In the United States Patent and Trademark Office

Before the Patent Trial and Appeal Board

MYLAN PHARMACEUTICALS INCORPORATED,

Petitioner

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

U.S. Patent No. 8,822,438 to Auerbach *et al.*
Issue Date: September 2, 2014
Title: Methods and Compositions for Treating Cancer

Inter Partes Review No. IPR2016-01332

DECLARATION OF MARC B. GARNICK, M.D.

I, Marc B. Garnick, M.D., do hereby declare:

I. INTRODUCTION

1. I am making this declaration at the request of Mylan Pharmaceuticals Inc., in the matter of the *Inter Partes* Review (IPR) of U.S. Patent No. 8,822,438 (the "'438 Patent"), as set forth in the above caption.

A. Education and Professional Background

2. I am a medical oncologist specializing in the care of patients with prostate cancer in the Division of Hematology and Oncology, Department of Medicine at the Beth Israel Deaconess Medical Center, Harvard Medical School, in Boston MA. My clinical and research interests have focused on urologic cancers, with a special interest in prostate cancer. I am actively involved in clinical research and in the past have devoted my professional activities to the development of drugs that are currently being used in the management of prostate cancer. I serve as the medical director for Cancer Services Brockton Hospital/Signature Health Care, Cambridge Health Alliance, which includes Cambridge Hospital and Whidden Memorial Hospital and the medical liaison for all of the cancer services that the BIDMC provide. I am the director of Cancer Programs for Network Development at the Beth Israel Deaconess Medical Center. I am Gorman Brothers Clinical Professor of Medicine at Harvard Medical School, an endowed professorial chair in medicine.

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3. I received a Bachelor of Arts degree in Biology from Bowdoin College, Brunswick, Maine. I obtained my medical degree from the University of Pennsylvania School of Medicine (now the Perelman School of Medicine at the University of Pennsylvania) in 1972. I completed my internship and residency in internal medicine at the Hospital of the University of Pennsylvania in 1974. I then completed two fellowships: one at the National Institutes of Health in the National Institute of Arthritis, Metabolism and Digestive Diseases in 1976 and then a fellowship in Medical Oncology at the Dana Farber Cancer Institute, Boston MA in 1978. My *curriculum vitae* is attached as Exhibit A.

4. From 1978 until 1996, I practiced medicine at the Dana Farber Cancer Institute and Brigham and Women's Hospital in Boston, MA. Since 1996, I have practiced at the Beth Israel Deaconess Medical Center. Between the years of 1987 and 2006, I also held positions at the Genetics Institute and Praecis Pharmaceuticals where my responsibilities dealt with the development of new drug therapies for cancer, including prostate cancer and other medical illnesses. I served as the academic principal investigator for the development and approval of leuprolide acetate (Lupron®), one of the world's most widely-prescribed medicines for prostate cancer, and most recently served as the industry leader for abarelix, a pharmaceutical that is used for a subset of patients with prostate cancer, which was previously marketed in the United States and Europe.

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5. I have been directly involved in the development of multiple drugs that have gained approval by both United States regulatory agencies and European regulatory agencies. I have participated as either an academic or industry leader and principal investigator/contributor for multiple drugs that have gained either FDA or European regulatory approvals.

6. I have had issued to me over 20 patents, mainly dealing with drug development and treatments for prostate cancer.

7. I enclose a representative sample of the types of activities I have been involved in relating to the diagnosis, treating, and evaluation of therapies for prostate cancer, with an emphasis on Lupron® and other hormonal therapies:

B. Representative sample of accomplishments related to prostate disorders, prostate cancer, and Lupron®-treated related disorders[1]

1. Prostate cancer and Lupron®-related accomplishments

a. Lupron®-related and LHRH analogue-related

- Academic Principal Investigator and one of three academic presenters to the FDA advisory committee related to the initial FDA approval of Lupron® for prostate cancer;

[1]Lupron® is one of the world's most prescribed therapies for prostate cancer; I served as the principal investigator that led to its approval by FDA and other worldwide regulatory bodies in the mid-1980s.

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- Lead investigator on multiple Phase II studies and the pivotal Phase III study of Lupron® for prostate cancer, published in the New England Journal of Medicine;
- Investigator on multiple follow-on studies following the approval of Lupron®, in order to assess its post-marketing safety and efficacy;
- Lead developer of abarelix, the first approved LHRH/GnRH antagonist for prostate cancer in the U.S., Germany, and other EU Countries;
- Co-organizer (with the late William Fair, M.D.) of the annual International Conferences on Neoadjuvant Hormonal Therapy for Prostate Cancer; and
- Inventor listed on multiple patents related to the use of LHRH analogues for the management of prostate cancer and other Lupron®-related disorders outside of prostate cancer (adjunct to mammography for dense breast imaging, differential suppression of FSH (follicle-stimulating hormone) between Lupron® and LHRH antagonists).

b. Prostate cancer-related

- Founder of Hershey Foundation for Basic and Clinical Research in Prostate Cancer, housed at the Beth Israel Deaconess Medical Center, that established basic and clinical research programs, young investigator awards, educational colloquia and *de novo* establishment of a prostate cancer tissue bank, available for use by all Massachusetts researchers;

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- Reviewer for SPORE (Specialized Program of Research Excellence) grant applications in the formative years of the SPORE program;
- Panel Reviewer on NIH Consensus Development Conference for management of clinically localized prostate cancer; and
- Special Government Employee (SGE) for United States Food and Drug Administration (FDA) and have served on approximately 15 advisory committees as an invited and voting member in multiple divisions of FDA.

2. Publishing and educational accomplishments

- Author, The Patient's Guide to Prostate Cancer, published by Viking/Penguin Imprints (a lay book on prostate cancer, based upon several articles initially published in Scientific American);
- Editor in chief and founder of Perspectives on Prostate Diseases, a quarterly journal published by Harvard Medical School's Harvard Health Publications, and founder of a companion website (available to anyone with an internet connection) at www.harvardprostateknowledge.org. This has now been supplanted by The Harvard Medical School Annual Report on Prostate Diseases;
- Founder and director (until 1992), HMS Continuing Medical Educational program entitled Urologic Cancer, the premier course in Urologic Cancer for physicians;

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- Author, American College of Physicians policy statement on Screening for Prostate Cancer, published through its PIER (Physician Information Educational Resource), a point of care resource for physicians worldwide;
- Author (along with three others) of a widely distributed prostate cancer and PSA decision tool for internists and primary care physicians, for Harvard Institutions Risk Management Foundation;
- Lecturer at multiple national and international colloquia on prostate-related disorders and prostate cancer and LHRH analogues, including Lupron® and other hormonal therapies for prostate cancer;
- Founder of Prostate Cancer Educational Breakfast Series, a series of colloquia for general education related to prostate cancer;
- Participant in several regional programs to increase awareness of prostate cancer issues for the African-American Communities;
- Lead author on two review articles on prostate cancer screening, published in Annals of Internal Medicine; and
- First author on three separate Scientific American articles on issues relating to prostate cancer, including an evaluation of the effectiveness of various therapies.

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8. In 2010, I was appointed as a Special Government Employee (SGE) to the United States Food and Drug Administration (FDA) Oncology Drug Advisory Committee (ODAC) to review matters related to cancer in general and prostate cancer specifically. I was a member of the FDA ODAC review panel that deliberated on the use of the five-alpha-reductase inhibitors, finasteride and dutasteride, as a means of preventing the development of prostate cancer, and recently served on the FDA ODAC advisory panel that deliberated the issues in drug development associated with non-metastatic castrate resistant prostate cancer. In 2014, I was a voting member of the FDA advisory committee in the deliberations of testosterone replacement therapy conducted by FDA in a joint meeting of Drug Safety and Division of Urologic Drug products.

9. I have participated as both an academic and industry investigator in the development of agents for the treatment of prostate cancer, and lecture nationally and internationally on issues related to prostate cancer diagnosis, management, treatment and assessment of outcomes.

10. I am Board Certified in both Internal Medicine and Medical Oncology. My clinical practice at the Beth Israel Deaconess Medical Center focuses on the management and counseling of patients who have been diagnosed with all stages of prostate cancer, including those eligible for treatments such as abiraterone and prednisone, as well as individuals who are questioning their risk of

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having prostate cancer. The discussion about the use of alternate or complementary forms of interventions is discussed frequently. In my position as Editor in Chief of the HMS Annual Report on Prostate Diseases, we cover, assess and write about information related to complementary and alternative methods of prostate cancer interventions.

11. I am an affiliate member of the American Urological Association; Fellow of the American College of Physicians; member of the American Society of Clinical Oncology and have held leadership positions in that organization; as well as other organizations. I have been asked to provide plenary lectures at the National Meetings of the American Urological Association and the American College of Physicians on topics that include an understanding of prostate cancer. I have also completed 15- and 9-year terms, respectively, as Trustee of Bowdoin College (2011); and Trustee of Penn Medicine and the Perelman School of Medicine of the University of Pennsylvania, where I have served as interim chairperson of its subcommittee on Research, Education and Patient Care.

12. I am, and have been, a reviewer for a number of medical journals, including New England Journal of Medicine; Annals of Internal Medicine; Journal of Clinical Oncology; Urology; British Journal of Urology International; and others. Over the past 30 years, I have peer reviewed numerous papers submitted for publication to scientific and medical journals which will often include studies

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that employ randomized, double-blind, placebo controlled studies. As part of this review process, I will evaluate the adequacy of the design, the conduct of the study and clinical research; and make an assessment as to the integrity of the data presented, and accuracy and rigor of the statistical methodologies employed. I also serve as the only physician-medical advisor to the World Book Encyclopedia. I have written and reviewed numerous US FDA regulatory submissions dealing with the evaluation of novel and investigational agents and have authored multiple Integrated Summary Basis of Risk Benefit documents, Integrated Summary of Safety and Efficacy, and Clinical Investigational Brochures, and contributed in meaningful ways to regulatory submissions from IND filings to NDA filings and post marketing approvals.

13. As detailed in my CV, I have engaged in scholarly research and writing from several perspectives: that of an academic principal investigator on many drugs that were approved or that had their label extended; as a leader in industry teams that develop pharmaceuticals, leading to approval by both U.S. and foreign regulatory bodies; and as a governmental employee who has advised members of FDA on the adequacy, conduct and interpretation of studies related to prostate cancer, including endpoints of studies, modulation of safety issues related to treatments, and surrogate markers of prostate cancer outcomes.

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14. I have authored several hundred articles, book chapters, books, reviews, and monographs pertaining to prostate cancer.

15. Based upon my education, training and experience, as summarized above, I believe I am qualified to provide opinion testimony as an expert in 1) medical oncology; 2) urologic cancer; 3) prostate cancer, including diagnosis, treatment, prevention, assessment of metrics to evaluate the disease, regulatory conduct of studies of prostate cancer, and evaluation of methods that claim efficacy and safety in prostate cancer; 4) all hormonal therapies for prostate cancer; and 5) assessment of adequate study design and conduct of studies that evaluate safety and efficacy carried out by academic, industry and government bodies.

16. In the past four years, I have testified as an expert in either deposition or trial in approximately 10 separate medical malpractice proceedings. I am being compensated at an hourly rate of $750/hour and am available to appear live for testimony in support of my opinions. My compensation in no way depends on the outcome of this proceeding. The opinions to which I will testify are based on the education, experience, training and skill that I have accumulated in the course of my career as a practicing medical oncologist and researcher, as well as materials I have reviewed in connection with this case.

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II. MATERIALS CONSIDERED

17. The list of materials I considered in forming the opinions set forth in this declaration includes the following:

Exhibit	Description
MYL 1001	U.S. Patent No. 8,822,438 to Auerbach and Belldegrun, "Methods and Compositions for Treating Cancer" ("the '438 patent")
MYL 1003	O'Donnell, A. *et al.*, "Hormonal impact of the 17α-hydroxylase/C17,20-lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer," Br. J. Cancer 90:2317-2325 (2004) ("O'Donnell")
MYL 1004	Gerber, G.S. *et al.*, "Prostate specific antigen for assessing response to ketoconazole and prednisone in patients with hormone refractory metastatic cancer," J. Urology 144(5):1177-9 (1990) ("Gerber")
MYL 1005	U.S. Patent No. 5,604,213, Barrie S.E. *et al.*, "17-Substituted Steroids Useful In Cancer Treatment" ("the '213 patent")
MYL 1006	Tannock, I. *et al.*, "Chemotherapy with mitoxantrone plus prednisone or prednisone alone for symptomatic hormone- resistant prostate cancer," J. Clin. Oncology 14(6):1756-1764 (1996)
MYL 1009	Ryan, C.J. *et al.*, "Abiraterone in metastatic prostate cancer without previous chemotherapy," New Engl. J. Med. 368:138-148 (2012).
MYL 1010	January 11, 2013 Response (excerpt from prosecution history of '438 patent)
MYL 1012	June 4, 2013 Response (excerpt from prosecution history of '438 patent)
MYL 1018	Zytiga® Prescribing Information (2011)
MYL 1019	Zytiga® Prescribing Information and Co-administration Brochure (2015)
MYL 1020	Harris, K.A. *et al.*, "Low dose ketoconazole with replacement doses of hydrocortisone in patients with progressive androgen independent prostate cancer," J. Urol. 168(2):542-5 (2002)
MYL 1021	Oh, W., "Secondary hormonal therapies in the treatment of prostate cancer," Urology, 60(Supp. 3A):87-93 (2002)
MYL 1022	Tannock, I. *et al.*, "Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer," N. Eng. J. Med. 351:1502-12 (2004)

Exhibit	Description
MYL 1023	Attard, G. *et al.*, "Selective blockade of androgenic steroid synthesis by novel lyase inhibitors as a therapeutic strategy for treating metastatic prostate cancer," Br. J. Urol. 96(9):1241-1246 (2005)
MYL 1024	Hellerstedt *et al.*, "The Current State of Hormonal Therapy for Prostate Cancer," CA Cancer J. Clin. 52:154-179 (2002)
MYL 1025	Kasper, D.L. *et al.* (Eds.), Harrison's Principles of Internal Medicine 549 (16th ed. 2005)
MYL 1026	Auchus, R.J. "The genetics, pathophysiology, and management of human deficiencies of P450c17," Endocrinol. Metab. Clin. North Am. 30(1):101-119 (2001)
MYL 1027	Costa-Santos, M. *et al.*, "Two prevalent CYP17 mutations and genotype-phenotype correlations in 24 Brazilian patients with 17-hydroxylase deficiency," J. Clin. Endocrin. & Metabol. 89(1):49-60 (2004)
MYL 1028	Jubelirer, S.J. *et al.*, "High dose ketoconazole for the treatment of hormone refractory metastatic prostate carcinoma," J. Urol. 142(1):89-901 (1989)
MYL 1029	U.S. Patent 5,688,977, Sisti, N.J. *et al.*, "Method for Docetaxel Synthesis"
MYL 1030	U.S. Food and Drug Administration ("FDA") FDA News Release dated May 19, 2004, "FDA Approves New Indication for Taxotere-Prostate Cancer"
MYL 1031	Tannock, I. *et al.*, "Treatment of metastatic prostatic cancer with low-dose prednisone: evaluation of pain and quality of life as pragmatic indices of response," J. Clin. Oncology, 7:590-7 (1989)
MYL 1033	Scher, H.I. *et al.*, "Increased survival with enzalutamide in prostate cancer after chemotherapy," New Eng. J. Med. 367:1187-97 (2012)
MYL 1034	de Bono, J.S. *et al.*, "Abiraterone and increased survival in metastatic prostate cancer," New Engl. J. Med. 364:1995-2005 (2011)
MYL 1035	Orange Book listing for Zytiga®
MYL 1078	Barrie *et al.*, "Pharmacology of novel steroidal inhibitors of Cytochrome $P450_{17\alpha}$ (17α-hydroxylase/C17,20 lyase)," J. Steroid Biochem. Molec. Biol. 50:267-73 (1994)

Exhibit	Description
MYL 1079	Fakih, M. *et al.*, "Glucocorticoids and treatment of prostate cancer: A preclinical and clinical review," Urology 60:553-561 (2002)
MYL 1080	Lam, J.S. et al., "Secondary hormonal therapy for advanced prostate cancer," J. Urology 175:28-34 at 30-31(2006).

III. LEGAL STANDARDS

18. In my opinion, given the disclosure of the '438 Patent, I consider a person of ordinary skill in the art at the time of filing of this patent to be someone who is a physician specializing in urology, endocrinology or oncology, or holds a Ph.D. in pharmacology, biochemistry or a related discipline.[2] Additional experience could substitute for the advanced degree.

19. I understand that, to the extent necessary, a person of ordinary skill in the art may collaborate with one or more other persons of skill in the art for one or more aspects in which the other person may have expertise, experience and/or knowledge that was obtained through his or her education, industrial or academic experiences.

20. I understand that a person of ordinary skill in the art may consult with an endocrinologist, oncologist or medical biochemist and thus may rely on the opinions of such specialists in evaluating the claims.

21. I have been told that the obviousness inquiry is a question of law based on four factual predicates: (1) "the scope and content of the prior art," (2) the

[2] A related discipline may include, for example, pharmaceutical sciences.

"differences between the prior art and the claims at issue," (3) "the level of ordinary skill in the pertinent art," and (4) "secondary considerations" such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results. I have been told that the combination of familiar pharmaceutical elements according to known methods is likely to be obvious when it does no more than yield predictable results. I have also been told that the motivation to combine may be found in many different places and forms. Thus, for example, a challenger is not limited to the same motivation that the patentee had.

22. I have been informed that secondary considerations of non-obviousness include commercial success, satisfaction of a long-felt unmet need, unexpected results, prior failure of others, industry praise, licensing, and copying. I understand that evidence of such secondary considerations is only relevant to the obviousness analysis if the patentee can show a direct link, or nexus, between the secondary consideration and the claims of the patent, and that the evidence must be commensurate in scope with the asserted claims. I also understand that for results to be considered unexpected for these purposes, there must be a substantial difference from the prior art. In other words, a difference of kind, and not merely of degree.

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IV. BACKGROUND AND THE '438 PATENT

A. Background

23. The prostate gland is part of the human male reproductive system and is involved in the synthesis and storage of seminal fluid. Prostate cancer is an androgen-dependent disease, meaning that the growth of prostate cancer is dependent upon male androgens such as testosterone and dihydrotestosterone (DHT) and derivatives, and is the most common non-cutaneous cancer among men and the second-most most common form of death from cancer among men in the United States. MYL Ex. 1001 ('483 patent) col. 1, ll. 20-52; MYL Ex. 1022 (Tannock) at 1503.

24. The activation of androgen receptors ("AR") on prostate cells regulates the transcriptional activation of a wide variety of genes involved in controlling the growth of the normal prostate gland and in promoting the progression and proliferation of prostate cancer. MYL Ex. 1023 (Attard) at 1241; MYL Ex. 1003 (O'Donnell) at 2317. The two most important androgens responsible for activating the AR are testosterone and its derivative DHT. Testosterone is synthesized primarily in the testes and secondarily in the adrenal gland. MYL Ex. 1003 (O'Donnell) at 2317. In non-castrate men, the testicles are responsible for producing the vast majority of circulating testosterone. MYL Ex. 1003 (O'Donnell) at 2317. The production of testosterone is regulated by

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endocrine feedback loops involving the hypothalamus and pituitary glands that respond to varying levels of hormones involved in the testosterone synthetic pathway, including hormonal precursors to testosterone, and testosterone itself.

25. The treatment options for treating prostate cancer depend to a great extent on whether the prostate cancer is confined or localized to the prostate, whether it is regionally advanced, which would include extension beyond the prostate capsule or into the seminal vesicles, or whether it has spread (i.e., metastasized) to other organs distant from the prostate, such as lymph nodes or bone. The goal of treating primary prostate cancer (i.e., prostate cancer localized to the prostate) is to remove the prostate gland, seminal vesicles and regional draining lymph nodes by surgical techniques or with the use of radiation therapy. For patients with advanced or metastatic prostate cancer, the mainstay of treatment is designed to interfere with the proliferation of prostate cancer cells by interrupting production of testosterone and DHT in the testes, or interfere with their function. MYL Ex. 1003 (O'Donnell) at 2317; MYL Ex. 1024 (Hellerstedt) at 154, Fig. 2.

26. As of 2006, the most common course of treatment for localized prostate cancer would have been surgical removal of the prostate (prostatectomy) or radiation therapy of the prostate. MYL Ex. 1001 ('438 patent) col. 1, ll. 26-28; MYL Ex. 1023 (Attard) at 1241. There are circumstances in which patients with

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localized prostate cancer, who are primarily treated with radiation, are also treated with pharmaceutical hormone agents that lower testosterone and DHT levels.

27. A significant number of patients either progress after localized therapy or present with metastatic/non-localized prostate cancer. MYL Ex. 1023 (Attard) at 1241. Metastatic prostate cancer is cancer that has spread beyond the primary tumor in the prostate to other parts of the body. "Prostate cancer metastasizes most often to pelvic lymph nodes and to bone," and the most significant symptom, if symptoms are present, may include pain, depending upon the anatomic location of the metastatic deposits. MYL Ex. 1025 (Harrison's) at 549; MYL Ex. 1006 (Tannock) at 1756. Non-localized disease and/or metastatic disease is usually treated with reduction of testosterone production by either hormonal manipulation or orchiectomy (surgical removal of the testicles).

28. The treatment of metastatic prostate cancer requires systemic therapy. It was known that as much as ten percent of baseline circulating testosterone remains in prostate cancer patients who have undergone localized androgen ablation through surgical or medical castration. MYL Ex. 1003 (O'Donnell) at 2317. The adrenal glands were known to be responsible for the production of a substantial amount of this extratesticular source of testosterone, which was known to be an important alternative source of AR stimulation. MYL Ex. 1003 (O'Donnell) at 2317. The first-line treatment for metastatic prostate cancer

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patients since at least the 1980s has involved systemic suppression of testicular testosterone production, either medically with estrogen agents or more routinely with so called LHRH analogues (both LHRH agonists such as Lupron and LHRH/GnRH antagonists such as degarelix). In addition, abrogation of the remaining adrenal sources of androgens can be blocked by the co-administration of agents that are antagonists of the androgen receptor, so called antiandrogens. These therapies are known as hormonal or endocrine therapies. MYL Ex. 1024 (Hellerstedt) at 154.

29. As the diagram below shows, approximately 90% of the testosterone is produced in the testes and 10% in the adrenals. MYL Ex. 1024 (Hellerstedt) at 159, Fig. 2. The diagram also shows that LHRH is produced in the hypothalamus, a small gland in the brain. "LHRH is normally released [by] the hypothalamus in pulses." MYL Ex. 1024 (Hellerstedt) at 157. This leads to the pulsatile release of LH from the anterior pituitary. MYL Ex. 1024 (Hellerstedt) at 157. LH then acts on receptors on the Leydig cells of the testes, leading to production of testosterone. MYL Ex. 1024 (Hellerstedt) at 157. LHRH agonists such as Lupron® bind to LHRH receptors in the hypothalamus and stimulate the increased production and release of LH by the pituitary. MYL Ex. 1024 (Hellerstedt) at 157. Initially, this surge in LH triggers a surge of testosterone production. *See, e.g.*, MYL Ex. 1024 (Hellerstedt) at 157, 159, Fig. 2.

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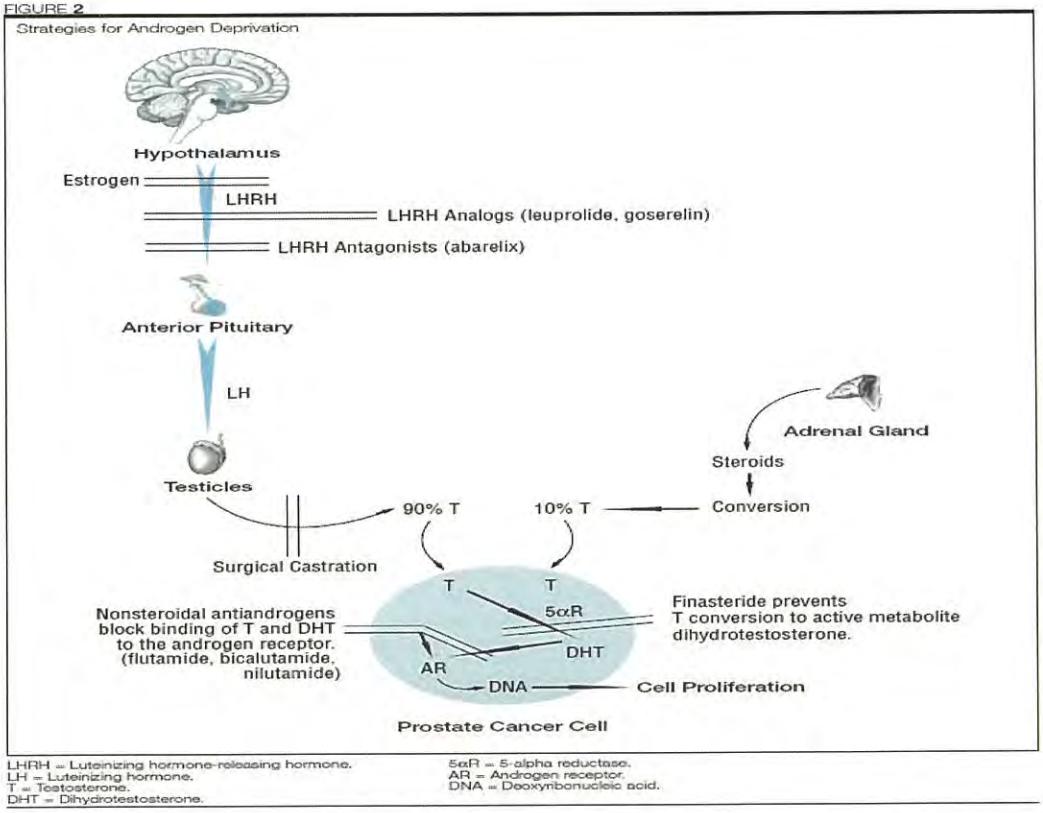
FIGURE 2



LHRH = Luteinizing hormone-releasing hormone.
LH = Luteinizing hormone.
T = Testosterone.
DHT = Dihydrotestosterone.
5αR = 5-alpha reductase.
AR = Androgen receptor.
DNA = Deoxyribonucleic acid.

30. The testosterone surge is followed by a decrease in testosterone production as the hypothalamic-pituitary-gonadal axis results in lowered or absent levels of luteinizing hormone (LH), as a result of internalization or down regulation/desensitization of LHRH receptors in the pituitary. In particular, the LHRH surge triggers downregulation of LHRH receptors in the pituitary, inhibiting further production and release of LH, and causing a corresponding decrease in the production of testosterone. MYL Ex. 1024 (Hellerstedt) at 157. In addition to the use of LHRH agonists to interrupt production of testosterone produced by the testicles, the first-line treatment of metastatic prostate cancer usually also includes systemic anti-androgen therapy using drugs such as

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bicalutamide. MYL Ex. 1024 (Hellerstedt) at 158. Anti-androgens work by interfering with or antagonizing the binding of testosterone and DHT to the androgen receptors on prostate cancer cells. MYL Ex. 1024 (Hellerstedt) at 158. The objective of anti-androgens is to prevent testosterone from binding to AR on prostate cancer cells.

31. In almost all cases, patients with metastatic prostate cancer over time, measured in months or years, develop what is referred to as metastatic castration-resistant (or hormone-refractory) prostate cancer ("mCRPC"), i.e., prostate cancer that has usually initially responded to lowered testosterone levels and now no longer responds to a reduction in testosterone levels and resumes growth. MYL Ex. 1023 (Attard) at 1241; MYL Ex. 1024 (Hellerstedt) at 154. It was known that in these patients, the sensitivity of the AR is greatly increased, so that activation of the AR is enhanced at lower levels of testosterone. MYL Ex. 1003 (O'Donnell) at 2317; MYL Ex. 1023 (Attard) at 1241.

32. It was also known that the prognosis for patients with mCRPC as of 2006 was poor and almost invariably resulted in incurable progression of the disease. MYL Ex. 1021 (Oh) at Abstract; MYL Ex. 1022 (Tannock 2004) at 1503; MYL Ex. 1023 (Attard) at 1241. The treatment of mCRPC usually also comprised the use of one or more "second-line" hormone therapies. MYL Ex. 1021 (Oh) Abstract; MYL Ex. 1023 (Attard) at 1241-1242.

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33. Ketoconazole, a non-specific antifungal inhibitor of 17α-hydroxylase, an enzyme critical to steroid synthesis, was commonly used off-label (in much larger doses than used for its antifungal activity) in combination with prednisone or hydrocortisone to treat mCRPC. MYL Ex. 1004 (Gerber) at 1177; MYL Ex. 1021 (Oh) at Abstract; MYL Ex. 1020 (Harris) at Abstract; MYL Ex. 1025 (Harrison's) at 548. It was well known that the co-administration of either prednisone or hydrocortisone was required with these large doses of ketoconazole to modulate or mitigate the adverse effects of mineralocorticoid excesses induced by ketoconazole. Although there were some data and publications suggesting that prednisone may have independent anti-cancer activity, *see, e.g.*, MYL Ex. 1020 (Harris) at 544; MYL Ex. 1021 (Oh) at 89, MYL Ex. 1079 (Fakih) at 553, 559, MYL Ex. 1080 (Lam) at 30-31, it was very well known that high doses of prednisone (supraphysiologic levels of substantially greater than 5-10 mg per day) had short-term palliative effects in patients with terminal prostate cancer.

B. The '438 patent

34. The '438 Patent is directed to a method for treating a prostate cancer in a human, the method including administration of a therapeutically effective amount of abiraterone acetate and a therapeutically effective amount of prednisone. The '438 Patent includes one independent claim and 19 dependent claims. Claim 1, the only independent claim, recites as follows:

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> 1. A method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone.
>
> MYL Ex. 1001 ('438 patent) at claim 1.[3]

35. The dependent claims of the '438 Patent further specify the amount of abiraterone acetate and/or prednisone administered to a human patient, the type of prostate cancer, including refractory prostate cancer, to be treated in such patient, and particular anti-cancer agents administered previously to such patient.

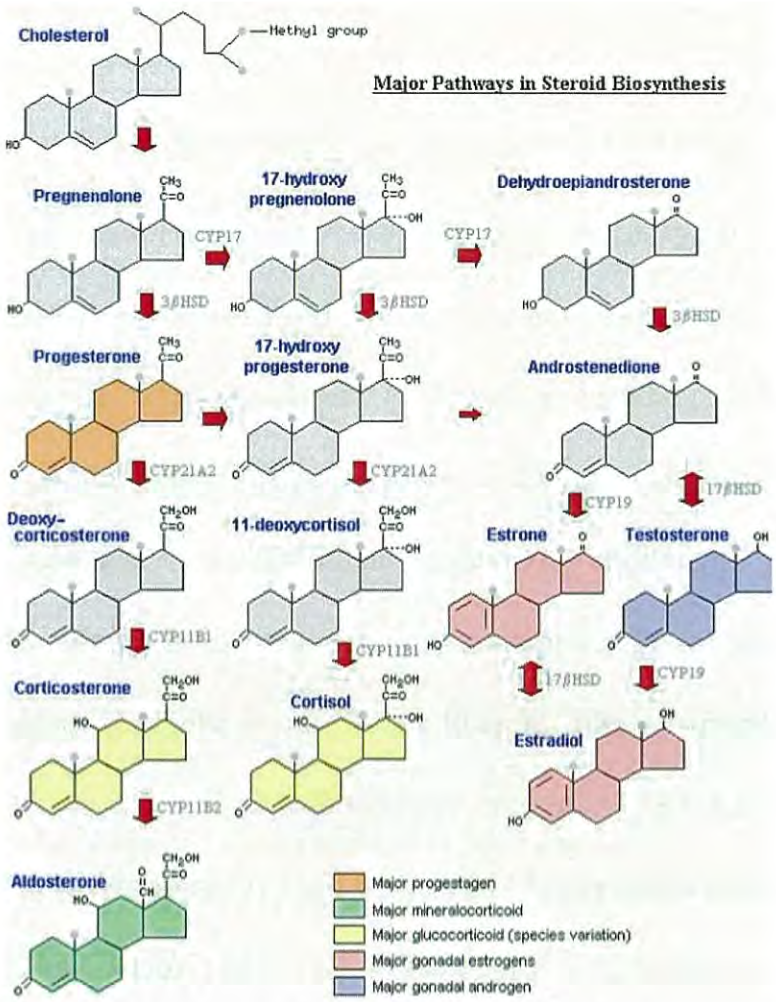
36. Abiraterone acetate is a 17α-hydroxylase/C17,20-lyase inhibitor. MYL Ex. 1003 (O'Donnell) at 2318, 2322. 17α-hydroxylase/C17,20-lyase inhibitors (also referred to as "CYP17 inhibitors") were known in the art to be useful in the treatment of androgen-dependent cancers, including prostate cancer, by contributing to suppression of peripheral androgen production. MYL Ex. 1003 (O'Donnell) at 2318, 2322-23. "The two sites thought to produce most of the androgenic steroids in human males are the testes and the adrenal cortex." MYL Ex. 1023 (Attard) at 1242-1243. It was known in the art that "[p]lasma testosterone is not completely suppressed by castration, in part because of peripheral conversion of adrenal androgenic steroids to testosterone" by other enzymes. MYL Ex. 1003 (O'Donnell) at 2317; MYL Ex. 1023 (Attard) at 1242-

[3] Claim 1 recites a "method for the treatment of a prostate cancer," but nothing in the language of the claim requires both drug compounds to have, or be used for, an anticancer effect.

1243. It was also known that AR on the prostate cancer cells of patients with refractory metastatic prostate cancer was "hypersensitive" to androgenic steroid stimulation and small amounts of residual androgens not fully eliminated by hormonal therapies. MYL Ex. 1003 (O'Donnell) at 2317; MYL Ex. 1023 (Attard) at 1241.

37. CYP17 inhibitors were known to inhibit 17α-hydroxylase/C17,20-lyase ("CYP17"), an enzyme that is critical to androgen synthesis in both the testes and the adrenal cortex. MYL Ex. 1003 (O'Donnell) at 2318; MYL Ex. 1023 (Attard) at 1242. The following diagram shows how CYP17 inhibitors work to inhibit production of testosterone.[4]

[4] The diagram shows CYP17 at the reaction in which it adds a hydroxyl (-OH) group to pregnenolone and removes the side chain from 17-hydroxypregnenolone. Similarly, CYP17 is used in the reaction to add a hydroxyl (-OH) group to progesterone and remove the side chain from 17-hydroxyprogesterone, although not explicitly labeled as such in the diagram. The use of CYP17 in these two reactions was well known as seen in, for example, MYL Ex. 1003 (O'Donnell) at 2318, Fig. 1, which has a diagram that shows CYP17 in these reactions.



(Carrell, D.T. and C.M. Peterson, Reproductive Endocrinology and Infertility: Integrating Modern Clinical and Laboratory Practice 157 at Fig. 11.4 (2010)).

38. The CYP17 enzyme has two activities in the steroidogenic pathway: (1) acting as a 17α-hydroxylase, and (2) acting as a 17,20 lyase. MYL Ex. 1003 (O'Donnell) at 2318, Fig. 1; MYL Ex. 1023 at 1243, Fig. 1. As a 17α-hydroxylase, CYP17 adds a hydroxyl group (-OH) to pregnenolone and progesterone at carbon 17 of the steroid D ring, converting both compounds to their 17-hydroxy forms. MYL Ex. 1003 (O'Donnell) at 2318, Fig. 1; MYL Ex.

1023 (Attard) at 1243, Fig. 1. As a 17,20 lyase, CYP17 acts to split the side chain off of 17-hydroxyprogesterone and 17-hydroxypregnenolone. MYL Ex. 1003 (O'Donnell) at 2318, Fig. 1. Importantly, the 17α-hydroxylase activity of CYP17 is essential to the synthesis of both (1) sex hormones, i.e., androgens (i.e., testosterone) and estrogens, and (2) cortisol. Cortisol is an essential steroid that is critical to basic metabolic functions including the regulation of glucose homeostasis, cardiovascular function, and the activation of the anti-stress and inflammatory pathways. One of skill in the art would have expected that the administration of a CYP17 inhibitor would interfere with the production of both testosterone (in men) and cortisol. MYL Ex. 1027 (Costa-Santos) at Abstract, 49; MYL Ex. 1023 (Attard) at 1243, Fig. 1; MYL Ex. 1026 (Auchus) at 103-104.

39. While the CYP17 enzyme is essential for androgen biosynthesis, it also plays an important role in the production of cortisol, a glucocorticoid. The diagram below shows the control of cortisol production in the adrenal cortex. As more cortisol is produced, there is a negative feedback on the hypothalamus and anterior pituitary that reduces the production of adrenocorticotropic hormone (ACTH), which consequently reduces the production of cortisol.

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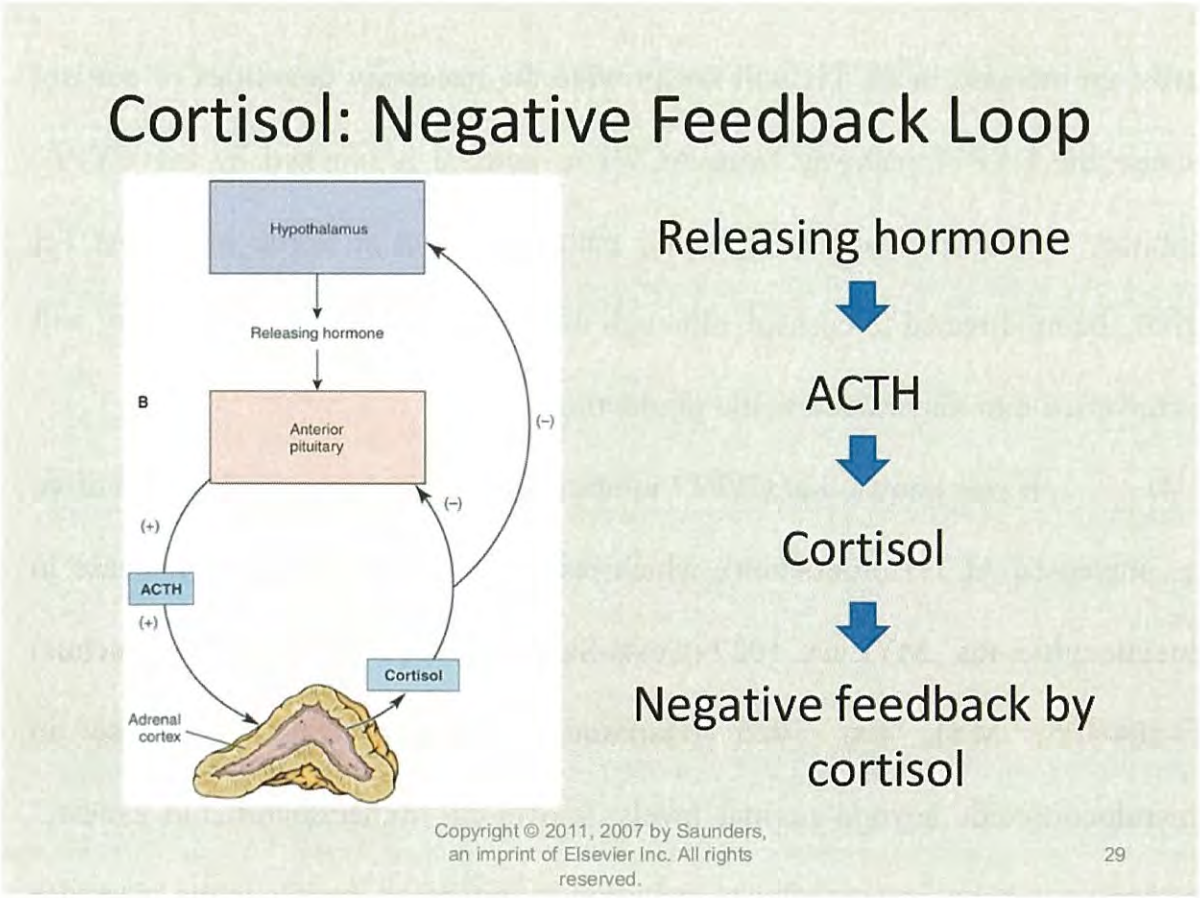

(Herlihy, B., The Human Body In Health and Illness Ch. 14 (endocrine system) (4th ed. 2010))

40. When a CYP17 inhibitor is administered, cortisol production is compromised (i.e., reduced), which interferes with the negative feedback mechanism that maintains cortisol levels within the normal physiological range. Specifically, the pituitary gland produces more ACTH to stimulate greater production of glucocorticoids, which are regulated from ACTH, in part, by a reaction involving CYP17. However, in the presence of a CYP17 inhibitor, the conversion in the CYP17 pathway from ACTH to cortisol cannot occur. In other

words, an increase in ACTH will not provide the necessary quantities of cortisol because the CYP17 pathway from ACTH to cortisol is blocked by the CYP17 inhibitor. However, a different, minor pathway results in some of the ACTH activity being directed to cortisol, although the majority of the ACTH activity will be converted into mineralocorticoid production.

41. It was known that CYP17 inhibition of cortisol increased ACTH drive (i.e., increased ACTH production), which resulted in a corresponding increase in mineralocorticoids. MYL Ex. 1027 (Costa-Santos) at 49; MYL Ex. 1026 (Auchus) at 104-105; MYL Ex. 1025 (Harrison's) at 2145. An increase in mineralocorticoids beyond normal levels, known as "mineralocorticoid excess," was known to have adverse effects, including hypertension, hypokalemia (decrease in circulating potassium levels), and fluid retention. MYL Ex. 1027 (Costa-Santos) at 49, 57; MYL Ex. 1025 (Harrison's) at 2143, 2145, 2146; MYL Ex. 1026 (Auchus) at 107.

42. It also was known in the art to administer a glucocorticoid, such as hydrocortisone or prednisone, to suppress ACTH drive by way of a negative feedback loop akin to that triggered by cortisol. MYL Ex. 1021 (Oh) at 89; MYL Ex. 1025 (Harrison's) at 2143-2146; MYL Ex. 1026 (Auchus) at 114-115. By suppressing ACTH drive, fewer mineralocorticoids are produced and the adverse

side effects of hypertension, hypokalemia, and fluid retention are reduced even in the presence of the CYP17 inhibition.

43. Ketoconazole was known to be a non-specific inhibitor of CYP17, to have a direct anti-tumor effect *in vitro*, and to be effective as a second-line treatment for mCRPC. MYL Ex. 1003 (O'Donnell) at 2318; MYL Ex. 1021 (Oh) at Abstract, 90; MYL Ex. 1020 (Harris) at 542-543.

44. However, the administration of ketoconazole to treat prostate cancer was known to reduce cortisol levels and potentially result in mineralocorticoid excess, giving rise to side effects commonly associated with mineralocorticoid excess, including hypertension, hypokalemia, and fluid retention. MYL Ex. 1023 (Attard) at 1242-43; MYL Ex. 1003 (O'Donnell) at 2318. These side effects reduced the safety and tolerability of administering ketoconazole. MYL Ex. 1023 (Attard) at 1242-43; MYL Ex. 1003 (O'Donnell) at 2318. To address these side effects, it was standard practice in the art to co-administer a glucocorticoid such as hydrocortisone or prednisone with ketoconazole to improve the safety and tolerability of administration of ketoconazole to treat prostate cancer in a human patient. MYL Ex. 1003 (O'Donnell) at 2323; MYL Ex. 1020 (Harris) at Abstract, 543.

45. The combination of ketoconazole with prednisone, although not approved by the FDA in combination for treating prostate cancer, was reported in

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the literature to be safe and effective in treating patients with mCRPC. MYL Ex. 1004 (Gerber) at Abstract.

46. Abiraterone acetate was known to be a more efficacious anti-cancer agent in the treatment of prostate cancer, including metastatic hormone-refractory prostate cancer, than prior art CYP17 inhibitors such as ketoconazole. MYL Ex. 1023 (Attard) at 1244; MYL Ex. 1078 (Barrie). In particular, abiraterone acetate was known to be more effective in inhibiting testosterone levels in vivo in a mammal than ketoconazole. MYL Ex. 1005 ('213 patent), col. 25, l. 13 – col. 26, l. 63; MYL Ex. 1003 (O'Donnell) at 2318; MYL Ex. 1078 (Barrie) at 272, Table 2.

V. CLAIM CONSTRUCTION

47. I understand that the claims in an IPR proceeding are construed in accordance with the broadest reasonable construction consistent with the specification.

48. I have been told that, for purposes of this declaration, the claim terms "treat," "treating" and "treatment" should be construed as those terms are defined in the specification of the '438 Patent to mean "include the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer." MYL Ex. 1001 ('438 Patent) col. 3, ll. 46–50. I agree with this construction because it is consistent with the broadest reasonable construction as understood by one of

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ordinary skill in the art. The definition makes clear that treatment includes adjunctive therapies that are used in conjunction with a specific anti-cancer agent(s) to mitigate, modulate or modify, in any way, the side effects or adverse effects induced by the administration of the anti-cancer agent.

49. The term "anti-cancer agent" should be construed as defined in the specification of the '438 patent as referring to "any therapeutic agent that directly or indirectly kills cancer cells or directly or indirectly prohibits, stops or reduces the proliferation of cancer cells." MYL Ex. 1001 ('438 Patent) col. 4, ll. 8-16. I agree with this construction because it is consistent with the broadest reasonable construction as understood by one of ordinary skill in the art.

50. The term "refractory cancer" should be construed as defined in the specification of the '438 patent to mean "cancer that is not responding to an anti-cancer treatment or cancer that is not responding sufficiently to an anti-cancer treatment." MYL Ex. 1001 ('438 Patent) col. 4, ll. 23-27. I agree with this construction because it is consistent with the broadest reasonable construction as understood by one of ordinary skill in the art.

51. The term "refractory patient" should be construed as defined in the specification of the '438 patent to mean "a patient who has refractory cancer." MYL Ex. 1001 ('438 Patent) col. 4, ll. 28-30. I agree with this construction

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because it is consistent with the broadest reasonable construction as understood by one of ordinary skill in the art.

52. The term "relapse cancer" should be construed as defined in the specification of the '438 patent to mean "cancer that was at one time responsive to an anti-cancer treatment but has become no longer responsive to such treatment or is no longer responding sufficiently to such treatment." MYL Ex. 1001 ('438 Patent) col. 4, ll. 31–35. I agree with this construction because it is consistent with the broadest reasonable construction as understood by one of ordinary skill in the art.

53. The term "recurring cancer" should be construed as defined in the specification of the '438 patent to mean "cancer that has returned after a patient has been earlier diagnosed with cancer, under gone treatment or had been previously diagnosed as cancer-free." MYL Ex. 1001 ('438 Patent) col. 4, ll. 36–39. I agree with this construction because it is consistent with the broadest reasonable construction as understood by one of ordinary skill in the art, including encompassing individuals whose cancer had previously been in either complete or partial remission.

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VI. INVALIDITY OF THE CLAIMS OF THE '438 PATENT

A. Claim 1 was Unpatentable as Obvious over O'Donnell in view of Gerber or the '213 patent in view of Gerber

54. Claim 1 is directed to a method for treating prostate cancer in a human comprising administration of therapeutically effective amounts of abiraterone acetate, or a pharmaceutically acceptable salt thereof, and prednisone. Because both the use of abiraterone acetate to treat prostate cancer and the co-administration of prednisone in treatment of prostate cancer with a CYP17 inhibitor were disclosed by one or more of O'Donnell (MYL Ex. 1003), Gerber (MYL Ex. 1004) and the '213 patent (MYL Ex. 1005), claim 1 was obvious. Each of the limitations of claim 1 was present in these prior art documents, as explained in detail below.

1. A method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate

55. Both O'Donnell and the '213 patent taught that abiraterone acetate is a selective CYP17 inhibitor that is more effective and/or more selective in suppressing testosterone levels in a mammal *in vivo* than ketoconazole, another CYP17 inhibitor known in the art. MYL Ex. 1003 (O'Donnell) at 2318, 2322-24; MYL Ex. 1005 ('213 patent) col. 25, l. 13 – col. 26, l. 63. O'Donnell taught that 500-800 mg of abiraterone acetate can be useful in suppressing testosterone levels in a human patient with prostate cancer, including mCRPC. MYL Ex. 1003

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(O'Donnell) at Abstract. The '213 patent disclosed that abiraterone acetate may be administered in a method of treating androgen- and estrogen-dependent disorders, especially prostate cancer, as a pharmaceutical composition. MYL Ex. 1005 ('213 patent) col. 10, ll. 47–56. The '213 patent further disclosed that a therapeutically effective amount of abiraterone acetate comprises 20-800 mg/patient per day. MYL Ex. 1005 ('213 patent) col. 10, ll. 55-56.

56. It would have been obvious to administer abiraterone acetate to a human with a prostate cancer in light of the teachings of either O'Donnell or the '213 patent to administer a therapeutically effective amount of abiraterone acetate to treat a human patient with a prostate cancer.

2. or a pharmaceutically acceptable salt thereof

57. The '213 patent also taught that a salt of abiraterone acetate may be administered to a human patient with prostate cancer to treat prostate cancer in said human patient. MYL Ex. 1005 ('213 patent), col. 10, ll. 22-26.

3. and a therapeutically effective amount of prednisone

58. O'Donnell taught that concomitant hormone replacement therapy with a glucocorticoid may be needed for continuous use of abiraterone acetate in treating a prostate cancer in a human patient. MYL Ex. 1003 (O'Donnell) at 2323. Gerber taught that the combination of ketoconazole and prednisone is safe and effective in treating human patients with mCRPC. MYL Ex. 1004 (Gerber). The

motivation to add prednisone to a method of treating prostate cancer in a human patient that includes abiraterone acetate was clearly seen in Gerber, which taught that the administration of ketoconazole, a CYP17 inhibitor, in combination with 5 mg prednisone twice daily was safe and effective in treating human patients with mCRPC. MYL Ex. 1004 (Gerber). As such, the skilled artisan would expect that the addition of 10 mg of prednisone daily to the treatment regimen of O'Donnell also would be safe and effective in treating a prostate cancer, including prostate cancer refractory to anticancer therapy, including hormone and anti-androgen therapy. Therefore, based on (a) the teaching of O'Donnell that concomitant hormone replacement therapy with a glucocorticoid may be needed for continuous use of abiraterone acetate in treating a prostate cancer in a human patient and (b) the teaching in Gerber to co-administer 10 mg of prednisone daily in combination with ketoconazole for the treatment of hormone refractory metastatic prostate cancer, one of skill in the art would have been motivated to co-administer 10 mg of prednisone daily with abiraterone acetate, a more selective CYP17 inhibitor than ketoconazole, to treat a human patient having prostate cancer, including prostate cancer refractory to previous anti-cancer therapy, including hormone and anti-androgen therapy. One of skill in the art would have had a reasonable expectation that such treatment would be successful, based on the teachings of the prior art.

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59. Alternatively, the '213 patent taught that abiraterone acetate is a CYP17 inhibitor that is more effective in suppressing testosterone levels in a mammal *in vivo* than ketoconazole, another CYP17 inhibitor known in the art. MYL Ex. 1005 ('213 patent) col. 25, l. 13 – 26, l. 63. Gerber taught that the combination of ketoconazole and prednisone was safe and effective in treating human patients with mCRPC. MYL Ex. 1004 (Gerber). The motivation to add prednisone to the method of treating prostate cancer of the '213 patent was clearly seen in Gerber, which taught that the administration of ketoconazole, a CYP17 inhibitor, in combination with 5 mg prednisone twice daily was safe and effective in treating human patients having hormone-refractory prostate cancer. MYL Ex. 1004 (Gerber). As such, the skilled artisan would expect that the addition of 5 mg twice daily prednisone to the treatment regimen of the '213 patent also would be safe and effective in treating a prostate cancer, including prostate cancer refractory to anti-cancer therapy, including hormone and anti-androgen therapy, in such patients. In addition, one skilled in the art would expect that the addition of prednisone (or hydrocortisone) would be required for co-administration with a therapeutically effective dose of abiraterone or abiraterone salt to mitigate, modulate or modify the deleterious effects of mineralocorticoid excess that would invariably be induced by administration of a therapeutically effective doses of abiraterone.

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B. Claims 2-20 were unpatentable as obvious over O'Donnell and/or the '213 patent in view of Gerber

60. Claims 2-20 all depend directly or indirectly from claim 1, and include additional limitations on the following: (i) the amount and/or dosage range of abiraterone acetate or a pharmaceutically acceptable salt thereof to be administered; (ii) the amount and/or dosage range of prednisone to be administered; (iii) the type of prostate cancer to be treated; or (iv) whether the patient has been previously treated with another anti-cancer agent, where the additional anti-cancer agent may be a hormonal ablation agent, an anti-androgen agent, or an anti-neoplastic agent. For the reasons set forth above for claim 1 and additionally for the reasons set forth below, these additional categories of limitations were variously disclosed in O'Donnell, the '213 patent and/or Gerber. Therefore claims 2-20 also were obvious over O'Donnell and/or the '213 patent in view of Gerber.

1. "the therapeutically effective amount of the abiraterone acetate or pharmaceutically acceptable salt thereof is from about 50 mg/day to about 2000 mg/day"

61. O'Donnell taught that 500-800 mg of abiraterone acetate can be useful in suppressing testosterone levels in a human patient with prostate cancer, including metastatic prostate cancer. *See, e.g.*, MYL Ex. 1003 (O'Donnell) at Abstract. The '213 patent taught that a therapeutically effective amount of

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abiraterone acetate for treating prostate cancer in a human patient included 20-800 mg/day. MYL Ex. 1005 ('213 patent) col. 10, ll. 47-56.

62. Both a therapeutically effective amount of 20-800 mg per day of abiraterone acetate, as expressly taught in the '213 patent, and 500-800 mg of abiraterone acetate, as expressly taught in O'Donnell, are within the range of "about 50 mg/day to about 2000 mg/day" that encompasses the abiraterone acetate dosage ranges of claims 2, 3, 10, and 18. For the foregoing reasons, the dosage amounts and ranges of abiraterone acetate recited in these claims were disclosed in O'Donnell and/or the '213 patent.

63. As well, O'Donnell taught that the dose of abiraterone acetate administered to a particular patient may need to be adjusted in order to attain suppression of testosterone levels at target levels. *See, e.g.*, MYL Ex. 1003 (O'Donnell) at Abstract, 2322-23. It would have been obvious to one of skill in the art to optimize the dosage range of abiraterone acetate to 1000 mg administered to treat prostate cancer in a human patient, as recited in claims 4 and 11, based on the teaching in O'Donnell that adjustments in the dosage amount of abiraterone acetate may be necessary to treat a patient.

64. In addition, optimizing the dosage range and dosage regimen of known active ingredients to be administered was considered well within the competence level of an ordinary skilled artisan in the pharmaceutical sciences as of

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at least 2006. Based on the teachings of O'Donnell or the '213 patent, it would have been well within the skill of one in the art to optimize the amount of abiraterone acetate to be administered to treat prostate cancer in a human patient.

2. "administered in at least one dosage form comprising about 250 mg of abiraterone acetate or a pharmaceutically acceptable salt thereof"

65. O'Donnell taught that capsules containing 10, 50, 100 and 200 mg of abiraterone acetate were used in the three Phase I clinical studies. It would have required only routine experimentation to increase the amount of abiraterone acetate in the capsules from 200 mg to 250 mg. Motivation for making this increase included the starting dose of 500 mg in Study C and the use of 500 mg of abiraterone in Studies A and B, which are a multiple of 250 mg. Therefore, one of skill in the art would have made a 250 mg dosage form of abiraterone acetate for the convenience of dosing. Based on O'Donnell it would have been obvious to administer at least one dosage form comprising about 250 mg of abiraterone acetate. Therefore claim 5 was obvious over O'Donnell in view of Gerber.

3. "the therapeutically effective amount of the prednisone is from about 0.01 mg/day to about 500 mg/day"

66. O'Donnell taught that abiraterone acetate is a CYP17 inhibitor that is effective in suppressing testosterone levels in a mammal *in vivo*, and more selective than ketoconazole. MYL Ex. 1003 (O'Donnell) at 2318, 2322-2324. O'Donnell taught that concomitant replacement therapy with a glucocorticoid may

be needed for continuous use of abiraterone acetate in treating patients with prostate cancer. MYL Ex. 1003 (O'Donnell) at 2323. Gerber taught that the combination of ketoconazole, another CYP17 inhibitor, and 5 mg of prednisone twice daily was safe and effective in treating patients with mCRPC. MYL Ex. 1004 (Gerber). The motivation to add prednisone to a method of treating prostate cancer that includes abiraterone acetate was clearly seen in Gerber, which taught that the administration of ketoconazole, a CYP17 inhibitor, in combination with 10 mg prednisone daily is safe and effective in treating human patients with hormone-refractory prostate cancer. MYL Ex. 1004 (Gerber). As such, the skilled artisan would expect that the addition of 10 mg daily prednisone to the treatment regimen of O'Donnell would also be safe and effective in treating prostate cancer, including prostate cancers refractory to anticancer therapy, including hormone and anti-androgen therapy.

67. Therefore, based on the teaching of Gerber to co-administer 10 mg of prednisone daily in combination with ketoconazole for the safe and effective treatment of hormone refractory metastatic prostate cancer, one of skill in the art would have been motivated to co-administer 10 mg of prednisone daily with abiraterone acetate, a more selective 17,20-lyase inhibitor than ketoconazole, in order to treat a patient with prostate cancer, including prostate cancer refractory to

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previous anti-cancer therapy, with a reasonable expectation that said treatment would be successful.

68. Alternatively, the '213 patent taught that abiraterone acetate is a selective CYP17 inhibitor that is more effective in suppressing testosterone levels in a mammal *in vivo* than ketoconazole, a CYP17 inhibitor known in the art. MYL Ex. 1005 ('213 patent) col. 25, l. 13 – col. 26, l. 63. Gerber taught that the combination of ketoconazole and 5 mg of prednisone twice daily is safe and effective in treating patients with hormone-refractory advanced prostate cancer. MYL Ex. 1004 (Gerber). The motivation to add prednisone to the method of treating prostate cancer of the '213 patent was clearly seen in Gerber, which taught that the administration of ketoconazole in combination with 10 mg prednisone daily is safe and effective in treating human patients with hormone-refractory prostate cancer.

69. Therefore, based on the teaching in the '213 patent that abiraterone acetate is more effective in treating a prostate cancer in a human patient than ketoconazole, and the teaching in Gerber to administer the combination of ketoconazole and 10 mg of prednisone daily to treat patients with hormone-refractory advanced prostate cancer, the skilled artisan would have expected that the addition of 10 mg daily prednisone to the treatment regimen of the '213 patent would also be safe and effective in treating prostate cancer, including prostate

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cancer refractory to anticancer therapy, including hormone and anti-androgen therapy.

70. A dosage of 10 mg of prednisone daily was expressly taught by Gerber, as explained above. Therefore, the dosage amount of 10 mg/day prednisone recited in claim 8 was obvious over both O'Donnell in view of Gerber and the '213 patent in view of Gerber. A dosage of 10 mg of prednisone daily is within the dosage ranges of "from about 0.01 mg/day to about 500 mg/day of prednisone" as recited in claims 6, 10, and 18, or "from about 10 mg/day to about 250 mg/day" as recited in claim 7. An amount of prednisone of "at least about 5 mg/day" as recited in claim 9, was not expressly taught in Gerber. However, optimizing the dosage range and dosage regimen of known active ingredients to be administered was considered well within the competence level of an ordinary skilled artisan in the pharmaceutical sciences as of at least 2006. Therefore, for the reasons set forth above, the dosage amount and/or dosage ranges of prednisone recited in claims 6-10 and 18 were obvious.

4. "said prostate cancer is refractory prostate cancer" and "the refractory prostate cancer is not responding to at least one anti- cancer agent"

71. The patients in the Phase I trial reported in O'Donnell were classified as having advanced or metastatic prostate cancer. MYL Ex. 1003 (O'Donnell) at Abstract, 2318-2319. In addition, one of the cohorts in O'Donnell had undergone

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hormone ablation surgery, *i.e.*, bilateral orchiectomy, and individuals in all three cohorts of patients in O'Donnell had previously undergone hormone or anti-androgen therapy or both, and therefore had been previously treated with at least one anti-cancer agent, and in particular a hormone ablation agent or anti-androgen agent. MYL Ex. 1003 (O'Donnell) at Abstract, 2318-2321.

72. Therefore, claims 12 and 13 were obvious for the reasons set forth above for claim 1 and additionally for the teaching in O'Donnell that abiraterone acetate may be administered to treat a human patient with metastatic prostate cancer that is refractory to at least one anti-cancer agent.

5. "the at least one anti-cancer agent comprises a hormone ablation agent, an anti-androgen agent, or an anti-neoplastic agent"

73. The patients in the Phase I trial reported in O'Donnell were classified as having advanced or metastatic prostate cancer. MYL Ex. 1003 (O'Donnell) at Abstract, 2318-2319. In addition, one of the cohorts in O'Donnell had undergone hormone ablation surgery, *i.e.*, orchiectomy, and all three cohorts of patients in O'Donnell had previously undergone hormone and anti-androgen therapy, and therefore had been previously treated with at least one anti-cancer agent, and in particular a hormone ablation agent or anti- androgen agent. O'Donnell reported that in Study A, all patients received an anti-androgen (cyproterone acetate or flutamide, the latter an anti-androgen agent recited in claim 16), and were

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receiving goserelin or leuprorelin, hormone ablation agents. MYL Ex. 1003 (O'Donnell) at 2320. Therefore, claims 14, 15, and 16 were obvious for the reasons set forth for claim 12 and additionally for the teaching in O'Donnell that abiraterone acetate may be administered to treat a human patient with metastatic prostate cancer that is refractory to at least one anti-cancer agent.

74. Docetaxel was well known as an anti-cancer compound, and, in particular, an anti-neoplastic agent at the priority date of the '438 patent. For instance, U.S. Patent No. 5,688,977, which issued on November 18, 1997, stated that docetaxel is an anti-cancer compound. MYL Ex. 1029 ('977 patent) at col. 2, ll. 29-32. And, docetaxel in combination with prednisone was known to increase overall survival of patients with metastatic refractory prostate cancer, MYL Ex. 1022 (Tannock) at Abstract, the first treatment known to do so, and was approved for the treatment of metastatic refractory prostate cancer in 2004. MYL Ex. 1030 (FDA News Release dated May 19, 2004). Therefore, claim 17 was obvious for the reasons set forth for claim 13 and additionally for the general knowledge in the art that docetaxel with prednisone was a first-line treatment for metastatic hormone refractory prostate cancer known to increase overall survival.

75. Claim 18 depends from claim 12 and additionally recites dosage ranges for abiraterone acetate and prednisone as recited in claims 3 and 6,

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respectively, or claim 10 itself. Therefore, claim 18 was obvious for the same reasons that claims 3, 6, 10, and 12 were obvious.

76. Claims 19 and 20 depend from claims 18 and 17, respectively, and additionally recite dosage amounts for abiraterone acetate and prednisone as recited in claims 4 and 8, respectively, or claim 11 itself. Therefore, claim 19 was obvious for the same reasons that claims 4, 8, 11, and 18 were obvious, and claim 20 was obvious for the same reasons that claims 4, 8, 11, and 17 were obvious.

C. Secondary Considerations Do Not Indicate that the Claims of the '438 Patent Are Non-Obvious

77. Review of the file history of the '438 patent indicates that the Applicants argued that treating a prostate cancer in a human patient by administering abiraterone in combination with prednisone was more effective than administering prednisone alone and that the purported greater efficacy of the combination of abiraterone acetate and prednisone was unexpected. MYL Ex. 1010 (January 11, 2013 Response in the prosecution history of the '438 patent) at 6-7. For example, the Applicants cited Ryan (MYL Ex. 1009) for purportedly showing an "unexpected survival benefit of abiraterone in combination with prednisone" in patients with refractory prostate cancer. *Id.* at 7. It is my opinion, however, that the secondary considerations do not indicate that the claims are non-obvious because an increase in the safety and tolerability of treating a patient with

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a prostate cancer by administering abiraterone acetate in combination with prednisone to such a patient was expected for all the reasons described here.

1. An improvement in the safety and efficacy of treating a patient with a prostate cancer by administering abiraterone acetate in combination with prednisone was not unexpected at least because the prior art taught co-administration of a glucocorticoid with a CYP17 inhibitor in order to increase the safety and tolerability of administering a CYP17 inhibitor

78. It was known in the art to co-administer a glucocorticoid with ketoconazole, a CYP17 inhibitor, to patients with a metastatic refractory prostate cancer in order to improve symptoms and/or quality of life. *See, e.g.*, MYL Ex. 1004 (Gerber) at Abstract, 1178-1179; MYL Ex. 1020 (Harris) at 544; MYL Ex. 1021 (Oh) at 90, Table III; MYL Ex. 1003 (O'Donnell) at 2323. In particular, it was known in the art that administering ketoconazole to treat a prostate cancer results in significant side effects, such as hypertension, hypokalemia and fluid retention as a result of a decrease in cortisol levels and consequent ACTH drive. MYL Ex. 1027 (Costa-Santos) at 49, 57; MYL Ex. 1025 (Harrison's) at 2143, 2145, 2146; MYL Ex. 1026 (Auchus) at 104-105, 107. These adverse effects reduced the tolerability and safety of administering ketoconazole as a single agent. MYL Ex. 1003 (O'Donnell) at 2318; MYL Ex. 1020 (Harris) at 542-543; MYL Ex. 1023 (Attard) at 1242-43; MYL Ex. 1028 (Jubelirer) at Abstract. It was common practice in the art to co-administer a glucocorticoid as replacement

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therapy when administering ketoconazole to treat prostate cancer in a human patient in order to improve the safety and enhance the tolerability of treatment. MYL Ex. 1020 (Harris) at 544; MYL Ex. 1021 (Oh) at 90, Table III; MYL Ex. 1003 (O'Donnell) at 2323.

79. The particular combination of ketoconazole and prednisone was known to be safe and effective in treating patients with metastatic refractory prostate cancer. *See, e.g.*, MYL 1004 (Gerber) at Abstract. However, from a clinical perspective, use of another replacement glucocorticoid, such as hydrocortisone, would be expected to be just as effective as prednisone in enhancing the tolerability and improving the safety profile of administering abiraterone. For instance, ketoconazole is commonly administered with hydrocortisone, as well as prednisone.

80. It was known in the art that administering the CYP17 inhibitor ketoconazole to treat a patient with prostate cancer could result in significant adverse effects triggered by a decrease in cortisol that required concomitant administration of a glucocorticoid as replacement therapy. MYL Ex. 1021 (Oh) at 89; MYL Ex. 1025 (Harrison's) at 2143, 2145, 2146; MYL Ex. 1026 (Auchus) at 107, 114–115; MYL Ex. 1027 (Costa-Santos) at 49, 57. Thus, one of skill in the art would have had a reasonable expectation that administration of abiraterone, a more selective CYP17 inhibitor than ketoconazole, to treat a patient with prostate

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cancer, would require co-administering a glucocorticoid such as prednisone in order to improve safety and enhance tolerability of administering the CYP17 inhibitor.

2. Any purported improvement in safety and efficacy of treating a patient with a prostate cancer by administering abiraterone acetate in combination with prednisone rather than prednisone alone is irrelevant for purposes of showing unexpected results over the closest prior art

81. Patent Owner asserts that the anti-cancer drug marketed under the brand name Zytiga is a commercial embodiment of the claimed invention of the '438 patent when prescribed according to the approved label. *See, e.g.*, MYL Ex. 1012 (Amendment and Response dated June 4, 2013) at 7 ("Taking Zytiga in accordance with the approved label represents a commercial embodiment of the presently claimed invention."); *see also* MYL Ex. 1019 (Prescribing Information for Zytiga® dated May 20, 2015) at, e.g., 1–2 (indicating that Zytiga (abiraterone acetate) is indicated in combination with prednisone for the treatment of mCRPC).

82. I understand that during prosecution of the '438 patent, the patentees argued that Zytiga demonstrated surprising and unexpected results in the treatment of patients with prostate cancer. MYL Ex. 1010 (January 11, 2013 Response in the prosecution history of the '438 patent) at 6-7. In particular, the Applicants cited the results reported in Ryan (MYL Ex. 1009) as evidence that the claimed

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invention demonstrated surprising and unexpected results over prednisone alone in increasing overall survival of patients with metastatic CRPC.

83. Although Ryan (MYL Ex. 1009) reports that the combination of abiraterone and prednisone may increase progression-free survival of patients with metastatic hormone refractory compared to placebo and prednisone, Ryan does not assess how the combination of abiraterone and prednisone compares with abiraterone alone in terms of efficacy or safety in treating patients with metastatic hormone refractory prostate cancer. This is a significant omission in my opinion because it is my understanding that another patent, the '213 patent (MYL Ex. 1005), claims both abiraterone acetate and a method of treating a patient with prostate cancer by administering abiraterone acetate to said patient.[5] An appropriate analysis to show superiority of the claimed invention over the closest prior art would have been to compare administering abiraterone and prednisone to patients with metastatic refractory prostate cancer versus administering abiraterone alone, in a randomized trial. In the absence of such comparative data, it is impossible to discern whether the addition of prednisone to a treatment comprising

[5] *See, e.g.*, the '213 patent (MYL Ex. 1005) at claim 1, which claims a chemical genus that includes abiraterone acetate; claim 2, which claims a method of treating an androgen-dependent or estrogen-dependent disorder by administering a compound of the genus that comprises abiraterone acetate; claim 16, which claims a method of treating a patient with prostate cancer by administering a compound of the genus that comprises abiraterone acetate; and claim 19, which claims a method of treating an androgen-dependent or estrogen-dependent disorder by administering abiraterone acetate.

abiraterone acetate has any unexpected *anti-cancer* effect.[6] In fact, it would be mandatory to conduct a randomized clinical trial that would include three arms—abiraterone alone, abiraterone plus prednisone, or prednisone alone—to make any claims of superior *anti-cancer* activity of the combination of abiraterone plus prednisone over abiraterone alone. Such a study is unlikely to be conducted for ethical reasons, however, because the adverse events of mineralocorticoid excess would invariably be induced by the doses of abiraterone alone, unaccompanied by concomitant prednisone administration.

84. Moreover, in my clinical experience, I would not expect that the addition of prednisone to a treatment for prostate cancer that includes abiraterone would result in any clinically significant enhancement of the anti-cancer or anti-tumor effect, as opposed to enhancement of the safety and tolerability of treatment. To the extent that addition of prednisone to a treatment for prostate cancer that includes abiraterone acetate increases the tolerability and duration of treatment with abiraterone acetate, and thereby enhances the efficacy of treatment, this enhanced efficacy is incidental to the reduction in side effects of abiraterone acetate from co-administration of prednisone, and not the result of any unexpectedly synergistic anti-cancer or anti-tumor effect.

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[6] *Cf.* MYL Ex. 1020 (Harris) at 544 ("the true benefit of adding ketoconazole to hydrocortisone can only be adequately addressed in a randomized trial.")

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85. Tellingly, the NDA holder and assignee of the '438 patent,[7] Janssen Biotech Inc., has never described the co-administration of prednisone with Zytiga as enhancing the anti-cancer or anti-tumor activity of Zytiga in information provided to healthcare practitioners. Instead, all of the prescribing information and marketing material for Zytiga with which I am familiar, including the 2011 Approval Prescribing Information (MYL Ex. 1018 at Sections 5.1 and 6.1) and the 2015 revised Prescribing Information and accompanying brochure on co-administration (MYL Ex. 1019 at 2-3), explain that co-administration of prednisone with Zytiga is intended to reduce adverse effects, such as hypertension, hypokalemia and fluid retention that may result from CYP17 inhibition of cortisol production and consequent ACTH drive.

86. For example, the 2015 brochure "Putting Prednisone in Perspective," which accompanies the 2015 revised Prescribing Information for Zytiga, states that "[p]rednisone reduces the incidence and severity of mineralocorticoid-related adverse reactions associated with Zytiga" and that "[c]oadministration of prednisone [with Zytiga] suppresses the ACTH drive and reduces the incidence

[7] *See* MYL Ex. 1001 (the assignee listed on the face of the '438 patent is Janssen Oncology, Inc., now Janssen Biotech); MYL Ex. 1035 (Orange Book listing for Zytiga, accessed June 30, 2016) at http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=202379&TABLE1=OB_Rx

and severity of mineralocorticoid excess adverse reactions." MYL Ex. 1019 (Prescribing Information for Zytiga® dated May 20, 2015) at 2.

87. Indeed, the Zytiga Prescribing Information makes clear that prednisone is co-administered as hormone replacement therapy and that "7.5 mg/day to 10 mg/day of prednisone is approximately the physiologic equivalent of the amount of endogenous cortisol normally produced on a daily basis." MYL Ex. 1019 (Prescribing Information for Zytiga® dated May 20, 2015) at 3.

88. To my knowledge, Janssen Biotech has never represented in any information provided to physicians that prednisone enhances the anti-cancer or anti-tumor effect of Zytiga.

3. Any hypothetical improvement in the efficacy of treating a patient with a prostate cancer by administering abiraterone in combination with prednisone rather than abiraterone alone is unlikely to have a clinically significant effect

89. It was reported in the art that the administration of prednisone at low doses (from about 7.5 to 10 milligrams per day) might be of some use in the palliative treatment of refractory prostate cancer by relieving symptoms and improving quality of life. *See, e.g.*, MYL Ex. 1031 (Tannock) at Abstract. It was also reported that prednisone might have some anti-tumor effect, such as by feedback inhibition of the hypothalamic-pituitary-adrenal axis, which could motivate one of skill in the art to administer prednisone for a possible anti-cancer effect. *See, e.g.*, MYL Ex. 1020 (Harris) at 544; MYL Ex. 1021 (Oh) at 89-90;

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MYL Ex. 1023 (Attard) at 1242; MYL Ex. 1079 (Fakih) at 553, 559; MYL Ex. 1080 (Lam) at 30–31. It is my experience in clinical practice, however, that the administration of prednisone alone does not have any clinically significant anti-cancer or anti-tumor effect, especially when compared to and dosed with a compound like abiraterone. Furthermore, in my experience, no treating physician would prescribe prednisone alone as an anti-cancer or anti-tumor agent to a patient with a prostate cancer. In certain circumstances, prednisone may be used at significantly higher doses than 10 mg per day for short term palliation of symptomatic, far advanced, terminal patients with mCRPC. Such short-term palliative benefits may include increase in appetite and sense of well-being, but there is no clinically-meaningful evidence that the dosing yields any alterations in survival, and any effects on possible patient sense of well-being were due to the palliative effects of the prednisone.

90. I am not aware of any study that has compared the efficacy in terms of anti-cancer or anti-tumor effect of administering an anti-cancer agent in combination with prednisone versus administering the anti-cancer agent alone. To the extent that prednisone might enhance in any statistically significant way an anti-cancer agent's efficacy in treating a prostate cancer, I would expect that effect would not be clinically significant in the context of the claimed invention. This is because the CYP17 inhibiting activity of abiraterone is so much more effective

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than any possible effect of prednisone in reducing levels of testosterone, that I do not believe any possible contribution to reduction in testosterone levels by prednisone would enhance the efficacy of abiraterone as an anti-cancer agent in a clinically significant way. Moreover, there is no evidence that I am aware of that prednisone contributes to further reduction of androgen levels or in any way interferes with androgen metabolism in prostate cancer cells themselves after testicular androgen production has ceased and circulating adrenal androgens have been blocked with antiandrogens. At best, while some evidence suggested that treatment with prednisone or other corticosteroids could result in a decline in prostate-specific antigen levels in some patients, *see, e.g.*, MYL Ex. 1020 (Harris) at 544; MYL Ex. 1021 (Oh) at 89-90; MYL Ex. 1023 (Attard) at 1242; MYL Ex. 1079 (Fakih) at 553, 559; MYL Ex. 1080 (Lam) at 30–31, this effect was, and is, dwarfed by prednisone's ability to provide palliative benefits.

4. The commercial success of Zytiga is not the result of unexpected synergies of the claimed invention

91. I understand that during prosecution the Patentees argued that the commercial success of Zytiga was evidence of the unexpected and surprising properties of the claimed invention. *See generally* MYL Ex. 1012 (Applicants' Amendment and Response dated June 4, 2013) at 6-9; *see also id.* at 8 (the "commercial success [of Zytiga] demonstrates the non-obviousness of the presently claimed invention.").

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92. There are no unexpected anti-cancer synergies resulting from co-administering abiraterone and prednisone.

93. The alleged commercial success of Zytiga is not the result of synergies in anti-cancer efficacy from the claimed invention. Instead, the alleged commercial success of Zytiga is due to the clinical efficacy, that is the anti-cancer effect, of administering abiraterone acetate to a patient with prostate cancer. It is my understanding that both abiraterone acetate and a method of treating a patient with prostate cancer by administering abiraterone acetate to said patient are claimed in the '213 patent. Consequently, it is my opinion that the commercial success of Zytiga is not as a result of the invention claimed in the '438 patent.

5. Other treatments for prostate cancer with similar efficacy but greater convenience and safety of administration than the claimed invention of the '438 patent are known

94. Although it has achieved allegedly significant commercial success, Zytiga's approved indication requires co-administering Zytiga and prednisone. In my opinion, this is a significant drawback of administering Zytiga because the administration of glucocorticoids, such as prednisone, is known to have many significant adverse effects, including osteopenia, weight gain, and hypertension. MYL Ex. 1025 (Harrison's) at 2147.

95. In my opinion, other treatments for refractory prostate cancer with similar efficacy but greater convenience and safety of administration than the

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claimed invention of the '438 patent exist that offer the advantage of not requiring co-administration of a glucocorticoid.

96. For example, the drug enzalutamide, marketed under the brand name Xtandi, has been shown to be similar to Zytiga in terms of its anti-tumor efficacy, as measured by survival endpoints such as progression-free or overall survival. MYL Ex. 1033 (Scher) at Abstract. For example, Scher *et al.* reported that in a double-blind, placebo-controlled Phase 3 clinical trial of patients with hormone refractory prostate cancer after chemotherapy, median overall survival for patients in the enzalutamide group was 18.4 months. MYL Ex. 1033 (Scher) at Abstract. These results in terms of median overall survival for enzalutamide are at least comparable to the median overall survival of 14.8 months reported in de Bono *et al.* for patients with metastatic prostate cancer who had received chemotherapy and who were administered abiraterone acetate and prednisone. MYL Ex. 1034 (de Bono) at Abstract. Unlike Zytiga, however, Xtandi does not need to be co-administered with prednisone. In my opinion, this is an advantage of Xtandi over Zytiga for reasons of both convenience and safety. It is more convenient for patients to take one pharmaceutical instead of two pharmaceuticals. And with Xtandi, patients avoid the side effects associated with administration of a corticosteroid.

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I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: June 30, 2016

Marc B. Garnick, M.D.

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EXHIBIT A

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Curriculum Vitae

Name: **Marc Bennett Garnick, M.D.**

Hospital Address: Beth Israel Deaconess Medical Center
330 Brookline Avenue
Boston, Massachusetts 02215

Place of Birth: Lawrence, Massachusetts

Education:

1968 AB	Bowdoin College, Brunswick, Maine
1972 MD	University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania

Postdoctoral Training:

Internships and Residencies:

1972-1973	Medical Intern, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania
1973-1974	Medical Resident, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania

Fellowships:

1974-1976	Clinical Associate, Division of Arthritis, Metabolism and Digestive Diseases, National Institutes of Health, Phoenix, Arizona, and Bethesda, Maryland
1976-1978	Clinical Fellow in Medicine, Harvard Medical School, Boston, Massachusetts
1976-1978	Clinical Fellow in Medical Oncology, Dana-Farber Cancer Institute, Boston, Massachusetts

Licensure and Certification

1976	Massachusetts License Registration
1976	American Board of Internal Medicine Certificate
1979	American Board of Internal Medicine/Medical Oncology Certificate

Academic Appointments

1978-1979	Instructor in Medicine, Harvard Medical School Boston, Massachusetts
1979-1982	Assistant Professor of Medicine, Sidney Farber Cancer Institute Harvard Medical School
1982-1984	Assistant Professor of Medicine, Harvard Medical School
1984-1987	Associate Professor of Medicine, Harvard Medical School
1987-1998	Associate Clinical Professor of Medicine, Harvard Medical School
1998	Clinical Professor of Medicine, Harvard Medical School
2014	Appointed Gorman Brothers Professor of Medicine, Harvard Medical School (endowed professorial chair at HMS)

Hospital Appointments

1976-1978	Assistant in Medicine, Peter Bent Brigham Hospital

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1978-1979	Clinical Associate, Dana-Farber Cancer Institute
1978-1984	Assistant Physician, Dana-Farber Cancer Institute
1978-1982	Junior Associate in Medicine, Brigham and Women's Hospital
1981-1989	Consulting Physician, Nantucket Cottage Hospital, Nantucket, Massachusetts

Other Professional and Major Visiting Appointments

1987-1994	Vice President, Clinical Development, Genetics Institute
2006	Medical Director, Oncology Services, Northeast Hospital Corporation
2007	Director Network Cancer Services, Beth Israel Deaconess Medical Center
2010	Member. Beth Israel Deaconess Medical Center Foundation Board of Dir.
2011	Member, Beth Israel Deaconess Board of Trustees
2012	Member, Active Medical Staff, Nantucket Cottage Hospital, Nantucket
2012	Member, Active Medical Staff, Lawrence General Hospital, Lawrence
2013	Medical Director, Cancer Network Services, Anna Jaques Hospital

Awards and Honors

1968	Magna Cum Laude, Bowdoin College
1968	Phi Beta Kappa, Bowdoin College
1972	Alpha Omega Alpha, University of Pennsylvania School of Medicine
1992, 1994,1996,	Listed in Best Doctors in America, Published by Woodward/White, Aiken, South Carolina
1996	Board of Trustees, Bowdoin College, Brunswick, Maine
1996	Executive Committee, Head of the Charles Regatta, Cambridge, Massachusetts
2002	Chairperson, Admissions and Financial Aid Committee of the Board of Trustees, Bowdoin College, Brunswick, Maine
1998-present	Listed Best Doctors in America
2000-present	Listed Best Cancer Doctors in America
2002-present	Listed America's Top Doctors
2004-2007	Director and Manager, Maria Mitchell Association, Nantucket MA
2005	Recipient Distinguished Medical Alumni Service Award, University of Pennsylvania School of Medicine
2006	Board of Trustees, University of Pennsylvania School of Medicine, Philadelphia PA (Now, Perelman School of Medicine at the University of Pennsylvania
2011	Trustee, Beth Israel Deaconess Medical Center (one of 5 Vice Chairs)
2014	Awardee, Men's Champion Award, Whittier Health Medical Center, Boston MA

Major Committee Assignments

National/Regional

1979	Consultant, National Academy of Sciences Task Force on Saccharin Labeling Act
1986	Member, Progression/Response Subcommittee on Prostate Cancer, through the Organ Systems Coordinating Center, Roswell Park Memorial Institute, Buffalo, New York
1987	Panel Member, NIH Consensus Localized Prostate Cancer, Bethesda, Maryland

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1987	Consultant, National Kidney and Urologic Diseases Advisory Board
1992	Reviewer, SPORE Grant for Prostate Cancer, National Institutes of Health
1995	Reviewer, SPORE Grant for Prostate Cancer, National Institutes of Health
1995	Reviewer for WW Smith and Mary L Smith Charitable Trust Foundations, Bryn Mawr, Pennsylvania
1996	Member, National Cancer Institute Working Group for Cancer Prevention

Medical

1980-1987	Admissions Committee (Subcommittee III), Harvard Medical School

Hospital

1978-1979	Chairman, Cardiopulmonary Resuscitation Review Committee, Dana-Farber Cancer Institute
1980-1983	Member, Biomedical Research Grant Review Committee, Dana-Farber Cancer Institute
1982-1987	Member, Scientific Protocol Review Committee, Dana-Farber Cancer Institute
1985-1987	Member, Free Care Committee, Dana-Farber Cancer Institute
1985-1987	Member, Internship Selection Committee, Dana-Farber Cancer Institute
1985-1987	Member, Clinical Planning Committee, Dana-Farber Cancer Institute
1997	Founder, Hershey Family Foundation for Basic and Clinical Prostate Cancer Research Beth Israel Deaconess Medical Center
2008	Founder and organizer of Breast Cancer Multi Disciplinary Clinic, North East Hospital System
2009	Founder and organizer of Thoracic Cancer Multi Disciplinary Clinic, North East Hospital System
2010	Member, Foundation Board, Board of Directors of Beth Israel Deaconess Medical Center
2011	Member, Board of Trustees, Beth Israel Deaconess Medical Center, Boston MA
2014	Member Search Committee for Editor in Chief of Harvard Health Publications

Governmental Assignments/Industry Assignments

2010-2015	Appointed to Food and Drug Administration Oncology Drug Advisory Committee (FDA ODAC) as Special Governmental Employee
2010	FDA ODAC voting panel member; Chemoprevention of prostate cancer with 5 Alpha Reductase Inhibitors (finasteride and dutasteride)
2011	FDA ODAC voting panel member; Study design considerations for Treatment of non –metastatic Castrate Resistant Prostate Cancer (NM-CRPC)
2012	FDA ODAC voting panel member – Evaluation of Axitinib for metastatic Renal Cell Cancer

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2013	FDA ODAC voting panel member – Evaluation of Mirabegon for urologic diseases
2013	FDA ODAC voting panel member- Evaluation of tivozinib for renal cancer
2014	FDA advisory panel member CDRH, Biologics Panels (four panels in 2014)
2014	FDA advisory panel SGE voting member: Gastrointestinal and Urologic Device Panel (CDRH); EDAP Ablatherm HIFU for clinically low risk prostate cancer
2014	FDA advisory panel SGE voting member: Gastrointestinal and Urologic Device Panel (CDRH); Reclassification of 5 urologic devices (non – voting)
2014	FDA Advisory panel SGE voting member on special Joint Committee: Bone Reproductive and Urologic Drug Products joint Meeting with Drug Safety Monitoring Committee; Review of safety and indications for Testosterone Replacement Therapy
2014	FDA Advisory panel SGE voting member on special Joint Committee: Bone Reproductive and Urologic Drug Products joint Meeting with Drug Safety Monitoring Committee; Review of Testosterone Replacement Product Roxtoro (Clarus Pharmaceuticals Inc)
2014	FDA advisory panel SGE voting member: Gastrointestinal and Urologic Device Panel (CDRH); SonaCare Medical using Sonablate for recurrent prostate cancer
2015	Reappointment as SGE for FDA Oncology Drug Advisory Committee for an additional 5 year term **(pending)**

Memberships, Offices and Committee Assignments in Professional Societies

1979	American Association for Cancer Research
1979	American Society of Clinical Oncology
1979-1982	Member, American College of Physician
1980	American Federation for Clinical Research
1980	Guest Member, American Urological Association, New England Section
1982	Fellow, American College of Physicians
1983	Affiliate Member, American Urological Association
1985-1993	Member, New England Cancer Society
1988	Corresponding Member, Argentinian Urological Association
1988	Chairman, Nominating Committee, American Society of Clinical Oncology
1988-1994	Member, American Society of Hematology
1990-1994	Corporate member, Society for Biological Therapy
1998	Corresponding Member, European Association of Urology

	1999	Board of Directors, Genome Therapeutics Corp.

Editorial Board

1983-1985	Editorial Board, Journal of Nutrition, Growth and Cancer
1985-1988	Editorial Board, Journal of Clinical Oncology
1989-1992	Board of Consultants, Journal of Urology
1996	Reviewer, New England Journal of Medicine
1996	Reviewer, Annals of Internal Medicine
1996	Reviewer, Urology
1997	Editorial Board, Molecular Urology
1997	Editorial Board, Urologic Oncology Case Management
1997	Editorial Board, Harvard Men's Health Watch
2006	Editor-in-Chief, Perspectives on Prostate Diseases, a Quarterly Publication from Harvard Health Publications
2009	Editor-in-Chief, www.HarvardProstateKnowledge.org
2010	Editor-in-Chief, HMS Annual Report on Prostate Diseases from Harvard Health Publications
2012	Editorial board, Harvard Men's Health Watch. Harvard Health publications
2012	Editorial board, Harvard Women's Health Letter, Harvard Health Publications
2012	Editorial board – Harvard Health Letter, Harvard Health Publications

Research Funding Information

Past:	1979-1986	**NIH/NCI/Contract Investigator** contract to study new Phase I anti-cancer agents
	1985	**NIH/CRC/BWH Investigator** Collaborator to study effects of radiation on thyroid function of long term cancer survivors
	1996	**Hershey Gift for Prostate Cancer Research (BIDMC) Co-PI** Benefaction for study of basic and clinical aspects of prostate cancer

Principal Clinical and Hospital Service Responsibilities

1978-1987	Medical Oncology, Attending Physician, Dana-Farber Cancer Institute (2 months per year)
1978-1987	Attending for Medical Oncology Consult Service, Brigham and Women's Hospital (1 month per year)
1981-1987	Medical Attending Physician, Ward Service, Brigham and Women's Hospital (1 month per year)
1985-1987	Attending for Medical Consult Service, Beth Israel Hospital (1 month per year)
1987-1996	Outpatient Attending Responsibilities, Dana-Farber Cancer Institute
1998	Member, Dana Farber/Harvard Cancer Center
1996	Outpatient Attending Responsibilities, Beth Israel Deaconess Medical Center
2008	Attending Physician, Oncology Inpatient Medical Service, Beth Israel Deaconess Medical Center

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Self Report of Teaching

1978-1987	**Medical Oncology, Attending Physician, Dana-Farber Cancer Institute** (2 months per year): 2-3 medical students; 2-3 interns; 2 residents; 4-5 fellows; 2 lectures per week; rounds 6 times per week; outpatient attending for medical oncology fellow
1978-1988	**Attending for Medical Oncology Consult Service, Brigham and Women's Hospital** (1 month per year); 1 fellow, 1 resident
1979-1981	**Preceptor, Introduction to Clinical Medicine (ICM), Harvard Medical School:** Preceptor for history and physical examination of general internal medicine patient; 2 students/year; 1 lecture per week
1980-1988	**Cancer Medicine**, Lecturer on Urologic Cancer, course under direction of DCE, Harvard Medical School
1980-1988	**Primary Care Medicine Course**, Lecturer on Prostate Cancer, course under direction of DCE, Harvard Medical School (Dr. Branch)
1981-1987	**Medical Attending Physician, Ward and HCHP Services, Brigham and Women's Hospital** (1 month per year): 2-3 medical students; 2-3 interns; 1 resident; 2-4 lectures per week; rounds 6 times per week
1984-1990	**Intensive Review of Internal Medicine**, Lecturer on Urologic Cancer, course under direction of DCE, Harvard Medical School
1985-1987	**Attending for Medical Oncology Consult Service, Beth Israel Hospital** (1 month per year); 1 resident; 1 medical student; 2-3 fellows; 2 lectures/week; rounds 4 times per week
1990-1992	**Genitourinary Oncology Course,** Lecturer, Massachusetts General Hospital, DCE, HMS
1994	**Lecturer, Second Year Pathophysiology Course**, Harvard Medical School (Endocrinology related to the management of cancer)
1995	**Lecturer, Intensive Review Internal Medicine**, Harvard Medical School/BIDMC (Update in Prostate Cancer)
2006	**Lecturer, Harvard Medial International/Specialty Practi-Med**, Harvard Medical School Dubai Center and Dubai Healthcare City 2006
2007	**Founder and Director,** Harvard Medical School Department of Continuing Education; Cancer Medical Malpractice and Primary Care: Improving Skills and Lessening Risks
2008	Advisor to Harvard Medical School First Year Class on Drug Development, FDA and bringing novel drug products to market

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2009	Lecturer for first year HMS-MIT/HST students on Cancer module and biology of cancer physiology
2008 - present	Director, Mentorship Program on Cancer Pathophysiology including thoracic, gastrointestinal, breast and genitourinary cancers
2010	Present: Expert Commentator for ASCO university, commenting on issues related to Bladder, prostate, renal and testis cancers;
2010	Organizer of Breast and Thoracic Multidisciplinary Oncology Tumor Board at Northeast Hospital System
2011	Expert commentator (teaching podcasts) for Journal of Clinical Oncology in bladder cancer
2012	Lecturer, Harvard Medical School Patient Safety and Quality Fellowship, Risk Management Foundation of Harvard Medical Institutions and CRICO
2013	Faculty Examiner, Harvard Medical School Comprehensive Clinical Examination for 4th year Medical Students a. Abdominal Pain Module b. Female Breast/Breast Cancer Examination module (breast cancer focus)
2015	Lecturer for GRASP section of Harvard Catalyst- for those young investigators who have a K grant, aspiring to an R-01

Advising Responsibilities

1979-1982	**Advisor for Health Science and Technology-Harvard Medical School** (HMS-HST), student thesis (anthracycline research)
1983-1985	**Internship Advisor (for fourth year Harvard Medical Students (1 student/year)**
1983-1985	**Tutor in Medical Sciences, Harvard Medical School**
1986-1987	**Advisor for Health Science and Technology-Harvard Medical School** (HMS-HST), student thesis (testis cancer); Presented at Soma Weiss Assembly

Leadership Roles

1982-1996	**Course Founder, Co-Director and Organizer, Urologic Cancer Course**, a biannual course under the auspices of the Department of Continuing Education (DCE), Harvard Medical School
1996	**Course Co-Director, First International Conference on Neoadjuvant Hormonal Therapy for Prostate Cancer** (International CME granting conference, with associated publication)

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1997	**Course Co-Director, Second International Conference on Neoadjuvant Hormonal Therapy for Prostate Cancer** (International CME granting conference, with associated publication)
1998	**Course Co-Director, Third International Conference on Neoadjuvant Hormonal Therapy for Prostate Cancer** (International CME granting conference, with associated publication)
1999	**Course Co-Director, Fourth International Conference on Neoadjuvant Hormonal Therapy for Prostate Cancer** (International CME granting conference, with associated publication)
1996 - present	**Hershey Family Foundation for Basic and Clinical Prostate Cancer Research, Beth Israel Deaconess Medical Center** (Founder and Originator)
2008	**Founder,** Hunt Foundation Gift for Prostate Cancer Genetics
2007	**Director, Cancer, Medical Malpractice and Primary Care: Improving Skills and Lessening Risks, a HMS CME course**
2009-2014	**Medical Director and Organizer, Multidisciplinary Thoracic Oncology and Breast Oncology Clinic, NorthEast Hospital Corporation (NHC) (Beverly Hospital) in role as Director Medical Oncology, NHC**
2010 - present	**Co-Director Harvard Medical School on Best Practices : Improving Skills and Lessening Risks**
2012	**Course director- National program on Evolving Biologic Concepts in Renal Cell Carcinoma**

Regional, National and International Contributions

Invited Presentations

1980-present	Medical Grand Rounds; on topics of Urologic Oncology, Prostate Cancer and Hematopoietic Growth Factors, at hospitals throughout the United States, Mexico, Canada, and Europe, at 4-8 hospitals per year
1980-present	Oncology Rounds, Tumor Conferences, Regional Symposia, National Symposia, International Congresses, on Urologic oncology, especially prostate cancer, 8-10 presentations per year
1990-1994	Scientific Symposia and Meet the Professor Sessions of both Regional and National American Society of Clinical Oncology (ASCO) Meetings
1995	Testicular Cancer Update, American Urological Association CME course National Meeting, Course Faculty
1996	Update in Prostate Cancer Treatments, a series of 10 regional meetings sponsored by the University of Kentucky CME department, throughout academic centers nationwide

1997-present	Update in Internal Medicine, Harvard Medical School Department of Continuing Education, Beth Israel Deaconess Medical Center Course Faculty
1998-present	International Prostate Cancer Update, Sponsored by Medical Education Collaborative, Course Faculty
1998-present	Lecturer, Testicular Cancer, Beth Israel Deaconess Medical Center
1999	Ninth International Congress on Anti-Cancer Treatment, Chaired Symposium on Prostate Cancer
2003	International Faculty, European Association of Urology, Annual Meeting, Madrid Spain March 2003, on Prostate Cancer
2003	Director, Harvard Medical School Sponsored Course. "Prostate Cancer for Internists, Department of Continuing of Medical Education
2007	Guest Lecturere, American College of Physicians, Annual Meeting, San Diego Ca : Prostate cancer screening- the great debate
2006	Faculty ,Harvard Medical International at Dubai
2008	Lecturer, Prostate Cancer, Beth Israel Deaconess Medical Center
2009	Lecturer, Prostate Cancer, Harvard Medical School and PriMed Medical Conferences (east coast)
2010	Invited Lecturer, Physician Education Day, on Screening for Prostate Cancer
2014-2016	Invited Lecturer, American College of Physicians, Annual Meeting, Plenary Session on Cancer Screening for 2014 and 2016 session
2015	Invited lecturer to Brigham and Women's Medical Residents on cancer biology and cancer screening issues

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Patents Issued

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