Plaintiffs,

v.

ACTAVIS LABORATORIES FL, INC., et al.,

Defendants.

OPINION
(*Markman* Patent Claim Construction)

MCNULTY, U.S.D.J.:

This Hatch-Waxman litigation arises out of the defendants' submissions of Abbreviated New Drug Applications ("ANDAs") with Paragraph IV certifications to the United States Food and Drug Administration (the "FDA").[1] The plaintiffs, BTG International Limited ("BTG"), Janssen Biotech, Inc., Janssen Oncology, Inc. ("Janssen Oncology"), and Janssen Research & Development, LLC (collectively, "Plaintiffs"), are the owners or exclusive licensees of two patents on a branded drug, ZYTIGA® (abiraterone acetate) Tablets ("ZYTIGA®"): United States Patent Nos. 8,822,438 (the "'438 patent") and 5,604,213 ("the '213 patent"). The defendants are generic drug companies who seek to engage in the commercial manufacture, use, offer for sale, or sale of a generic version of the plaintiffs' drug.

The plaintiffs claim that the defendants have infringed by submission of their ANDAs, and that the defendants' manufacture or sale of a generic version

[1] A Paragraph IV certification submits that the patent covering the branded drug currently being marketed is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the proposed generic drug product for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* Defendant Actavis Laboratories Fl, Inc.'s Answer and Counterclaims to Plaintiffs' First Amended Complaint for Patent Infringement (ECF No. 85).

September 2, 2014. That patent covers all FDA-approved indications of ZYTIGA®, a therapy that has demonstrated efficacy in extending the lives of advanced prostate cancer patients.[3] In connection with preparations for a

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[2] BTG owns the '213 patent and Janssen Oncology owns the '438 patent. The Janssen plaintiffs are the exclusive licensees of the '213 patent. (*See* Amended Complaint (ECF No. 47) ¶¶ 57–60.) Currently pending before this court is a separate motion to amend the complaint seeking to add patent infringement claims against certain of the Defendants as to U.S. Patent No. 8,236,946 and U.S. Patent No. 8,389,714, both also owned and/or licensed by the plaintiffs, but neither of which is at issue in this Opinion. (*See* ECF No. 204.)

Also pending is a motion to Set a Hearing and Correct Inventorship of the '438 patent by Plaintiffs, with which Plaintiffs filed a proposed Second Amended Complaint (No. 176) that seeks to add an additional inventor to the '438 patent and to add BTG as a plaintiff with respect to counts asserted and recovery sought under the '438 patent. Thus, BTG is not a plaintiff with respect to the counts asserted under the '438 patent at this time.

[3] For purposes of this opinion, citations to the record will be abbreviated as follows:

- '438 patent = Copy of U.S. Patent No. 8,822,438, Exhibit 1 to the Declaration of Brendan F. Barker in Support of Defendants' Claim Construction Brief (ECF No. 210-3)
- Pl. Br. = Plaintiffs' Opening Claim Construction Brief (ECF No. 209)
- Def. Br. = Defendants' Opening Claim Construction Brief (ECF No. 210)
- Pl. Resp.= Plaintiffs' Responsive Claim Construction Brief (ECF No. 220)
- Def. Resp. = Defendants' Responsive Claim Construction Brief (ECF No. 221)
- Barker Decl. = Declaration of Brendan F. Barker in Support of Defendants' Claim Construction Brief (ECF No. 210-2)
- Barker Resp. Decl. = Declaration of Brendan F. Barker in Support of Defendants' Responsive Claim Construction Brief (ECF No. 221-1)
- Fruehauf Decl. = Declaration of John P. Fruehauf, M.D., Ph.D. on Claim Construction (ECF No. 210-1)
- Miller Decl. = Declaration of Keith J. Miller, Esq. in Support of Plaintiffs' Opening Claim Construction Brief (ECF No. 209-1)

what is the meaning of the terms "treatment" and "treating" in the claimed methods? Claim 1, the only independent claim of the '438 patent, states:

> 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.

('438 patent, 16:16–20 (emphasis on disputed term).) "Treatment" is the only disputed term that appears in claim 1. The parties also include the term "treating," however, because "treating" appears in their proposed joint construction of the term 'therapeutically effective amount." The parties agree that a "therapeutically effective amount" means "an amount effective for **treating** cancer." (*See* Def. Br. 5 n.4 (emphasis on disputed term).)[4]

Plaintiffs submit that "treatment" and "treating" must be given a restrictive construction that encompasses only "reducing the growth and spread of cancer cells." (Pl. Br. 2) Defendants, on the other hand, argue for a more inclusive construction that covers "all of the uses and therapeutic benefits known" when this method for treating prostate cancer in patients was invented. Defendants' more inclusive construction would encompass

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- MJCC = So-Ordered Letter Modifying Joint Claim Construction and Prehearing Statement (ECF No. 208)

[4] Additionally, the parties agree that the preamble of claim 1, on which claims 2-20 of the '438 patent depend and reads "A method for the treatment of a prostate cancer in a human," is "limiting, and limits the claims to the treatment of a prostate cancer in a human." They agree that "refractory prostate cancer" means "Prostate cancer that is not responding to an anti-cancer treatment or prostate cancer that is not responding sufficiently to an anticancer treatment. Refractory prostate cancer can also include recurring or relapsing prostate cancer." And, they agree that "therapeutically effective amount" means "an amount effective for treating cancer." (MJCC 2.)

Defendants agree that it covers this, but say the patent *also* covers pain relief and glucocorticoid replacement.

To reflect their positions, the parties propose the following constructions of "treatment"/"treating":

- Plaintiffs propose: "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."

- Defendants propose: "**including** 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."

(*See* MJCC; ECF Nos. 231, 232 (October 21, 2016 letters from parties reflecting further revision to joint construction)(emphasis added).) The proposed definitions are identical, except for the word "including" which appears at the beginning of Defendants' proposal.

The '438 patent itself defines the disputed terms in the specification as follows:

> As used herein, and unless otherwise defined, the terms "treat," "treating" and "treatment" 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.

('438 patent 3:46–50 ("Definitions" section).)[5]

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[5] Plaintiffs have informed this court they "have no objection to the Court's adopting this express definition from the patent with the word 'include,' so long as the Court clarifies that the word 'include' is used in this definition in its restrictive sense." (October 21, 2016 Letter from Justin T. Quinn (ECF No. 232).)

for prostate cancer is androgen deprivation therapy ("ADT"). ADT aims to lower the body's production and circulation of testosterone, a naturally occurring androgen, in the body. The drug abiraterone acetate belongs to a class of drugs known as CYP17 inhibitors, which block production of testosterone in a patient's adrenal glands. CYP17 inhibitors, however, also block production of other steroids and hormones, which can lead to serious side effects. To reduce such side effects, patients receiving this class of drugs often receive steroid replacement therapy. Steroid replacement therapy often involves administration of prednisone, a synthetic type of a subclass of steroid called a glucocorticoid. Steroids like prednisone inhibit the growth of cancer cells; they also provide pain relief, or palliative treatment, to prostate cancer patients. (*See* Pl. Br. 2–3; Def. Br. 3–4.)

ADT is not considered a cure for prostate cancer because in most patients, it eventually loses effectiveness in inhibiting tumor growth. Prior to the invention described in the '438 patent, prostate cancer not responsive to ADT (known as or metastatic castration-resistant prostate cancer ("mCRPC"), had few treatment options. The '438 patent invention—specifically the combination of therapeutically effective amounts of abiraterone acetate and prednisone, marketed as ZYTIGA®—has proven effective in extending the lives of patients with mCRPC. (*See* Pl. Br. 3–4; Def. Br. 3–4.)

Plaintiffs submit that the efficacy of the '438 patent invention was novel and surprising. At the time of the invention, they say, researchers doubted that an androgen-suppression drug like abiraterone acetate would be effective in castration-resistant prostate cancer patients; the prior art, moreover, did not suggest that prednisone could have any anti-cancer effect, alone or in combination with abiraterone acetate. (Pl. Br. 3.) Plaintiffs acknowledge that

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