

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: OZEMPIC (SEMAGLUTIDE)
PATENT LITIGATION

)
) MDL NO. 22-MD-3038 (CFC)
) **ANDA CASE**
)
)

NOVO NORDISK INC. and
NOVO NORDISK A/S,

Plaintiffs,

v.

RIO BIOPHARMACEUTICALS INC.,
et al.,

Defendants.

)
) C.A. No. 22-294 (CFC)
) CONSOLIDATED
) **ANDA CASE**
)
)
)

NOVO NORDISK INC. and
NOVO NORDISK A/S,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.

Defendant.

)
) C.A. No. 22-1040 (CFC)
) **ANDA CASE**
)
)
)

[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 claims of the patents set forth below are construed as follows:

U.S. Patent No. 8,920,383	
Term	Court's Construction
"piston rod" (Claims 1, 2, 3, and 8)	Plain and ordinary meaning, which is "shaft that causes the piston to be moved."
"housing" (Claims 2, 3, 6, 10, and 11)	Plain and ordinary meaning, with no further construction necessary. ¹
"defining a passage" (Claim 1)	No construction necessary.

U.S. Patent No. 9,775,953	
Term	Court's Construction
"piston rod" (Claim 1)	Plain and ordinary meaning, which is "shaft that causes the piston to be moved."
"housing" (Claims 1, 2, 8, 9, 19, 21, and 24)	Plain and ordinary meaning, with no further construction necessary. ²
"defining a passage" (Claim 1)	No construction necessary.

U.S. Patent No. 10,335,462	
Term	Court's Construction
"A method for treating type 2 diabetes" (Claim 1)	The preamble term is an express limitation of claims 1-10, and it means that "the claimed administration is for the purpose of care and management of

¹ As stated during the July 13, 2023 hearing, if the parties need a synonym for "housing," they could use "enclosure." Tr. 48:16-19.

² As stated during the July 13, 2023 hearing, if the parties need a synonym for "housing," they could use "enclosure." Tr. 48:16-19.

U.S. Patent No. 10,335,462	
Term	Court's Construction
	a patient with Type 2 diabetes” or “the claimed administration is intended to care for and manage a patient with Type 2 diabetes.”

IT IS FURTHER ORDERED that the Court will defer any ruling on claim construction of the following terms of U.S. Patent Nos. 8,920,383 and 9,775,953 until after additional extrinsic evidence, including in the form of expert testimony, is presented for the Court’s consideration. The parties shall meet and confer to discuss an appropriate time for the Court to consider such additional extrinsic evidence and present their proposal to the Court by **August 4, 2023**.

U.S. Patent No. 8,920,383	
Term	Claim(s)
“coupled”	1
“limiter”	1, 5, and 8
“driver”	1, 5, and 10

U.S. Patent No. 9,775,953	
Term	Claim(s)
“coupled”	1 and 9
“limiter”	1, 4, 7, and 17

U.S. Patent No. 9,775,953	
“driver”	1, 8, 9, 19, 21, and 24

IT IS FURTHER ORDERED that the Court herein adopts the parties’ agreed-to constructions set forth in the Amended Joint Claim Construction Chart (D.I. 145) and discussed on the record at the July 13, 2023 hearing. These constructions are set forth below:

CLAIM TERMS AGREED UPON IN U.S. PATENT NO. 8,114,833		
Term	Claim(s)	Construction
“about”	1, 7, 16, and 22	When used in connection with pH, “[plus] or [minus] 0.1 pH units from [the stated number]”
“A method for reducing deposits on production equipment during production of a GLP-1 agonist formulation”	23	The phrase is an express limitation of claim 23 and it carries its plain and ordinary meaning.
“A method for reducing deposits in the final product during production of a GLP-1 agonist formulation”	26	The phrase is an express limitation of claim 26 and it carries its plain and ordinary meaning.
“A method for reducing the clogging of injection devices by a GLP-1 agonist formulation”	29	The phrase is an express limitation of claim 29 and it carries its plain and ordinary meaning.

CLAIM TERMS AGREED UPON IN U.S. PATENT NO. 8,114,833		
Term	Claim(s)	Construction
“replacing the isotonicity agent previously utilized in said formulation with propylene glycol”	23, 26, and 29	“Having a first formulation that utilized an isotonicity agent other than propylene glycol and having a second formulation wherein the isotonicity agent used in the first formulation is substituted or replaced with propylene glycol”
“the isotonicity agent to be replaced by propylene glycol”	25, 28, and 31	“Having a first formulation that utilized an isotonicity agent other than propylene glycol and having a second formulation wherein the isotonicity agent used in the first formulation is substituted or replaced with propylene glycol”

CLAIM TERMS AGREED UPON IN U.S. PATENT NO. 8,920,383		
Term	Claim(s)	Construction
“dose setting member”	1	Plain and ordinary meaning, which is “the member used to set the dose”
“medicament”	1	Plain and ordinary meaning, which is “medication”
“reservoir”	1	Plain and ordinary meaning, which is “a component that contains the medication, which component is included only once in the injection device”
“the piston rod rotates and translates axially forward”	1	“The piston rod rotates relative to the outermost housing of the injection device and moves axially toward the needle end that expels the medicament”

CLAIM TERMS AGREED UPON IN U.S. PATENT NO. 8,920,383		
Term	Claim(s)	Construction
“locking means”	3	Plain and ordinary meaning, which is “a mechanism for locking the piston rod against rotation in at least one direction”
“engaging surface”	5, 8, and 9	Plain and ordinary meaning, which is “a surface adapted to engage a corresponding surface”
“ratchet mechanism”	10	Plain and ordinary meaning, which is “a mechanism that allows linear or rotary motion in only one direction while preventing motion in the opposite direction”

CLAIM TERMS AGREED UPON IN U.S. PATENT NO. 9,775,953		
Term	Claim(s)	Construction
“longitudinal direction”	1	Plain and ordinary meaning, which is “running lengthwise”
“dose setting member”	1	Plain and ordinary meaning, which is “the member used to set the dose”
“medicament”	1	Plain and ordinary meaning, which is “medication”
“reservoir”	1	Plain and ordinary meaning, which is “a component that contains the medication, which component is included only once in the injection device”

CLAIM TERMS AGREED UPON IN U.S. PATENT NO. 9,775,953		
Term	Claim(s)	Construction
“causes the piston rod to be displaced relative to the housing in a longitudinal direction”	1, 2, 7, and 17	Plain and ordinary meaning, which is “causes the piston rod to move, relative to the housing, in the longitudinal direction”
“engaging surface”	4, 7, and 17	Plain and ordinary meaning, which is “a surface adapted to engage a corresponding surface”
“ratchet mechanism”	8, 9, 19, 21, and 24	Plain and ordinary meaning, which is “a mechanism that allows linear or rotary motion in only one direction while preventing motion in the opposite direction”
“adapted to be locked”	9	Plain and ordinary meaning, which is “adapted such that movement can be restricted”

CLAIM TERMS AGREED UPON IN U.S. PATENT NO. 8,129,343		
Term	Claim(s)	Construction
“ N-ε26-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetyl amino)ethoxy]ethoxy) acetyl] [Aib8,Arg34]	4 and 5	Plain and ordinary meaning, which is “the compound corresponding to the chemical name N-ε26-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetyl amino)ethoxy]ethoxy) acetyl] [Aib8,Arg34] GLP-1-(7-37) peptide, which is also called ‘semaglutide’”

CLAIM TERMS AGREED UPON IN U.S. PATENT NO. 8,129,343		
Term	Claim(s)	Construction
GLP-1-(7-37) peptide”		
The chemical structure identified in claims 1 and 2	1 and 2	Plain and ordinary meaning, which is “a compound corresponding to the claimed structure, which is also called ‘semaglutide’”

CLAIM TERMS AGREED UPON IN U.S. PATENT NO. 10,335,462		
Term	Claim(s)	Construction
“once weekly in an amount of 1.0 mg”	1	Plain and ordinary meaning, which is “one administration per week in an amount of 1.0 mg”
“solution”	3, 4, 5, 7, and 9	Plain and ordinary meaning which is “a solution comprising semaglutide”
“sodium dihydrogen phosphate”	8 and 9	Plain and ordinary meaning, which is “sodium dihydrogen phosphate, the molecular formula for which may be written as NaH ₂ PO ₄ ”

SO ORDERED this 25th day of July, 2023.


CHIEF, UNITED STATES DISTRICT JUDGE