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 CBM: Unassigned

PETITION FOR COVERED BUSINESS METHOD PATENT REVIEW OF U.S. PATENT NO. 7,765,107 UNDER 35 U.S.C. § 321 AND § 18 OF THE LEAHY-SMITH AMERICA INVENTS ACT

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I. INTRODUCTION AND STATEMENT OF RELIEF REQUESTED (37 C.F.R. § 42.22(a))

Roxane Laboratories, Inc. and Par Pharmaceutical, Inc. (collectively, "Petitioners") petition for covered business method patent ("CBM") review and seek cancellation of claims 1-6 of U.S. Patent No. 7,765,107 ("the '107 patent") (ROX1001). According to Office records, the '107 patent is assigned to Jazz Pharmaceuticals, Inc. ("Jazz"). Jazz is currently asserting the '107 patent against Petitioners in litigation. (ROX1024-ROX1025.)

II. OVERVIEW

Claims 1-6 of the '107 patent are unpatentable because they: (i) claim ineligible subject matter under 35 U.S.C. § 101; (ii) are anticipated by the prior art under 35 U.S.C. § 102(b); and (iii) are obvious over the prior art under 35 U.S.C. § 103, even in view of secondary considerations of nonobviousness.

Because the compound sodium oxybate has been known at least since the 1970s, and is not the subject of patent protection, Jazz has sought to patent a broad and abstract method of distributing the drug. The challenged claims simply claim the abstract idea of centralizing retail drug distribution using an exclusive central pharmacy that encompasses the non-technical steps of interfacing with financial businesses (patient's insurance company), rendering them incidental to a financial product or service. The claim preambles reciting a method for controlling abuse of a prescription drug does not change their abstract nature. All claim steps are

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directed to non-technical drug distribution steps and define a complete method. The preambles do not change the claims' basic characteristic of covering the abstract idea of centralizing drug distribution.

Further, the claims are not directed to any technological invention. The claims' recitation of a generic computer processor and central database do not change this conclusion. Moreover, the claimed distribution methods are not novel or nonobvious and do not solve a technological problem with any technological solution. CBM review is, therefore, appropriate.

By law, no patent should issue if it claims: "A prior art method X," which is simply an abstract idea, and nothing more. Yet, the '107 patent claims are just that. The claims are drawn to abstract ideas, nothing more than artfully drafted to monopolize the abstract idea itself, as warned against in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012). Challenged claims 1-6 claim the abstract idea of centralizing distribution of abuse-prone drugs to reduce their associated risks without any meaningful limitations. The claimed steps can be performed by a human intermediary with no computer operation. (ROX1007, ¶¶ 46-47.)

The challenged claims are also unpatentable as anticipated by and obvious in view of the relevant prior art. Published materials that were used in an FDA Advisory Committee Meeting (the "Advisory Committee Art" or the "ACA")

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