

Gilead's hypertension drug darusentan will likely receive patent extension, attorneys say

by Jacqueline Kwong in New York

* If filed in a timely fashion, Gilead should receive a patent extension for darusentan, one attorney said

* Even if darusentan is approved after its patent has expired, Gilead can still apply for interim patent extensions, one attorney said

Gilead's (NASDAQ:GILD) hypertension drug darusentan will likely receive a patent extension, but the extension is not guaranteed, attorneys said.

Darusentan is a selective endothelin receptor antagonist used to treat resistant hypertension. On 2 April 2009, Gilead announced positive results from darusentan's Phase III DORADO trial, in which the drug was compared to placebo.

Darusentan's patent expires in 2015. A spokesperson from Gilead said that the company plans to file a new drug application for darusentan, at the earliest, in the fourth quarter of 2010.

There is a high probability that darusentan's patent will get extended, said Michael Siekman, a shareholder and co-practice group leader for the biotechnology group at Wolf, Greenfield & Sacks. If the application is properly filed and everything is timely, there is no reason for Gilead not to get an extension, added Keith McWha, counsel at Day Pitney.

It is common to get a patent extension upon receiving FDA approval for the drug, said Narinder Banait, a partner in the intellectual property group at Fenwick & West. John Garvish, an associate at McKool Smith, agreed and explained that patent extensions were given to compensate for the time the FDA spends on the approval process. This benefit is given to patent owners to not take anything away from the innovative process, Garvish added.

It is imperative that Gilead receives a patent extension, said Banait. If darusentan gets on the market two years from now, the drug's patent, without being extended, will only protect the drug for an additional three years, he said.

Yet a patent extension is not guaranteed. To get an extension, the patent cannot have expired before the FDA grants approval, said Banait. If the FDA grants approval in 2015, then Gilead might not receive an extension, he added.

Even if the FDA approves of darusentan in 2015 and the patent has expired, Gilead can apply for interim patent extensions, said Gaby L. Longsworth, a partner at Sterne Kessler Goldstein Fox. Interim patent extensions must be renewed every year, and applicants can only receive these extensions up to five years, she explained.

Companies sometimes are late with filing for extensions, said Siekman. The United States Patent and Trademark Office (PTO) requires that patent extensions be filed within 60 days of when FDA approval is received, and some companies have missed their deadline by one day, he noted.

In particular, Siekman pointed out that The Medicines Company (NASDAQ:MDCO) had problems receiving an extension for Angiomax. Despite their lobbying efforts, The Medicines Company was not able to get the PTO to grant an extension for the Angiomax patent, just because they were one day late in filing, he said.

AstraZeneca (NYSE:AZN) was also having problems with getting a patent extension for Symbicort Inhalation Aerosol, McWha noted. Similar to The Medicines Company, AstraZeneca filed one day too late, but the company is still waiting to see how the PTO will reconsider its petition, he added.

The reason why the PTO is so strict with the 60 day deadline is probably because a patent extension is viewed as a benefit, but not a right - meaning that the PTO may not feel the need to accommodate for patent holders who filed late, Garvish said. Yet he said he felt that few companies have difficulties meeting the 60 day deadline.

If Gilead is unable to get a patent extension, darusentan will receive protection from test data exclusivity, said Banait. Test data exclusivity prevents the FDA from using the company's data to approve of generic versions of the drug, but does not prevent generic companies from performing their own studies, he explained. Banait also admitted that patent protection was ultimately preferred, because with a patent, not only is the FDA prohibited from approving a generic version of the drug, but the generic companies can also be prohibited from conducting clinical trials.

McWha also pointed out that the patent extension process could be delayed if a generic drug company challenges the validity of darusentan's patent. The PTO must consider the factors raised in such proceedings if invalidity is brought up, said McWha.

Test data exclusivity could protect the drug for an additional five years, Banait added.

Gilead has a market cap of USD 43.40bn.