

Insights: Alerts

UPDATE PTAB Denies Request to Use Covered Business Method Review for Orange Book-Listed Patents

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The Patent Trial and Appeals Board (PTAB) denied the request to review four Orange Book-listed patents owned by Jazz Pharmaceuticals, Inc. under the covered business method (CBM) review procedure. The CBM petitions filed by Amneal Pharmaceuticals, Par Pharmaceutical, and Roxane Laboratories (collectively “Petitioners”) were the first attempt to use the CBM procedure on pharmaceutically related patents.

The claims of the challenged patents related to computerized methods for controlling the distribution of sodium oxybate, known as XYREM[®]. XYREM[®] is used to treat excessive daytime sleepiness and cataplexy (marked by sudden muscle weakness or paralysis) associated with narcolepsy. The compound is also widely known as a “date rape” drug, so its distribution is tightly controlled due to the potential for abuse or diversion.

Petitioners set forth several arguments that the patents were, in fact, covered business methods and should be subject to review under the CBM review procedures. Petitioners first argued that the claimed method of “distributing a prescription drug” is a covered business method because the method “would be used in commerce.” The PTAB rejected Petitioner’s argument finding that the claims fail to recite a product or service that was particular to or characteristic of a financial institution, such as banks, insurance companies, or investment houses. The PTAB further noted that the claim language did not require any sales, processing of payments, determination of the cost of insurance or prescription benefits, facilitation of payment, or extension of credit for the purchase of the drug. Further, the PTAB rejected the argument that CBM review may be instituted for a claimed business method that is “used in commerce,” as it is not supported by the plain language of the statute or its legislative history. Finally, Petitioners argued that the classification of at least one of the patents in Class 705, subclass 2, which includes billing systems based on entered medical codes supported their position that the claims were directed to activities that were “financial in nature, incidental . . . or complementary to a financial activity.” The PTAB rejected this argument as well based on, at least in part, the lack of evidence presented by the Petitioner as to how the claimed methods related to medical code billing systems.

In this case, the PTAB adopted a narrow interpretation of the subject matter that qualifies as a covered business method; however, the Court of Appeals for the Federal Circuit is currently considering an appeal from Versata Development Group (Case No. 14-1194) in which Versata argued that the PTAB took too broad a view of

covered business methods and improperly invalidated its patent relating to methods for determining the price of products offered to purchasing organizations. Any tension or conflict between the upcoming Federal Circuit decision and the present PTAB decision is unlikely to be addressed, as the statutory provisions of the America Invents Act bars appeal of “initiation” decisions by the PTAB.

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