

Vivus's Qnexa has strong patent although drug composed of two generic compounds - attorneys

by Jacqueline Kwong in New York

2009-09-25 Pharmawire

Vivus' (NASDAQ:VVUS) Qnexa patent is unlikely to face obviousness challenges in the future, despite the fact that the obesity pill is composed of two generic components, attorneys said.

Qnexa is a weight loss drug that combines two compounds, phentermine and topiramate – both off-patent – into one drug. Phase III trials have been completed and the company plans to file an NDA before the end of this year.

The '818 patent, covering the subject matter of Qnexa, was filed in 1999 and approved in 2009 by the United States Patent and Trademark Office.

"I don't think the patent is obvious," said Narinder Banait, a partner at Fenwick & West. He explained that when the '818 patent was filed, Fen-phen was pulled off the market because of its serious side effects. At that time, phentermine's label indicated that it should not be used in combination with any other weight loss drugs and the FDA also put out a warning saying that phentermine was suitable as monotherapy only, he added.

Fen-phen was an anti-obesity drug that consisted of fenfluramine and phentermine. After regulators found that fenfluramine caused pulmonary hypertension, Fen-phen was pulled off the market in 2004.

Because of the history of problems with Fen-phen and phentermine's label change, it would not be obvious to combine phentermine and topiramate together at that time, Banait noted.

Vivus could not be reached for comment.

Barry Negrin, a partner with Pryor Cashman, noted that it was not necessarily obvious to combine phentermine with another compound when the Qnexa patent was filed. He agreed that the FDA's warning against combining phentermine with another compound could strengthen Vivus's patent position.

Yet Gregory Hillyer, a partner with Feldman Gale, disagreed that the Fen-phen incident would strengthen Vivus's case in the event of a patent challenge. Just because physicians and the FDA said that phentermine should not be used with

other compounds does not strengthen the patent's sustainability, he noted. Marketability and approvability do not play a part in whether something is patentable, he explained.

Negrin noted, however, that the Qnexa patent would survive the "main test for obviousness" - whether two known elements, when combined, produce unexpected results. If this combination does provide unexpected results, then it is not obvious, he added. Because phentermine and topiramate have synergistic effects, and not just additive effects, the combination has unexpected results and would survive an obviousness attack, he said.

The claim in the patent is that topiramate offsets phentermine's loss of efficacy, added Hillyer. This is probably unknown in the prior art and hence, combining topiramate and phentermine would not be obvious, he said.

Yet Gary Spier, a shareholder at Schwegan Lundberg & Woessner, noted that an obviousness claim may successfully challenge the Qnexa patent. He said Vivus may have problems defending its patent if prior art, published before 1999, indicates that both phentermine and topiramate have the ability to cause weight loss.

A study titled "Safety of Topiramate: Adverse Events and Relationships to Dosing," which was published in 1996, noted that topiramate was associated with mild weight loss.

"[Vivus] is in pretty good shape," Negrin said, after analyzing the Qnexa '818 patent. In addition to the '818 patent, Vivus has additional pending patents that could cover different doses of Qnexa that could provide this compound with additional protection against generic competition, he added.

Vivus has a market cap of USD 715.89m.