

Patent Trial and Appeal Board Rejects Petitions for Covered Business Method Patent Review of Orange Book-Listed Patents Claiming Methods of Controlling Access to Sensitive Drugs

On January 13, 2015, the Patent Trial and Appeal Board (PTAB) denied institution of four Covered Business Method (CBM) patent reviews of Orange Book-listed patents owned by Jazz Pharmaceuticals plc (“Jazz”), holding that the patents did not claim activities that are financial in nature, incidental to a financial activity, or complementary to a financial activity, the requisites for CBM review.

Jazz had sued Petitioners (Par Pharmaceutical, Inc., Roxane Laboratories, Inc., and Amneal Pharmaceuticals, LLC) for patent infringement based on their plan to market generic versions of the drug Xyrem®, which is indicated for the treatment of cataplexy and excessive daytime sleepiness in narcoleptic patients. The CBM petitions, filed June 24, 2014, are notable because it is the first time generic drug makers facing an infringement suit under the Hatch-Waxman Act, or indeed any petitioners, have sought CBM review of Orange Book-listed patents.

A “covered business method patent” is defined in § 18(d)(1) of the Leahy-Smith America Invents Act (Pub. L. No. 112-29, 125 Stat. 284 (2011)) (“AIA”) as “a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions.” In its very first Institution Decision for CBM review, the PTAB explained that “[t]he term financial . . . simply means relating to monetary matters” and is not limited to traditional financial service industries. *SAP America, Inc. v. Versata Development Group, Inc.*, CBM2012-00001 (January 9, 2013) (Paper 36).

The Jazz patents at issue relate to methods for controlling access to “sensitive drugs” that are prone to potential misuse, abuse, or diversion by utilizing a central pharmacy and database to track all prescriptions for the drug. Specifically, the patents relate to controlling access to the prescription drug Xyrem® (sodium oxybate), which is a Schedule III controlled substance. Xyrem® is commercially available only through a restricted distribution program using a centralized pharmacy. The claimed method traces the workflow of receiving, processing, and filling a prescription and requires an exclusive database associated with an exclusive central pharmacy for analysis of potential abuse situations such that all prescriptions are processed only by the central pharmacy using only the central database.

The Petitioners argued that the claims qualified for CBM review because the methods “would be used in commerce” and distributing a prescription drug “is financial in nature.” In support, the Petitioners pointed to the patent specification’s description of steps for verifying insurance coverage or a patient’s ability to pay for the prescription, and provided an expert declaration stating that filling a prescription necessarily involves checking a patient’s insurance coverage or ability to pay, which “ultimately relate[s] to the financial transaction of providing a prescription drug.”

In denying CBM review, the PTAB focused on the claims. It held that the claims themselves do not recite a financial product or service. In particular, the claims do not recite or require “activity involving the movement of money or extension of credit in connection with the sale of a prescription drug.” The PTAB further explained that the claims do not recite a product or service “particular to or characteristic of financial institutions such as banks, insurance companies, and investment houses.” The PTAB also noted that neither Petitioners nor their expert had explained (1) why the claimed method steps recited or otherwise included the steps of verifying insurance coverage or a patient’s ability to pay that were referred to in the specification, or

(2) why any of the claimed methods should be “considered ‘financial’ when considered in the context of the claim language as a whole.” The PTAB concluded that the claims constituted “checks” and “controls” for the prescription drug -- not financial activity.

The PTAB also rejected the Petitioners’ argument that the patents qualified for CBM review because the methods are “used in commerce,” noting that this was an improper attempt to expand CBM review to cover all business methods, not just financial ones. Finally, the PTAB rejected the Petitioners’ argument that CBM review was appropriate because the Patent Office had classified the patent in Class 705, Subclass 2, which includes “billing systems” and that the Examiner, during examination, had cited prior art billing systems. Again, the PTAB focused on the claims themselves and stated that the Petitioners had not explained “how the claim language of [the patent] recites method steps used in medical code billing systems or prior art payment systems.” The PTAB performed its analysis with respect to the claims in one of the four patents, but addressed differences in claim language in the other patents, and came to the same conclusion that those claims also did not qualify for CBM review.

At bottom, this decision underscores that the PTAB is likely to exclude from CBM review Orange Book-listed patents unless they expressly recite or otherwise clearly encompass something financial in nature, or incidental or complementary to a financial activity. While every patent must be assessed on its own specifics, the decision is also a reminder that Petitioners for CBM review must be careful to explain in detail with specific analysis of the claim language and specification why at least one claim of the challenged patent satisfies the “financial” restriction on the PTAB’s CBM jurisdiction.

A copy of the PTAB’s decision is available [here](#). To discuss further the potential impact of this decision or other decisions related to CBMs, please contact your usual Ropes & Gray attorney or one of the Ropes & Gray attorneys listed below.

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