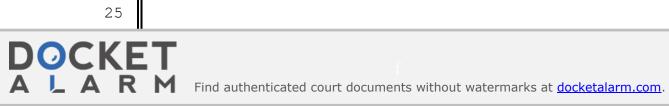
1	IN THE UNITED STATES DISTRICT COURT
2	IN AND FOR THE DISTRICT OF DELAWARE
3	
4	NOVO NORDISK INC. and NOVO : CIVIL ACTION
5	NORDISK A/S, :
6	Plaintiffs, :
7	vs. :
8	MYLAN INSTITUTIONAL LLC, :
9	Defendant. : NO. 19-1551-CFC-SRF
10	
11	
12	Wilmington, Delaware Wednesday, September 9, 2020
13	9:00 o'clock, a.m. ***Telephone conference
14	
15	BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.
16 17	
18	APPEARANCES:
19	MORRIS, NICHOLS, ARSHT & TUNNELL LLP
20	BY: BRIAN P. EGAN, ESQ.
21	-and-
22	
23	
24	Valerie J. Gunning
25	Official Court Reporter



1	APPEARANCES (Continued):
2	
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L3	BRANDON M. WHITE, ESQ. (Washington, D.C.)
L4	(
L5	-and-
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L7	BY: AUTUMN N. NERO, ESQ. (Madison, Wisconsin)
L8	
L9	Counsel for Defendant
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22	
23	



#### PROCEEDINGS

(The following telephone conference was held beginning at 9:00 a.m.)

THE COURT: All right. Good morning, everyone. Plaintiff, would you identify counsel, please?

MR. EGAN: Good morning, Your Honor. This is Brian Egan from Morris Nichols on behalf of Novo Nordisk plaintiffs.

Joining me on the call today are Jeff Oelke,
Ryan Johnson and Laura Moran from the Fenwick & West law
firm, and Mr. Oelke will be handling the argument today.

MR. OELKE: Good morning, Your Honor.

THE COURT: All right. Good morning. And your name again, please?

MR. OELKE: Jeff Oelke, Your Honor.

THE COURT: Okay. Great. Okay. And then from the defense, please?

MR. COTTRELL: Good morning Your Honor. Fred

Cottrell for defendant Mylan at Richards, Layton & Finger,

and on the phone with me from Perkins Coie, Shannon

Bloodworth, Brandon White and Autumn Nero, and our client is

on from Mylan, Preston Imperatore.

And Mr. White will be speaking on behalf of



Mylan, although any time anybody jumps in, I will expect they'll introduce themselves.

THE COURT: Great. Thank you very much.

All right. Plaintiff, you're up.

MR. OELKE: Good morning, Your Honor. Jeff
Oelke from Fenwick & West for the Novo Nordisk plaintiffs.

Now, today, this claim construction proceeding really concerns only one issue as to one patent, and that patent is the '833 patent, and the issue is whether the preamble of the method claims in that patent are central enough to the invention that they should be construed as limitations.

Now, in order to look at the issue, it really helps to look at how the method of reducing deposits and reducing clogging, how those method claims came about, and it came about, Your Honor, because the active ingredient in Victoza, liraglutide, the initial work that was done on that was what led to discovery over years in which the actual peptide itself, liraglutide, turned out to be a very difficult molecule to formulate. It couldn't be made into an oral dosage form, so they had to come up with a way to put it into an injectable solution and to put it into early clinical trials.

So when the work was done on the discovery of the molecule, it was passed out to the formulation team, and



the formulation team then had this difficult issue because liraglutide turned out to be very ornery, a very difficult molecule to formulate. It had issues relating to stability, Your Honor. It aggregated or fibrillated, so it intended to come together in solution and cause basically a cloudy result, which was unacceptable, even for purposes of conducting clinical trial.

So the formulation group had to come up with a way to deal with that stability problem and they did that by balancing out the pH, and they did that on very small scale batches, and those initial small scale batches of liraglutide in formulation were sufficient to conduct these initial clinical trials. Those initial clinical trials were Phase 1 and Phase 2, but they were successful and they were promising, and so what Novo Nordisk decided was we have to quickly from a bench scale to a manufacturing scale on manufacturing equipment.

And so when they took it up to manufacturing equipment on a production scale, what they found is they had a problem with their formulation, and that problem really and its solution goes to the heart of the preambles in the method claims 23, 26 and 29.

Now, an injectable formulation for a peptide like liraglutide has a series of different ingredients in it. It has a buffer, it has -- which controls pH. It has a



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