

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.
Petitioner,

v.

UCB BIOPHARMA SPRL
Patent Owner.

U.S. Patent No. 8,633,194 to Fanara *et al.*

Issue Date: January 21, 2014

Title: Pharmaceutical Composition of Piperazine Derivatives

Inter Partes Review No.: IPR2019-00400

**PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION TO
EXCLUDE EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(c)**

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I. INTRODUCTION

UCB is seeking to exclude damaging excerpts from the prior art book series of its *own expert*—Dr. Niazi. That cannot be understated, because UCB’s motion seeks no more than to allow UCB to ignore those impeaching excerpts while at the same time advancing the Niazi Declaration for the truth in support of its tenuous validity positions. This approach should not be condoned.

Dr. Niazi was very aware of the content in the Niazi Series before he submitted his Declaration in this proceeding. EX1043, 220:1-221:21, 266:19-21.¹ Moreover, there is no dispute that a POSA in this matter would have used the Niazi Series. EX1043, 262:16-19; 8:22-9:2. Dr. Niazi must have known (or should have known) that the information in the Niazi Series conflicted with the positions he was advancing in this proceeding. Whether deliberately, or through sheer negligence on the part of Dr. Niazi, the excerpts of the Niazi Series were withheld

¹ To eliminate any doubt as to Dr. Niazi’s exhaustive understanding of the contents of the Niazi Series, when Dr. Niazi provided his PTAB Declaration (October 14, 2019), the 3rd Ed. of the Niazi Series was scheduled to come out a week after Dr. Niazi’s deposition in this proceeding. EX1040, EX1043, 180:4-6, 220:7-221:10; 242:21-243:11. To that end, Dr. Niazi had been laboriously editing the Niazi Series during “all” of 2019. EX1043, 220:17-221:7.

in violation of 37 C.F.R. § 45.51(b)(1)(iii) which then allowed UCB and Dr. Niazi to advance factually misleading or simply untrue opinions and statements to the PTAB in the Niazi Declaration. EX2034.

For example, the Niazi Series contained no less than 33 prior art formulations having a 9:1 ratio of methylparaben to propylparaben. EX1031, EX1032-1037, EX1043, 171:16-172:14, 173:15-175:19. Yet, when opining that such a 9:1 ratio would not have been obvious, Dr. Niazi made no mention of his awareness of these 33 prior art 9:1 formulations. The Niazi Series also reported the prior art 9:1 ratio of methylparaben to propylparaben formulation of the cetirizine hydrochloride syrup. EX1031 (entry #4); EX1034, 99; EX1043, 185:9-25. Further, Dr. Niazi stated that he was unaware of any prior art examples where the combined amount of methyl and propyl paraben was less than 2 mg/mL; the Niazi Series exemplified no less than seven such prior art examples. EX2034, ¶184; EX1031; EX1043, 215:24-217:3, 239:16-22. In addition to impeaching numerous other material propositions, the Niazi Series showed that Dr. Niazi ignored certain material facts about UCB's commercial cetirizine hydrochloride formulation. EX1031, (entry #4); EX1034, 99; EX1043, 185:9-25, 264:22-25. Specifically, Dr. Niazi suspected that the Niazi Series' 9:1 prior art cetirizine hydrochloride formulation was UCB's cetirizine hydrochloride formulation, but refused to confirm such facts with UCB. EX1043, 181:7-9, 184:5-12. Apotex,

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