

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

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

Plaintiffs,

v.

LUPIN LTD., LUPIN
PHARMACEUTICALS, INC.,
Defendants.

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

Plaintiffs,

v.

LUPIN LTD., LUPIN
PHARMACEUTICALS, INC.,
Defendants.

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

Plaintiffs,

v.

LUPIN LTD., LUPIN
PHARMACEUTICALS, INC.,
Defendants.

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]

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.

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.

APPEARANCES:

Melissa A. Chuderewicz, Esq.
PEPPER HAMILTON LLP
Suite 400
301 Carnegie Center
Princeton, NJ 08543

-and-

Bryan C. Diner, Esq.
Justin J. Hasford, Esq.
Chiaki Fujiwara, Esq.
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001

-and-

Jessica M. Lebeis, Esq.
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
303 Peachtree Street, NE
Atlanta, GA 30308

Attorneys for Plaintiffs

Michael E. Patunas, Esq.

Mayra V. Tarantino, Esq.
LITE DEPALMA, GREENBERG, LLC
570 Broad Street, Suite 1201
Newark, NJ 07102

-and-

Elizabeth J. Holland, Esq.
Daniel P. Margolis, Esq.
Natasha E. Daughtrey, Esq.
Sarah Fink, Esq.
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018

-and-

Emily L. Rapalino, Esq.
GOODWIN PROCTER LLP
53 State Street
Boston, MA 02109
Attorneys for Defendants Lupin Limited and Lupin
Pharmaceuticals, Inc.

Arnold B. Calmann, Esq.
Jeffrey Soos, Esq.
Katherine A. Escanlar, Esq.
SAIBER LLC
One Gateway Center, 10th Floor
Newark, NJ 07102

-and-

Deepro R. Mukerjee, Esq.
Lance A. Soderstrom, Esq.
Leah W. Feinman, Esq.
ALSTON & BIRD LLP
90 Park Avenue
New York, NY 10016
Attorneys for Defendants Innopharma Licensing, Inc.,
Innopharma Licensing, LLC, Innopharma, Inc., and
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:¹

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

¹ 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,"² 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:³

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

² 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.)

³ 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.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.