Filed: May 10, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., ACTAVIS LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL CORP., and HIKMA PHARMACEUTICALS, LLC,

Petitioners,

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner.

Case IPR2016-01332[1]
Patent 8,822,438 B2

PETITIONERS' OPPOSITION TO PATENT OWNER'S MOTION TO EXCLUDE

[1] Case IPR2017-00853 has been joined with this proceeding.

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I. INTRODUCTION

The patent at issue (U.S. Patent No. 8,822,438, or the '438 patent) relates to the administration of abiraterone acetate and prednisone to treat metastatic castration-resistant prostate cancer ("mCRPC"). Abiraterone acetate and prednisone have both been in the prior art since at least the mid-1990s, and both were known to be useful agents in prostate cancer treatment. Janssen now seeks to uphold a patent on the combination of these two agents, arguing that a skilled artisan would not have been motivated to use prednisone—commonly co-administered with other anti-cancer agents—with abiraterone acetate. The prior art provided ample motivation to combine these drugs. Indeed, during prosecution of the '438 patent, the Examiner found that the claimed method was *prima facie* obvious over the prior art and allowed the patent to issue solely on the basis of Janssen's commercial success arguments. Janssen now moves to exclude evidence that reinforces Petitioners' obviousness positions. The motion has no merit.

In its Motion, Janssen seeks to exclude three categories of evidence: (1) expert declarations and exhibits on the subject of commercial success; (2) sections of Petitioners' expert declarations and exhibits that Patent Owner argues are irrelevant; and (3) certain exhibits Janssen claims are not authentic or constitute inadmissible hearsay.

None of this evidence should be excluded. In order to evade Petitioners' strong commercial success rebuttal, Janssen misconstrues the aim of Petitioners' commercial success arguments by characterizing those arguments as a "ground" for invalidating the '438 patent. Not so. Petitioners' arguments simply set forth why the patent examiner possessed an incomplete picture of commercial success when allowing the '438 patent to issue solely on that basis. Petitioners thus set forth a fulsome commercial success analysis to establish why this secondary indicia does not overcome the obviousness of the '438 patent.

Janssen also asserts that certain exhibits and paragraphs of Petitioners' expert declarations are irrelevant simply because they are not explicitly cited within Petitioners' Reply or Petition. The record is not limited to the Petitioners' Petition and Reply Brief. The objected-to exhibits are discussed in Petitioners' expert declarations, and the objected-to declaration paragraphs provide highly relevant information and detail supporting Petitioners' obviousness arguments.

Finally, Janssen asserts that numerous exhibits lack authenticity, failing to even mention Petitioners' supplemental evidence. Janssen also claims three exhibits constitute hearsay, only providing reasoning for two of the three exhibits. All three exhibits do not constitute inadmissible hearsay and should not be excluded.

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