Filed: March 24, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN INSTITUTIONAL LLC and PFIZER INC.,

Petitioners,

v.

NOVO NORDISK A/S,

Patent Owner.

Case No. IPR2020-00324[1]
U.S. Patent No. 8,114,833

PETITIONERS' DEMONSTRATIVE EXHIBITS

[1] IPR2020-01252 has been joined with this proceeding.

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United States Patent and Trademar
Before the Patent Trial and Appea

MYLAN INSTITUTIONA
and PFIZE
Peti

NOVO NORDIS
Patent

Mylan

IPR202
U.S. Patent No. 8

Grounds of Unpatentability

Ground 1: Claims 1-15 of the ’833 patent are anticipated by Fl
(Ex. 1004)

Ground 2: Claims 1-15 of the ’833 patent are obvious over Fli
(Ex. 1004)

Ground 3: Claims 1-31 of the ’833 patent are obvious over Fli
(Ex. 1004) in view Betz (Ex. 1005)

Claim 1 of the ’833 Patent

1. A pharmaceutical formulation comprising at least one GLP-1 agonist, a disodium phosphate dihydrate buffer and propylene glycol, wherein said propylene glycol is present in said formulation in a final concentration of from about 1 mg/ml to about 100 mg/ml and wherein said formulation has a pH of from about 7.0 to about 10.0.

‘833 patent (Ex.1001), claim 1 (annotated)

1. GLP-1 agonist
2. Disodium phosphate dihydrate buffer
3. Propylene glycol at a concentration of 1-100 mg/ml
4. pH of 7-10

Claim 16 of the ’833 Patent

16. A method of preparing a GLP-1 agonist formulation suitable for u
an injection device, said method comprising preparing a formu
containing a GLP-1 agonist, propylene glycol, a disodium phos
dihydrate buffer, and a preservative, wherein said propylene glyc
present in a concentration from about 1 mg/ml to about 100 mg/m
wherein said formulation has a pH from about 7.0 to about 10.0
wherein said GLP-1 agonist, said propylene glycol and said buffe
preservative are mixed together to produce said formulation as follow

a) preparing a first solution by dissolving preservative, prop
glycol and buffer in water;

b) preparing a second solution by dissolving the GLP-1 ag
in water;

c) mixing the first and second solutions; and adjusting the p
the mixture in c) to a pH of from about 7.0 to about 10.0.

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