

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

FOREST LABORATORIES, LLC, FOREST)
LABORATORIES HOLDINGS, LTD.,)
MERCK KGAA and MERCK PATENT)
GESELLSCHAFT MIT BESCHRÄNKTER)
HAFTUNG,)
) C.A. No. 15-272-GMS
Plaintiffs,) (consolidated)
)
v.)
)
ACCORD HEALTHCARE, INC.,)
)
Defendant.)

DEFENDANTS' ANSWERING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

Defendants¹ respectfully submit this brief in response to the proposed claim constructions set forth in the opening brief (D.I. 87) filed by Plaintiffs² on June 22, 2016, in this Hatch-Waxman case regarding proposed generic versions of the drug Viibryd®. The patents-in-suit are U.S. Patent Nos. 7,834,020 (the “’020 patent”), 8,193,195 (the “’195 patent”), 8,236,804 (the “’804 patent”), and 8,673,921 (the “’921 patent”), which all relate to crystalline forms of the chemical vilazodone hydrochloride (“HCl”) and their use in treating depression and other disorders.

II. LEVEL OF ORDINARY SKILL IN THE ART

Defendants concur with Plaintiffs’ assertion that a person of ordinary skill in the art (“POSA”) would have “at least a bachelor’s degree in chemistry, pharmaceutical sciences, or a related discipline, along with several years of experience working in pharmaceutical solid product development and/or solid state chemistry.” Plaintiffs’ Opening Claim Constr. Br. at 3 (D.I. 87, June 22, 2016) (“Pls.’ Br.”). In addition, a POSA would have taken the prescribed number of Good Manufacturing Practice trainings. *See* Declaration of Piotr H. Karpinski ¶¶ 17-18 (July 27, 2016) (“Karpinski Decl.”) (filed concurrently with this motion). For purposes of the disputed method of treatment claims, a POSA may also be an M.D. with extensive experience in the study and treatment of mood disorders, including depression. *See* Karpinski Decl. ¶ 19; Declaration of Eric Lenze ¶ 6 (July 27, 2016) (“Lenze Decl.”) (filed concurrently with this motion).

¹ The “Defendants” are Accord Healthcare, Inc., Alembic Global Holding SA, Alembic Pharmaceuticals Inc., Alembic Pharmaceuticals Ltd., Apotex Inc., Apotex Corp., Teva Pharmaceuticals USA, Inc., and InvaGen Pharmaceuticals Inc.

² The Plaintiffs are Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Merck KGaA, and Merck Patent Gesellschaft mit beschränkter Haftung.

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