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Filed: November 26, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ROXANE LABORATORIES, INC. and PAR PHARMACEUTICAL, INC.
Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.
Patent Owner

Case CBM2014-00175
Patent 7,765,107

PATENT OWNER PRELIMINARY RESPONSE
PURSUANT TO 35 U.S.C. § 323 and 37 C.F.R. § 42.207

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I. INTRODUCTION

Pursuant to 35 U.S.C. § 323 and 37 C.F.R. § 42.207(a), Patent Owner Jazz Pharmaceuticals, Inc. ("Jazz") submits this Preliminary Response to Roxane Laboratories, Inc. and Par Pharmaceutical, Inc.'s ("Petitioners") Petition for Covered Business Method ("CBM") review (the "Petition") of U.S. Patent No. 7,765,107 (the "'107 patent"). For the reasons discussed below, the Petitioners fail to meet the threshold requirement to show that the '107 patent is a covered business method patent under the statute and subject to CBM review. The Patent Trial and Appeal Board (the "Board"), therefore, should not institute review of the '107 patent. Petitioners also fail to show that the Advisory Committee Art ("ACA") materials constitute prior art to the '107 patent. Accordingly, even if the Board does not deny the Petition in its entirety, it should not institute Petitioners' second (§ 102(b)) and third (§ 103(a)) grounds for unpatentability.

The claims of the '107 patent cover methods of controlling the abuse, misuse and diversion of a prescription drug, particularly a drug containing GHB—a substance notorious for its illicit use in drug-facilitated sexual assaults. The claims specifically cover the methods ultimately approved by FDA to ensure the safe administration of Jazz's FDA-approved form of sodium GHB—Xyrem®—to treat patients while preventing the abuse, misuse, and diversion known to have occurred with illicit forms of this drug. Xyrem is the ***only*** approved treatment for cataplexy,

a debilitating symptom of narcolepsy, and excessive daytime sleepiness in patients with narcolepsy. The technological solution to the problem of how to get Xyrem to patients who need it, while mitigating the risk of abuse, misuse or diversion of this drug, was critical to Xyrem's approval by the FDA. The solution resulted in the claimed methods which utilize a computer processor/central database controlled only by an exclusive entity, which have numerous safety checks and/or controls, including restriction of availability, extensive determination of patient and physician identity, and identification of behavioral patterns that suggest illicit drug use.

By statute, a patent is subject to CBM review only if the patent "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***. . . . " AIA § 18(d)(1); 37 C.F.R. 42.301(a) (emphasis added). Petitioners cannot meet their burden to establish that the '107 patent covers "data processing or other operations used in the practice, administration, or management of a financial product or service" because the '107 patent has nothing to do with a financial product or service. Here, the '107 patent's claims do not cover a financial product or service, or any activities incidental to a financial product or service. As a result of Petitioners' improper attempt to expand the scope of CBM

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