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

**DECLARATION OF IAN JUDSON, MD
IN SUPPORT OF JANSSEN ONCOLOGY, INC.'S
PATENT OWNER RESPONSE**

I, Ian Judson, M.D. hereby declare as follows:

1. I am over the age of eighteen (18) and am otherwise competent to make this Declaration. I have personal knowledge of the facts set forth in this Declaration and am competent to testify to the same. I am a Consultant Medical Oncologist at the Royal Marsden. I was appointed Senior Lecturer at the Royal Marsden and The Institute of Cancer Research (ICR) in 1989, and became Professor of Cancer Pharmacology in 2001. I have been involved in the early development of a number of anti-cancer drugs including carboplatin, temozolomide, raltitrexed, imatinib and abiraterone acetate.

2. I have been asked by counsel for Patent Owner Janssen Oncology Inc. ("Janssen") to provide a short declaration as background for the panel of Administrative Patent Judges of the Patent Trial and Appeal Board of the United States Patent and Trademark Office ("Panel") as it considers issues relating to the patentability of U.S. Patent No. 8,822,438 (the '438 Patent) (Ex. 1001) in an *inter partes* review requested by Mylan Pharmaceuticals, Inc. (hereinafter "Mylan") in Case No. IPR2016-01332. Other than compensation for discussions leading to this declaration, I have personally received no funding from Janssen Oncology Inc. but I have received what is termed Rewards to Discoverers payments from the ICR for my involvement in the development of abiraterone.

3. I was the principal investigator for a series of phase one trials carried out in 1998-1999 in which the 17α-hydroxylase/C17,20-lyase inhibitor abiraterone acetate (CB7630) was tested in humans for the first time. I was assisted by Professor David Dearnaley, a Clinical Oncologist at the Royal Marsden with a special interest in prostate cancer, and a number of investigators from other hospitals. The ICR / Royal Marsden were initially partnered with Boehringer Ingelheim for this project, and Boehringer Ingelheim assisted by synthesising a batch of clinical grade abiraterone acetate for the phase one trials.

4. The trials involved three studies conducted to determine the dose of abiraterone acetate that would result in suppression of testosterone and to obtain safety, pharmacokinetic and endocrine data. The scope of the studies, including the numbers of patients and duration of treatment was restricted by the limited supply of clinical grade abiraterone acetate. The results of these phase one trials were eventually reported in *O'Donnell et al., BJC, 90, 2317-2325 (2004)*. I have been asked to refer to this publication as "O'Donnell" (Ex. 1003).

5. The studies showed that specific inhibition of the CYP17 enzyme by abiraterone acetate could reduce testosterone levels in both castrate and non-castrate males to below castrate levels. This was proof-of-principle of the action of the drug on testosterone levels.

6. Abiraterone acetate proved to be well tolerated. Mild side effects included headache, flushing and low mood. Cortisol levels were in general maintained. Although the response to an injection of synthetic ACTH (described as the "Synacthen test" in O'Donnell (Ex. 1003)) was reduced, this was not thought at the time to be a major concern, since cortisol levels were maintained and there was still some response to ACTH. Our conclusion, as summarised in page 2323 of O'Donnell (Ex. 1003), was that there were three possibilities: (i) that concomitant therapy with glucocorticoid would be required on a continuous basis, (ii) that glucocorticoid would be needed only at times of physiological stress, when patients became symptomatic, or (iii) that there would be no requirement for glucocorticoid at all. Regarding (ii), the option discussed at the time, if there had been concerns (which there were not), was to give patients a steroid warning card, and a supply of hydrocortisone tablets to take in an emergency, such as infection, trauma etc. At the time, hydrocortisone was the standard steroid administered as a glucocorticoid replacement with ketoconazole and aminoglutethimide, which were inhibitors of steroid synthesis that were known to reduce cortisol levels.

7. Subsequent to the completion of the study and submission of the final report at the end of 1999, Boehringer Ingelheim decided not to continue their involvement in the project. Attempts to find an alternative commercial

partner for clinical development proved extremely difficult. In the years following 2000, a number of major multinational pharmaceutical companies were approached. On one trip to the United States I visited several such companies in Princeton and Philadelphia. In these meetings, we presented the results of the phase one trials reported in O'Donnell. Following these meetings, none of these companies proved willing to support taking abiraterone acetate into further clinical trials.

8. During a similar period, we submitted the O'Donnell manuscript to various medical journals, including Clinical Cancer Research, but were met with scepticism and the study was not published (as O'Donnell) until 2004, in the British Journal of Cancer. No further data were generated or analysis performed after the rejections and before the eventual publication in O'Donnell.

9. In response to our submission of the O'Donnell manuscript to Clinical Cancer Research, I received a Clinical Cancer Research Peer Review Letter dated May 12, 2003, a true and correct copy of which was filed as Exhibit 2030 in IPR2016-01332 on March 8, 2017.

10. In April 2004, Cougar Biotechnology Inc. signed a licence agreement giving it rights to develop and commercialise abiraterone acetate. I took part in initial discussions with Cougar at the end of 2003 / early 2004 but played no significant role in the subsequent clinical development of the drug.

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