

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and)	
NOVO NORDISK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 23-101 (CFC)
v.)	ANDA CASE
)	
MYLAN PHARMACEUTICALS INC.,)	
)	
Defendant.)	

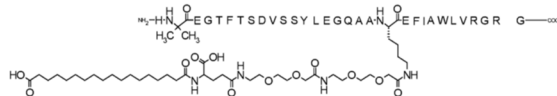
[PROPOSED] CLAIM CONSTRUCTION ORDER

After having considered the submissions of the parties and hearing oral argument on the matter, and in accordance with the reasoning set forth on the record during oral argument, **IT IS HEREBY ORDERED** that the following terms in the asserted claims of the patents set forth below are construed as follows:

U.S. Patent No. 9,764,003 (“’003 Patent”)	
Term	Court’s Construction
“A method for reducing body weight” (Claims 1, 2, 5, and 6)	The preamble is limiting. It requires that the method be employed for the purpose of reducing the patient’s body weight, and it does not require a showing of efficacy. (Claim Construction Hr’g Tr. at 21:20–24.)

U.S. Patent No. 10,888,605 (“’605 Patent”)	
Term	Court’s Construction
“A liquid pharmaceutical composition comprising semaglutide and phenol . . . wherein the phenol is no more than 0.1 mg/ml” (Claims 6, 8, 10, 12, and 14)	Plain and ordinary meaning; the composition comprises semaglutide and phenol wherein the phenol is no more than 0.1 mg/ml. (Claim Construction Hr’g Tr. at 100:14–18.)

IT IS FURTHER ORDERED that the Court herein adopts the parties' agreed upon constructions set forth in the Amended Joint Claim Construction Chart (D.I. 67) and the letters submitted to the Court pursuant to the December 11, 2023 Oral Order, (D.I. 74, 75).

Claim Terms Agreed Upon in U.S. Patent No. 8,129,343	
Term	Agreed Upon Construction
<p>“A compound of the structure</p>  <p>where the amino acid sequence is that of SEQ ID NO: 7.” (Claims 1 and 2)</p>	<p>Plain and ordinary meaning, which is “a compound corresponding to the claimed structure, which is also called ‘semaglutide’”</p>
<p>“N-ϵ^{26}-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl] [Aib8,Arg34]GLP-1-(7-37)peptide” (Claims 4 and 5)</p>	<p>Plain and ordinary meaning, which is “the compound corresponding to the chemical N-ϵ^{26}-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl] [Aib8,Arg34]GLP-1-(7-37)peptide, which is also called ‘semaglutide’”</p>

Claim Term Agreed Upon in the '605 Patent	
Term	Agreed Upon Construction
<p>“therapeutically effective amount” (Claim 14)</p>	<p>Plain and ordinary meaning, which is “an amount intended to have a beneficial effect on obesity”</p>

Claim Terms Agreed Upon in U.S. Patent No. 11,318,191	
Term	Agreed Upon Construction
<p>“0[.0]% (w/w) to 0.1% (w/w) phenol” (Claims 2, 10, 11, 14, 15, 18, 21, 22, 24, and 26)</p>	<p>Plain and ordinary meaning, which is “0[.0]% (none) to 0.1% (w/w) phenol”</p>
<p>“therapeutically effective amount” (Claims 15, 22, and 26)</p>	<p>Plain and ordinary meaning, which is “an amount intended to have a beneficial effect on the disease”</p>

Claim Terms Agreed Upon in U.S. Patent No. 11,318,191	
Term	Agreed Upon Construction
“optionally one or more agents for adjusting pH” (Claims 16 and 23)	Plain and ordinary meaning, which is “one or more agents for adjusting pH can be, but need not be, present”
“optionally histidine” (Claim 16)	Plain and ordinary meaning, which is “histidine can be, but need not be, present”
“disodium hydrogen phosphate dihydrate” (Claim 11)	Plain and ordinary meaning, which is “a compound having the formula Na ₂ HPO ₄ in the dihydrate form”

Claim Term Agreed Upon in the '003 Patent	
Term	Agreed Upon Construction
“at least 0.8 mg” (Claim 2)	Plain and ordinary meaning, which is, in conjunction with the limitations of claim 1 from which claim 2 depends, “at least 0.8 mg and up to 1.6 mg of semaglutide”

The Court has taken under advisement the constructions of “without another therapeutic agent” and “once weekly in an amount of at least 0.7 mg and up to 1.6 mg” from asserted claims 1, 2, 5, and 6 of the '003 Patent and will issue a separate order regarding those terms in due course.

SO ORDERED this ____ day of December, 2023.

The Honorable Colm F. Connolly
Chief, United States District Judge