VIVUS Qsymia Patents: Challenges Filed to Second Family of European Applications

Robert Diggs Deeper: Can Vivus overcome the prior disclosure of formulation details in Europe?

SAN FRANCISCO, USA, November 11, 2013 /EINPresswire.com/ -- A pair of prior art challenges was filed with the European Patent Office against two Vivus patent applications (European Application Nos: 09763480.2 and 09763479.4) that are directed to formulations and dosages of the company's obesity drug Qsymia. The challenges allege the applications are not patentable in view of a conference call that occurred prior to the filing of the patent applications, during which the subject matter of the later-filed patent applications was discussed. The challenges can be viewed directly by the public on the European Patent Register by opening the "All documents" for each respective application.

> "It appears Vivus may have severely compromised its foreign patent rights when it disclosed the details of Qsymia's once-a-day formulation too soon."
>
> *Robert F. Diggs*

The company currently has two patent families directed to Qsymia: the first of which was first filed in 1999 (the Najarian patents) and a second family first filed nine years later in 2008, which contains both of the patent applications that are the subject of the present patent challenges in Europe.

There has been considerable controversy surrounding the strength of the first family of Qsymia patents, which are scheduled to expire in 2020. The company recently received notification from the USPTO that two U.S. applications from the second family are scheduled to issue today, and these applications, if issued, are not scheduled to expire until 2029. The corresponding pending European applications are directed to pharmaceutical compositions and methods comprising the specific once-a-day formulation and dosages of its approved drug, Qsymia® (fixed dose combinations of controlled release topiramate with phentermine). Vivus has been seeking approval for Qsymia in Europe under the trade name Qsiva. For a complete review of Vivus' patent position on Qsymia, please view the series of patent reports here.

At the heart of the challenges to Vivus' patent position is the discovery of a Vivus 8-K disclosure that includes a conference call transcript (Exhibit 99.1) from November 9, 2007. On the conference call, Leland Wilson and Peter Tam, both named inventors on the second family of patents, disclosed the details of its once-a-day formulation. On the same day, the company

released a press release entitled, “VIVUS Initiates Pivotal Phase 3 Trial in Obese Patients and Announces Qnexa Dose“, which also disclosed Qsymia’s once-a-day formulation and dosage details. Both of these documents pre-date the earliest filing of Vivus’ corresponding patent applications to this subject matter, which occurred eight months later on June 9, 2008.

Under US law, patent applicants are afforded a one-year grace period to file patent applications to subject matter disclosed prior to patent filing; however, most jurisdictions outside of the U.S., including Europe, do not offer this grace period. Therefore, Vivus’ early disclosure of the Qsymia formulation details may serve as a major blow to the company’s foreign patent rights. As a reminder, Vivus’ earlier patent family was only filed in the U.S., Europe, Canada and Australia, and the pending European application (European Patent Application No: 07011472.3) is the subject of an earlier-filed third party observation.

“It appears we have another instance of Vivus either not executing on its patent strategy or not having a strategy to begin with. While the ramifications from this most recent mistake may be muted by the grant of non-patent exclusivity in some jurisdiction upon approval, this most recent blunder does not reflect well on the company,” commented Robert Diggs. “How long has the company known about this reference and have investors been given the opportunity to contemplate a Qsymia franchise with extremely compromised foreign patent rights?”

A review of the patent prosecution history in Europe for both applications shows an examiner that was already highly skeptical that the applications met the inventive step standards required of patents in Europe. The examiner cited the earlier Najarian patent application (US Publication No. US 2004/002462) and an Elan patent application (WO 2006/063078) to controlled release topiramate in combination with phentermine for weight loss as prior art. The introduction of the conference call transcript should provide the examiner with the necessary art to perfect a novelty rejection over many, if not all, of the pending claims and strengthen his inventive step rejection over all of the pending claims.

About RFD IP Business Services

RFD IP Business Services (“RFD”) provides intellectual property-related business diligence services for the pharmaceutical and biotech industries.

Robert F. Diggs
RFD IP Business Services
415-200-6895
email us here