

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Clark S. Cheney
Chief Administrative Law Judge**

In the Matter of

**CERTAIN DRUG PRODUCTS
CONTAINING C-TYPE NATRIURETIC
PEPTIDE VARIANTS, AND COMPONENTS
THEREOF**

Investigation No. 337-TA-1447

DISPUTED AND AGREED CLAIM CONSTRUCTIONS

Pursuant to the Amended Procedural Schedule (Order No. 17), the parties submit the following chart of disputed and agreed constructions for claim terms of U.S. Patent No. RE48,267 (“the RE’267 Patent”).

APPENDIX A
Disputed Claim Constructions

Term	Complainant	Staff	Respondents
“CNP variant” [claims 15–22, 31–49, and 54]	The preamble of claims 15-20 and 31-48 is non-limiting. Construction not necessary. Ordinary and customary meaning to a person of ordinary skill in the art in the context of the RE’267 patent, <i>i.e.</i>, a variant of C-type natriuretic peptide (CNP).	The preamble of claims 15 and 18 is limiting at least to the extent it provides antecedent basis for “the CNP variant” Plain and ordinary meaning, <i>i.e.</i>, a version of C-type natriuretic peptide that has reduced affinity to NEP and/or NPR-C, and reduced susceptibility to cleave by NEP and/or clearance by NPR-C, but which has substantially similar or better functionality than wild-type CNP22	The preamble of claims 15 and 18 is limiting. C-type natriuretic peptide comprising the amino acid sequence that is Cys6 to Cys22 of CNP-22 along with any modifications, substitutions, deletions, or conjugations, and that is capable of binding to and activating NPR-B, and thereby inducing cGMP production
“formulation” [claims 18-20 and 40-48]	The preamble of claims 18-20 and 40-48 is non-limiting. Construction not necessary. See below. In the context of “sustained release CNP variant formulation,” ordinary and customary meaning to a person of ordinary skill in the art in the context of the RE’267	The preamble of claim 18 is limiting at least to the extent it provides antecedent basis for “the CNP variant” Plain and ordinary meaning, <i>i.e.</i>, a pharmaceutical composition of a CNP variant and one or more pharmaceutically acceptable	The preamble of claim 18 is limiting Plain and ordinary meaning, <i>i.e.</i>, a pharmaceutical composition of a CNP variant and one or more pharmaceutically acceptable excipients, carriers and/or diluents

Term	Complainant	Staff	Respondents
	patent, <i>i.e.</i> , a mixture containing a system for maintaining a relatively constant level of CNP variant over a desired time period.	excipients, carriers and/or diluents	
“sustained release CNP variant formulation” [claims 18-20 and 40-48]	The preamble of claims 18-20 and 40-48 is non-limiting. Construction not necessary. Ordinary and customary meaning to a person of ordinary skill in the art in the context of the RE’267 patent, <i>i.e.</i>, a mixture containing a system for maintaining a relatively constant level of CNP variant over a desired time period.	Plain and ordinary meaning, <i>i.e.</i>, a CNP variant formulation that is formulated as a system for maintaining a relatively constant level of dosage over a desired time period	a pharmaceutical composition, which includes a CNP variant coupled to synthetic polymeric group through a hydrolysable linkage, that is formulated in a system known in the art for maintaining a relatively constant level of dosage over a desired time period
“hydrolysis” [claims 15-17 and 31-39]	Construction not necessary. In the context of “hydrolysis of the hydrolysable linkage,” ordinary and customary meaning to a person of ordinary skill in the art in the context of the RE’267 patent, <i>i.e.</i>, chemical reaction in which water reacts with another	Plain and ordinary meaning, <i>i.e.</i>, chemical reaction in which water reacts with another substance to form two or more new substances	Plain and ordinary meaning, <i>i.e.</i>, reaction between a compound and water in which a bond in the compound is cleaved and the water components (H⁺ and OH⁻) are added where the bond was broken

Term	Complainant	Staff	Respondents
	substance to form two or more new substances.		
“coupled to . . . through a hydrolysable linkage” [claims 15-20 and 31-48]	Construction not necessary. In the context of “a synthetic polymeric group coupled to the CNP variant through a hydrolysable linkage,” ordinary and customary meaning to a person of ordinary skill in the art in the context of the RE’267 patent, <i>i.e.</i>, connected to the CNP variant through a connection capable of chemical reaction in which water reacts with another substance to form two or more new substances.	Plain and ordinary meaning, <i>i.e.</i>, connected to the CNP variant through a connection capable of chemical reaction in which water reacts with another substance to form two or more new substances	Plain and ordinary meaning, <i>i.e.</i>, connected to the CNP variant through a chemical bond cleaved by the addition of a water molecule
“macromolecule” [claims 15-17 and 31-39]	The preamble of claims 15-17 and 31-39 is non-limiting. Construction not necessary. Ordinary and customary meaning to a person of ordinary skill in the art in the context of the RE’267 patent, <i>i.e.</i>, molecule with a molecular mass greater than a few thousand daltons.	The preambles of the claims are not limiting with respect to the term “macromolecule” Plain and ordinary meaning, <i>i.e.</i>, molecule with a molecular mass greater than a few thousand daltons	The preambles of the claims are limiting. a functionally active molecule with a molecular mass greater than a few thousand daltons

Term	Complainant	Staff	Respondents
“synthetic polymeric group” [claims 15-20 and 31-48]	Construction not necessary. Ordinary and customary meaning to a person of ordinary skill in the art in the context of the RE’267 patent, <i>i.e.</i> , a man-made large molecule formed by the polymerization of molecules of low molecular mass.	Plain and ordinary meaning, <i>i.e.</i> , a man-made large molecule formed by the polymerization of molecules of low molecular mass	a man-made large molecule formed by the polymerization of molecules of low molecular mass that, when coupled to CNP, confers NEP resistance to CNP while retaining CNP’s functionality
“contacting the / a cell” [claims 21, 22, 49, and 54]	Construction not necessary. Ordinary and customary meaning to a person of ordinary skill in the art in the context of the RE’267 patent, <i>i.e.</i> , contacting the / a cell, including NPR-B	Plain and ordinary meaning, <i>i.e.</i> , touching the / a cell itself	Plain and ordinary meaning, <i>i.e.</i> , touching the / a cell itself

APPENDIX B
Agreed Claim Constructions

Term	Agreed Construction
“overcoming cell growth arrest” [claims 22 and 54]	Ordinary and customary meaning/plain and ordinary meaning, <i>i.e.</i> , at least partially reversing cell growth arrest.
“wherein the CNP variant is selected from the group consisting of” / “with a CNP variant selected from the group consisting of” [claims 15-22, 31-49, and 54]	Ordinary and customary meaning/plain and ordinary meaning, <i>i.e.</i> , CNP variant chosen from the following closed group of alternative members.
The preambles of claims 21, 22, 49, and 54	The preambles of claims 21, 22, 49, and 54 are limiting.

Dated: September 22, 2025

Respectfully submitted,

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I certify that on this day, a true and correct copy of the foregoing document was filed with the Commission and served upon the following parties as indicated:

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