Plaintiff, **v.** **FERA PHARMACEUTICALS, LLC, et al.,** **Defendants.**	**OPINION** **(*Markman*)**
FRESENIUS KABI USA, LLC, **Plaintiff,** **v.** **INNOPHARMA LICENSING, LLC, et al.,** **Defendants.**	

KEVIN MCNULTY, U.S.D.J.:

This Opinion contains the Court's construction of key patent terms following a *Markman* hearing. This patent infringement case is brought by the plaintiff, Fresenius Kabi USA, LLC, against the defendants, Fera Pharmaceuticals, LLC and Oakwood Laboratories, LLC (collectively, "Fera") and InnoPharma, Inc. and InnoPharma Licensing, LLC (collectively, "InnoPharma").[1] The patents-in-suit are Patent Nos. 9,006,289 ("the '289 patent"), 9,168,238

[1] The suit against InnoPharma was originally filed under the docket number 15–3655, but the cases were consolidated for pretrial purposes upon request of the parties. (*See* ECF No. 79) A third suit, docket number 15–3853, was originally consolidated with these two, but those defendants settled with Fresenius after the opening briefs were filed. (*See* ECF No. 120)

thyroid. (Pl. Opening 1).[2]

The Food and Drug Administration approved Fresenius's New Drug Application ("NDA") on June 24, 2011. (3AC Fera ¶ 15) The '289 patent was issued on April 14, 2015, and is due to expire on October 3, 2032. (3AC Fera ¶¶ 10, 16) The '238 and '239 patents were issued on October 27, 2015, and are due to expire on August 29, 2032. (3AC Fera ¶¶ 11–12, 16) Fera and InnoPharma filed Abbreviated New Drug Applications ("ANDA") that sought

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[2] Citations to the record will be abbreviated as follows:

"3AC Fera" — Third Amended Complaint of Fresenius against Fera (ECF No. 83).

"Fera Answer" — Fera's Answer to 3AC Fera (ECF No. 84).

"InnoPharma Answer" — InnoPharma's Answer to the Second Amended Complaint of Fresenius against InnoPharma (ECF No. 85).

"Joint Br." — Parties' Joint Claim Construction and Prehearing Statement (ECF No. 92).

"Pl. Opening" — Plaintiff's Opening Markman Brief (ECF No. 101).

"Pl. Ex." — Plaintiff's Exhibits (ECF Nos. 101–2 to 101–5), attached to the Declaration of Justin T. Quinn (ECF No. 101–1).

"Pl. Response" — Plaintiff's Responsive Markman Brief (ECF No. 171).

"Def. Opening" — Defendants' Amended Opening Markman Brief (ECF No. 157).

"Def. Ex."— Defendants' Exhibits (ECF Nos. 102–2 to 102–19), attached to the Certification of Christina L. Saveriano (ECF No 102–1).

"Def. Response" — Defendants' Responsive Markman Brief (ECF No. 170).

"'289 Patent" — United States Patent No. 9,006,289, Pl. Ex. 1 (ECF No. 101–2).

"'238 Patent" — United States Patent No. 9,168,238, Pl. Ex. 2 (ECF No. 101–3).

"'239 Patent" — United States Patent No. 9,168,239, Pl. Ex. 3 (ECF No. 101–4).

"Remington" — *Remington: The Science and Practice of Pharmacy*, (Alfonso R. Gennaro et al. eds. 20th ed. 2000), Def Ex. G (ECF No. 102–8).

A. Standard

"The purpose of claim construction is to 'determin[e] the meaning and scope of the patent claims asserted to be infringed.'" *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384 (1996)). "[T]he words of a claim are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks and citations omitted). Courts interpret claim terms according to an objective standard: "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313. To make this determination, courts may consider evidence intrinsic to the patent, *i.e.*, "the words of the claims themselves, the remainder of the specification, [and] the prosecution history," as well as "extrinsic evidence, which consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id.* at 1314, 1317 (internal quotation marks and citations omitted).

In *Phillips*, the United States Court of Appeals for the Federal Circuit, sitting en banc, explained that its prior case law had "attempted to explain why, in general, certain types of evidence are more valuable than others." *Id.* at 1324 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996)). *Phillips* assigned significant value to intrinsic evidence and less weight to extrinsic evidence, holding extrinsic evidence useful only to the extent

Cir. 2016). "[C]laims must be read in view of the specification, of which they are a part" because the specification "is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315. "[I]f the specification reveals a special definition given to a claim term by the inventor, then the inventor's lexicography governs, even if it differs from the term's ordinary meaning." *David Netzer Consulting Eng'r LLC v. Shell Oil Co.*, 824 F.3d 989, 994 (Fed. Cir. 2016) (citing *Phillips*, 415 F.3d at 1316). The court may also consider, where relevant, the patent's prosecution history, "which consists of the complete record of the proceedings before the PTO and [] the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. Extrinsic evidence, considered in the context of the intrinsic evidence, may "help educate the court regarding the field of the invention and [] help the court determine what a person of ordinary skill in the art would understand claim terms to mean." *Phillips*, 415 F.3d at 1319.

B. Levothyroxine

The specification section of the patents[3] provides some background information on levothyroxine:

> A healthy thyroid produces hormones that regulate multiple metabolic processes and that play important roles in growth and development, in maturation of the central nervous system and bone including augmentation of cellular respiration and thermogenesis, and in metabolism of proteins, carbohydrates and lipids. The thyroid accomplishes its regulation functions by producing the hormones L-triiodothyronine (liothyronine; T3) and L-thyroxine (levothyroxine; T4).

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[3] The three patents all contain the same specification, so a citation to the specification of the '289 Patent applies equally to all. (*See* Pl. Opening 7 n.4)

maintenance dose of 50-100 micrograms (µg) of levothyroxine sodium. A patient in need of additional intervention may be treated by administration of an initial dose of 200-500 µg or 300-500 µg of levothyroxine sodium and/or with a 2nd day dose of 100-300 µg of levothyroxine sodium.

('289 Patent 1:13–47) The drug at issue in this suit is a lyophilized, or freeze-dried, formulation of levothyroxine that is later reconstituted and injected into patients. (Pl. Opening 1)

Levothyroxine injections have been available in the United States since 1969. (Def. Opening 3) Fresenius's newly patented formulations contain levothyroxine, a buffer, and a specific amount of a bulking agent called mannitol. The mannitol provides bulk to the "cake" that remains after the formulation is freeze dried. Fresenius's patents are based on the discovery that, contrary to expectation, a reduction in the proportion of mannitol improved the stability of the freeze dried cake. (Pl. Opening 1–2)

C. Disputed Claims

The parties presented charts that jointly summarize their positions as to the eleven disputed claims. I will present the charts in groups of related terms as I consider the claim construction arguments.

1. "Buffer" and "Phosphate Buffer"

While Fresenius "does not believe that the construction of any disputed term will be most significant to the resolution of the case" (Joint Br. 5), both Fera and InnoPharma consider construction of the term "buffer" to be potentially case dispositive. (*Id.* at 5–6) As to the "buffer" term, the parties summarize their positions as follows:

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