis. The agency understands that it is bound by statutes and regulations not to act inconsistently, said the source. Granting Vyvanse NCE exclusivity was probably a decision that is consistent with the FDA's past actions, and therefore, changing that decision could make the FDA's actions inconsistent with the statutes and regulations, he explained.

The majority of attorneys interviewed also noted that regardless of the

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administrative decision made, the courts would likely side with the FDA. The courts do not like dealing with situations involving science, as it is the FDA's responsibility to make such decisions, said Stephen Paul Mahinka, a partner of Morgan Lewis & Bockius. In such situations, the courts like to defer to the administrative agency and tend to support the agency's decision, he added.

Mahinka, however, said it is difficult to project what decision the FDA would make. Mark Mansour, a partner at Bryan Cave, agreed.

As a matter of law, the courts are fairly deferential to the FDA, agreed Philip Katz, a partner of Hogan & Hartson. The court often side with the FDA, and will oppose the agency's decision only if the decision were blatantly arbitrary and capricious, he added.

Mahinka explained that decisions are considered to be arbitrary and capricious only if the agency acted without considering evidence, or acted inconsistently to past decisions. In this situation, it does not seem that the FDA acted arbitrarily or capriciously, said Mahinka. Thompson agreed and added that the FDA did not abuse its discretion.

Yet Mansour noted that the courts would not necessarily agree with the FDA's decision. The FDA has been acting overtly cautious and because of the amount of science involved with this decision, the decision may seem arbitrary to the judge, said Mansour.

Shire has a market cap of USD 9.31bn.