VIVUS Qsymia Patents: Two Vivus Patent Applications Covering Qsymia Allowed by the USPTO

Robert Diggs Deeper: Assuming the allowed applications issue as patents, Qsymia's patent term may now extend into 2028

SAN FRANCISCO, USA, October 2, 2013 /EINPresswire.com/ -- As of market close on October 1st, the prosecution status of two pending Qsymia patent applications (US Application Nos. 12/481,540 and 12/481,548) was updated on the USPTO's Patent Application Information Retrieval (PAIR) site indicating the applications were now in a condition for allowance. More specifically, the transaction history for both applications was updated with a "Reasons for Allowance" event notice (one dated September 27th and the other September 30th), and the image file wrapper for the '540 application showed a terminal disclaimer had been filed.

> The allowance of new Qsymia patents likely eliminates the company's dependence on the earlier Najarian patents and the focus turns to the strength of the new patents.
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> *Robert F. Diggs*

Both of these events strongly suggest the applications are now in a condition for allowance (although a formal Notice of Allowance has not yet been issued by the USPTO). After allowance, Vivus will have three months to pay the issue fee and applications typically issue as patents about 6-8 weeks thereafter. There are instances when either the patent examiner or the patent applicant may pull an application from issuance (e.g., if new prior art is introduced), however, this is generally not the case.

The newly allowed Vivus applications claim priority to an application (US Application No. 12/135,953, now abandoned) filed on June 9, 2008, and name Najarian, Tam and Leland as inventors. The allowed claims are narrow and appear to be limited to specific compositions and methods that cover the Qsymia dosages, formulations and treatment regimens approved by the FDA.

Why is the allowance of these claims from a new patent family significant?

* If the applications issue, they will be presumed to be valid, and will thereby extend the patent term for Qsymia from 2020 to 2028 (plus patent term adjustment, which could add about another year).

* Assuming the issued patents are added to the Orange Book, they will represent two more patents (in addition to the earlier issued Najarian patents) that generics will have to show are invalid, unenforceable or not infringed in order to gain approval for generic Qsyima under the Hatch-Waxman ANDA rules.

Certain caveats around this event worth noting:

* The information from the US Patent and Trademark Office is not always complete. For example, sometimes prosecution information is not offered in chronological order or the corresponding

documents are not immediately available for download. However, based on the information available as of market close on October 1st, it seems reasonable to conclude the applications have been allowed.

* It is unclear when the company will publicly disclose these patent developments. Most companies wait until the patents actually issue, however, the USPTO PAIR site is available to the public so the company can direct investors and potential investors to the site for patent-related updates.

Validity and enforceability analysis of the new claims:

Admittedly, the allowance of these applications comes as a surprise to RFD IP Business Services ("RFD"). In an earlier report, RFD stated it did not believe the applications would ever issue, especially in light of Dr. Najarian's extensive prior use of the alleged invention, or a close variant thereof, while practicing medicine at his Los Osos, California weight loss clinic.

For now, RFD is withholding judgment as to the validity and enforceability of these likely soon-to-be issued patents until it has a chance to carefully analyze the entire patent family.

What does the allowance mean for Vivus?

To be clear, the strength of the new Qsymia patents will be highly material to the value of Vivus. In many ways this development further illustrates the binary nature of Vivus' future. It is still the opinion of RFD that the earlier Najarian patents (listed here in the Orange Book) are not likely to survive a validity or enforceability challenge from a generic that files a paragraph IV challenge – not to mention the unresolved assignment issues associated with the Najarian patents. For these reasons, RFD predicted the entry of generic competition during the second half of 2015 or some time in 2016 (see the report here) – far before the scheduled expiration of the Najarian patents in 2020. However, with the presumed issuance of new Qsymia claims, the Qsymia patent term now extends into 2028 (plus any patent term adjustment).

It is unusual for new, unrelated applications to be allowed when the original alleged invention was the subject of a patent application filed ten years earlier. For now, however, this appears to be the case, and credit to Vivus and Mintz Levin is in order. While reserving the right to change this position based on a complete analysis of the new applications, it appears the majority of the problems discussed in the earlier RFD reports (e.g., potential assignment issues, lack of novelty and inequitable conduct) are isolated to the Najarian patent family. Therefore, a partnership or buyout now seems more likely than before the allowance of the new applications – based solely on the patent landscape. However, potential partners still may wait to see how Vivus fares during ANDA litigation since Qsymia's status as a new combination allows challenges to be filed anytime after the drug's approval and only affords Qsymia non-patent exclusivity until July 2015.

Visit: http://vivuspatent.wordpress.com to view all of the reports.

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