VIVUS Qsymia Patents: Vivus and Its Lawyers Acknowledge the Materiality of Weaknesses in the Qsymia Patent Position

Robert Diggs Deeper: Vivus' patent counsel Mintz Levin makes all RFD patent reports a matter of the official record at the USPTO

SAN FRANCISCO, USA, September 24, 2013 /EINPresswire.com/ -- On September 16th, Vivus' patent counsel Mintz Levin filed a set of patent prosecution documents with the U.S. Patent and Trademark Office (USPTO) that discloses, among other things, a series of critical patent reports from RFD IP Business Services ("RFD"). By submitting the RFD reports in an information disclosure statement (IDS), Vivus and its patent counsel acknowledge that the content of the reports is sufficiently material to warrant its official disclosure to the USPTO – in this particular case for US Application Nos. 12/481,540 (the '540 application) and 12/481,548 (the '548 application).

> I believe those with an interest in Vivus will watch closely as the information from a series of critical patent reports is considered by the U.S. and European patent offices
>
> *Robert F. Diggs*

In the same IDS, Vivus also discloses the McElroy provisional patent application (60/121,339), which describes the combination of phentermine with topiramate for the treatment of obesity. The McElroy application is the subject of a third party observation filed on August 6, 2013 that alleges the Qsymia invention is anticipated by the earlier filed McElroy patent.

With the filing of the IDS, which can be viewed here, the content of the reports as well as the McElroy patent application will now be considered by the patent office when it determines the patentability of the pending Vivus applications.

Has the duty of candor been satisfied?

As defined in 37 CFR 1.56, "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability."

That leaves the following questions unanswered:

* When did Mintz Levin know about the information put forward in the reports, and when did it decide to include the blog in an IDS? When did the other parties that share the same duty of candor and good faith when dealing with the USPTO, namely Vivus employees substantially involved in the preparation or prosecution of the Qsymia applications, Vivus' former outside patent counsel as well as the named inventors (Thomas Najarian, Peter Tam and Leland Wilson), know of all or some of the information in the reports.

* Does disclosing the blog in an IDS satisfy Vivus and Mintz Levin's duty of candor obligation under

37 CFR 1.56? For example, does the USPTO now have enough information about the below alleged instances of misconduct, misstatements and omissions to properly determine if or how they are material to the patentability of the Qsymia patents?
a. Failure to notify the USPTO of its position that earlier issued Najarian patents are not enabled throughout the scope of the currently issued claims;
b. Conflicting characterization of Qsymia's side effect profile before the USPTO versus the FDA;
c. Failure to correct the record regarding the earlier mischaracterization of the lack of prior art from 1996-1999 when the parties were almost certainly aware of the McElroy patent; and
d. Failure to disclose the details of Dr. Najarian's 2001-2008 prescribing history of combination treatments of phentermine and topiramate at his Los Osos, California weight loss clinic as potential prior public use.

It should be noted that for all patents filed after 2001, the failure to disclose the details of Dr. Najarian's 2001-2008 prescribing history may well be the most important prior art because a named inventor, Dr. Najarian, was practicing the alleged invention for years, which according to a colleague's statement in the New York Times included treating "thousands of patients" and presumably the outcomes from said treatments. Neither Dr. Najarian, Vivus nor its patent counsel have ever provided a summary, let alone a detailed account, of this extensive prior use. How is this consistent with the duty of candor?

Next Steps

With the USPTO now notified of the weaknesses inherent in the Qsymia patent portfolio, there are two jurisdictions where the public can follow Vivus patent prosecution:

* The United States Patent and Trademark (USPTO) as it considers the content of the RFD patent reports; and
* The European Patent Office (EPO) where a third party observation was filed that challenges Qsymia pharmaceutical composition and kit claims in light of the McElroy patent.

In the U.S., another IDS is likely to be filed for US Application No. 12/683,353 (the '353 application) when Mintz Levin responds to the Non-Final Rejection that was mailed in August 2013. This pending application is from the earlier-filed family of patents that names Dr. Thomas Najarian as the sole inventor, and it includes the issued Qsymia patents listed in the Orange Book. The '353 IDS may also include the Mintz Levin Office Action Responses from the '540 and '548 applications that call into question the enablement of the earlier Najarian patents.

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