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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioners,

v.

JANSSEN ONCOLOGY, INC.
Patent Owner.

Case IPR2016-01332
Patent 8,822,438 B2

PATENT OWNER'S RESPONSE

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I. INTRODUCTION

This proceeding involves a breakthrough in the treatment of prostate cancer patients with an advanced stage of the disease known as metastatic castration-resistant prostate cancer ("mCRPC"). Before the invention of U.S. Patent No. 8,822,438 ("the '438 patent"), these patients faced a dismal prognosis, with few meaningful treatment options. The invention – a two time FDA priority approved method of administering abiraterone acetate with prednisone that corresponds directly to the claims of the '438 patent – changed this picture dramatically; prostate cancer patients treated with this therapy enjoy a striking increase in patient survival that could not have been predicted.

Despite this unpredictable result, and the striking commercial success of this new and effective treatment, Mylan Pharmaceuticals Inc. ("Mylan") contends it would have been obvious to the skilled person to co-administer prednisone with abiraterone acetate, advancing in its petition the same hindsight-infused theory of obviousness advanced previously by Amerigen Pharmaceuticals, Ltd. (*See* IPR2016-00286) ("Amerigen IPR").[1] (*See* Mylan ID at 2-3). Under that theory, a skilled person would have co-administered abiraterone with prednisone based on experiences with another "CYP17 inhibitor," ketoconazole, which Mylan contends was a safe and effective method for treating prostate cancer before 2006.

[1] IPR2016-0317 was joined with IPR2016-00286.

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