

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BAXTER HEALTHCARE CORPORATION,
BAXTER INTERNATIONAL INC., and
BAXTER HEALTHCARE S.A.,

Plaintiffs,

v.

MYLAN LABORATORIES LTD. and
MYLAN PHARMACEUTICALS INC.,

Defendants.

BAXTER HEALTHCARE CORPORATION,
BAXTER INTERNATIONAL INC., and
BAXTER HEALTHCARE S.A.,

Plaintiffs,

v.

SAGENT PHARMACEUTICALS INC.,

Defendant.

HONORABLE JEROME B. SIMANDLE

Civil Action Nos.

14-7094 (JBS/JS)

15-1684 (JBS/JS)

MARKMAN OPINION

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I. INTRODUCTION

These related patent infringement actions under the Hatch-Waxman Act, 35 U.S.C. §§ 271, 282, generally concern the assertions of Plaintiffs Baxter Healthcare Corporation, Baxter International Inc., and Baxter Healthcare S.A. (collectively, “**Baxter**”) that the proposed generic esmolol hydrochloride

products of Defendants Mylan Laboratories Ltd., Mylan Pharmaceuticals Inc. (hereinafter, "**Mylan**"), and Sagent Pharmaceuticals Inc. (hereinafter, "**Sagent**" and collectively, "**Defendants**")¹ infringe the various patents covering Baxter's esmolol hydrochloride product, U.S. Patent Nos. 6,310,094 (hereinafter, "'094 Patent") and 6,528,540 (hereinafter, "'540 Patent" and collectively, the "patents-in-suit" or "Patents"), a "continuation-in-part" of the '094 Patent.²

Following factual and claims construction discovery, the parties now request that the Court construe the following three claim terms:³

1. "**Sterile**," as it appears in asserted claims 4 through 9 of the '094 Patent, and claims 6, and 12 through 16 of the '540 Patent;⁴

¹ Although Defendants seek to market generic esmolol products under different abbreviated new drug applications (hereinafter, "ANDAs"), they jointly briefed the disputed claim terms at issue here.

² As a result, the patents-in-suit share essentially identical specifications and disclosures. (Compare '094 Patent, with '540 Patent.) For that reason, the Court will, in the interests of simplicity, primarily cite to the '094 Patent, unless otherwise indicated.

³ The parties initially sought construction of the claim term "osmotic-adjusting agent," but subsequently stipulated that the Court's construction of "osmotic-adjusting agent" in a related case, Baxter Healthcare Corp. v. HQ Specialty Pharma Corp., ___ F. Supp. 3d ___, No. 13-6228, 2015 WL 5646779, at *6 (D.N.J. Sept. 23, 2015) (hereinafter, the "HQ case"), would govern these actions. [See Docket Item 82 in 14-7094; Docket Item 58 in 15-1684.]

⁴ Although Baxter purports to seek construction of only the term "sterile," the definition proposed by Baxter contains two discrete components, and ultimately requires (if adopted) construction of the terms "sterile" and "state of sterility."

2. **"Aqueous,"** as it appears in asserted claims 1 through 9 of the '094 Patent, and claims 6, and 12 through 16 of the '540 Patent;⁵ and
3. **"Injectable, aqueous pharmaceutical composition,"** as it appears in asserted claims 1 through 9 of the '094 Patent.

In seeking construction, Baxter takes the position, on essentially each disputed claim term, that the intrinsic record discloses a specific definition, and/or reflects the patentee's intention that the term be defined by reference to the "ordinary" meaning advanced in its extrinsic sources (namely, expert testimony and dictionary definitions). (See, e.g., Baxter's Opening Br. at 8-23; Baxter's Responsive Br. at 2-20.) More specifically, though, Baxter claims (1) that the inventors acted as their own lexicographer in reciting the term "sterile," (2) intended to incorporate their view on the "ordinary mean" of the term "aqueous," and (3) limited the scope of the phrase "injectable, aqueous pharmaceutical composition" through reference, in the specification, to the characteristics that form the "heart" of Baxter's claimed invention (namely, a stable, ready-to-use composition, capable of being autoclaved). (Baxter's Opening Br. at 8-23; Baxter's Responsive Br. at 2-20.)

⁵ Similar to the situation the Court confronts relative to the term "sterile," the parties' positions on the term "aqueous" reflect the need to construe the concept of an "aqueous" pharmaceutical composition, as opposed to simply the term "aqueous."

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