WOCKHARDT BIO AG
Petitioner

v.

JAZZ PHARMACEUTICALS, INC.
Patent Owner

Case IPR: Unassigned

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,765,107 UNDER 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123

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reasonably likely that published materials used in an FDA Advisory Committee Meeting (the "Advisory Committee Art" or "ACA") would have rendered obvious claims 1-6 of the '107 patent more than a year before the '107 patent's earliest effective filing date. *See* IPR2015-00547, Paper 25 at 28-35.

Wockhardt Bio AG ("Wockhardt") submits this Petition for IPR ("Petition") also seeking cancellation of claims 1-6 of the '107 patent as unpatentable under 35 U.S.C. §103(a) over the Advisory Committee Art. This petition presents the same arguments, based on the same prior art presented in the IPR2015-00547 Petition (IPR2015-00547, Paper 3), and on which the Board instituted IPR in IPR2015-00547, along with a Motion for Joinder to join this Petition with the IPR2015-00547 proceedings. Indeed, this petition is an almost verbatim copy of the petition in IPR2015-00547, but missing the discussion of uninstituted Ground 2 in that case.

For the reasons explained below, and for the reasons the Board instituted IPR in IPR2015-00547, Wockhardt is reasonably likely to prevail on Ground 1 with respect to the challenged claims. Wockhardt requests that this Board institute

III. Statement of the precise relief requested and the reasons therefore

The Office should institute IPR under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80 and 42.100-42.123, and cancel claims 1-6—all claims—of the '107 patent as unpatentable under 35 U.S.C. § 103.

IV. Overview

A. Person of ordinary skill in the art ("POSA")

A POSA is a hypothetical person who is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. A POSA may work as part of a multi-disciplinary team and draw upon not only his or her own skills, but also take advantage of certain specialized skills of others in the team, to solve a given problem. (Ex. 1007, ¶21.) For example, a POSA would hold a Bachelor's or Doctor of Pharmacy degree and a license as a registered pharmacist with 3-5 years of relevant work experience, or a computer science undergraduate degree or equivalent work experience and work experience relating to business applications, including familiarity with drug distribution procedures. (*Id.*) Alternatively, a POSA may have a blend of computer science and pharmacy drug distribution knowledge and/or experience. (*Id.*) Such a

would have had knowledge of the literature concerning pharmacy practice and prescription drug distribution, such as the prior art presented herein, that was available before the earliest effective filing date of '107 patent, including knowledge about methods employed in the art. (*Id.*) Accordingly, a POSA would have been well aware of techniques related to the mitigation of the risk associated with the distribution of potentially hazardous, but therapeutically beneficial prescription drugs. (*Id.*)

B. State of the art

The '107 patent generally pertains to centralizing the distribution of hazardous or abuse-prone drugs. The '107 patent is listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" ("OB"), in connection with the prescription drug product Xyrem®. The active ingredient in Xyrem®—sodium oxybate, the sodium salt of gamma hydroxybuyrate ("GHB")—was well-known in the prior art as being susceptible to diversion and abuse. (Ex. 1007, ¶41.) So, as a prerequisite to FDA approval, the sponsor of Xyrem®, with assistance and direction from an FDA advisory committee, agreed to employ a centralized distribution program to attempt to reduce abusive and illicit uses of Xyrem®, now

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