

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

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SENJU PHARMACEUTICAL CO.,  
LTD., BAUSCH & LOMB, INC.,  
BAUSCH AND LOMB PHARMA  
HOLDINGS CORP.,

Plaintiffs,

v.

LUPIN LTD., LUPIN  
PHARMACEUTICALS, INC.,

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Defendants.

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SENJU PHARMACEUTICAL CO.,  
LTD., BAUSCH & LOMB, INC.,  
BAUSCH & LOMB PHARMA HOLDINGS  
CORP.,

Plaintiffs,

v.

LUPIN LTD., LUPIN  
PHARMACEUTICALS, INC.,

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Defendants.

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SENJU PHARMACEUTICAL CO.,  
LTD., BAUSCH & LOMB, INC.,  
BAUSCH & LOMB PHARMA HOLDINGS  
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LUPIN LTD., LUPIN  
PHARMACEUTICALS, INC.,

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Defendants.

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SENJU PHARMACEUTICAL CO.,  
LTD., BAUSCH & LOMB  
INCORPORATED, BAUSCH & LOMB  
PHARMA HOLDINGS CORP.,

Plaintiffs,

v.

LUPIN, LTD., LUPIN  
PHARMACEUTICALS, INC.,

---

Defendants.

HONORABLE JEROME B. SIMANDLE

Civil Action Nos.

14-667 (JBS/KMW)

14-4149 (JBS/KMW)

14-5144 (JBS/KMW)

15-335 (JBS/KMW)

14-6893 (JBS/KMW)

15-3240 (JBS/KMW)

**MARKMAN OPINION**

[Caption Continues]

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SENJU PHARMACEUTICAL CO.,  
LTD., BAUSCH & LOMB, INC.,  
BAUSCH & LOMB PHARMA HOLDINGS  
CORP.,

Plaintiffs,

v.

INNOPHARMA LICENSING, INC.,  
INNOPHARMA LICENSING, LLC,  
INNOPHARMA, INC., INNOPHARMA,  
LLC,

Defendants.

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SENJU PHARMACEUTICAL CO.,  
LTD., BAUSCH & LOMB  
INCORPORATED, BAUSCH & LOMB  
PHARMA HOLDINGS CORP.,

Plaintiffs,

v.

INNOPHARMA LICENSING, INC.,  
INNOPHARMA LICENSING, LLC,  
INNOPHARMA, INC., INNOPHARMA,  
LLC,

Defendants.

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Innopharma, LLCit only happens

**SIMANDLE, Chief Judge:**

**I. INTRODUCTION**

Plaintiffs Senju Pharmaceutical Co., Ltd., Bausch & Lomb  
Inc., and Bausch & Lomb Pharma Holdings Corp. (collectively,  
"Plaintiffs") brought these various patent infringement actions

under the Hatch-Waxman Act, 35 U.S.C. §§ 271, 281, against Defendants Lupin, Ltd., Lupin Pharmaceuticals, Inc., Innopharma Licensing, Inc., Innopharma Licensing, LLC, Innopharma, Inc., and Innopharma, LLC (collectively, "Defendants") concerning Defendants' submissions of abbreviated new drug applications ("ANDAs") seeking FDA approval to market a generic version of Plaintiffs' drug Prolensa®, which is used to treat patients who have undergone cataract surgery. Plaintiffs allege that Defendants' ANDA submissions infringe the various patents covering Plaintiffs' Prolensa® product: U.S. Patent Nos. 8,129,431 ("the '431 patent"), 8,669,290 ("the '290 patent"), 8,754,131 ("the '131 patent"), 8,871,813 ("the '813 patent"), and 8,927,606 ("the '606 patent") (collectively, the "patents-in-suit").

Before the Court is the parties' request for claim construction of three disputed terms in these patent infringement actions:<sup>1</sup>

1. **"in an amount sufficient to stabilize said first component,"** as it appears in asserted claim 1 of the

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<sup>1</sup> The parties initially disputed a fourth term, "EDTA sodium salt" and "sodium edetate" (which the parties agree are equivalent terms), in their Markman briefs, but subsequently stipulated to a joint proposed construction of the two terms. (See, e.g., Stip. [Docket Item 102], Senju Pharm. Co. Ltd. v. Lupin, LTD., Civ. No. 14-667.) The Court will therefore adopt the parties' construction and construe "EDTA sodium salt" and "sodium edetate" to mean "A sodium salt of ethylenediaminetetraacetic acid. This phrase encompasses, for example, the disodium salt of ethylenediaminetetraacetic acid."

'290 patent, claim 1 of the '131 patent, claim 1 of the '813 patent, and claim 1 of the 606 patent; and "stable," as it appears in asserted claims 1, 7, 8, 10, 13, 14, 19, 20, 22, 25 of the '290 patent, claims 1, 6, 7, 9, 12, 13, 18-22, 24 of the '131 patent, claims 1, 7, 9, 13, 19-21 of the '813 patent, claims 1, 9, 11, 12, 18, 19, 25, 26 of the '606 patent.

2. "consisting essentially of" and "consists essentially of,"<sup>2</sup> as they appear in asserted claims 1 and 18 of the '431 patent, claims 1, 7, and 13 of the '813 patent, claims 7, 13, 19, and 25 of the '290 patent, claims 6, 12, 18, and 24 of the '131 patent, and claims 9, 18, and 25 of the '606 patent;
3. "satisfies the preservative efficacy standard of US Pharmacopoeia as follows: viable cell counts of bacteria (*S. aureus*, *P. aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans*, *A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation," as it appears in asserted claims 25-29 of the '131 patent.

For the reasons that follow, the Court construes the disputed phrases as follows:<sup>3</sup>

Term	Court's Construction
"in an amount sufficient to stabilize said first component" and "stable"	"in an amount sufficient to stabilize said first component" means "an amount sufficient to confer sufficient resistance to

<sup>2</sup> The parties agree that "consisting essentially of" and "consists essentially of" have the same meaning. (See Def. Opening Claim Constr. Br. at 24 n.8.)

<sup>3</sup> The Court held a Markman hearing on November 2, 2015, and considered the lengthy Markman submissions by the parties, which included thousands of pages of exhibits, along with declarations from Plaintiffs' experts, Dr. Robert O. Williams, Ph.D. and Dr. Thomas K. Green, Ph.D., and Defendants' expert, Dr. Jayne Lawrence, Ph.D.

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