Filed: April 22, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and
AMNEAL PHARMACEUTICALS LLC

Petitioners,

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD.

Patent Owner.

Case No. IPR2015-00643 (8,232,250 B2)
Case No. IPR2015-00644 (8,399,413 B2)
Case No. IPR2015-00830 (8,969,302 B2)[1,2]

PETITIONERS' OPPOSITION TO PATENT OWNER'S MOTION TO EXCLUDE

[1] Case Nos. IPR2015-01976, IPR2015-01980 and IPR2015-01981 have been joined with these proceedings.

[2] A word-for-word identical Opposition is being filed in each proceeding.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

RULES

I. INTRODUCTION

The three patents at issue relate to a 40 mg dose of glatiramer acetate ("GA") administered as few as three times per week. Since 1997, Patent Owner marketed a 20 mg GA product that required daily injections. From day one, the daily injections of Copaxone 20 mg were a problem. They caused injection site reactions and patients simply did not like daily administration. The problem became particularly acute as competitor products entered the market with less frequent dosing schedules. For years before the claimed August 2009 priority date, skilled artisans investigated dosing protocols that sought to address the well-known problems of daily administration of Copaxone 20 mg. The body of prior art gave the skilled artisan ample motivation to look to less frequent dosing schedules and to specifically believe a 40 mg three-times-per week schedule would be safe and efficacious. Patent Owner now seeks to exclude evidence that reinforces Petitioners' positions. The motion has no merit.

In its Motion, Patent Owner seeks to exclude five relevant references: Exhibits 1068, 1086, 1089, 1098 and 1140. Khan 2009 (Ex. 1068 and 1089), a clinical abstract published in 2009, reflects work that began no later than two years earlier in 2007. This work supports Petitioners' evidence that skilled artisans were motivated to investigate less-than-daily GA dosing regimens.

Teva's patient-directed website (Ex. 1086) instructs patients that they may

skip a dose of Copaxone if they forget to take a daily injection. This instruction is not new, and the website cites no post-priority date clinical data in support. As Dr. Green testified, and as other unchallenged documentary evidence shows, skilled artisans have told patients to skip a missed dose for years.

LeBano (Ex. 1098) establishes that even as of 2012, conventional techniques could not routinely evaluate gray matter pathology. This is proper evidence that as of August 2009, skilled artisans could not easily evaluate gray matter atrophy.

The Wolinsky Transcript (Ex. 1140) is an excerpt from the deposition testimony of Dr. Jerry Wolinsky, the principal investigator on Teva GA clinical trials (including one relied on in these proceedings by Patent Owner) and a physician who qualifies as one of the world's most knowledgeable about GA. Dr. Wolinsky testified that he prescribed Copaxone 20 mg GA on an every-other-day basis long before the August 20, 2009 priority date to combat injection site reactions in patients. That Dr. Wolinsky prescribed GA less frequently than daily for the purpose of reducing injection site reactions is powerful evidence that skilled artisans were interested in (and were indeed using) GA on a less than daily basis. Dr. Wolinsky's testimony also flatly contradicts Patent Owner's remarkable argument that skilled artisans would have expected *fewer* GA injections to *increase* injection site reactions. Patent Owner not only failed to disclose Dr. Wolinsky's testimony to the Board, but they constructed roadblocks to try to prevent

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