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IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

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NOVO NORDISK INC. and NOVO : CIVIL ACTION
NORDISK A/S, :
 :
 Plaintiffs, :
 :
 vs. :
 :
 MYLAN INSTITUTIONAL LLC, :
 :
 Defendant. : NO. 19-1551-CFC-SRF

- - -

Wilmington, Delaware
Wednesday, September 9, 2020
9:00 o'clock, a.m.
***Telephone conference

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

- - -

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
BY: BRIAN P. EGAN, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

1 APPEARANCES (Continued) :

2
3 FENWICK & WEST LLP

4 BY: JEFFREY J. OELKE, ESQ.,
5 RYAN P. JOHNSON, ESQ. and
6 LAURA T. MORAN, ESQ.
7 (New York, New York)

8
9 Counsel for Plaintiffs

10
11 RICHARDS, LAYTON & FINGER, P.A.

12 BY: FREDERICK L. COTTRELL, III, ESQ.

13
14 -and-

15
16 PERKINS COIE LLP

17 BY: SHANNON M. BLOODWORTH, ESQ. and
18 BRANDON M. WHITE, ESQ.
19 (Washington, D.C.)

20
21 -and-

22
23 PERKIN COIE LLP

24 BY: AUTUMN N. NERO, ESQ.
25 (Madison, Wisconsin)

Counsel for Defendant

- - -

P R O C E E D I N G S

(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

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

3 THE COURT: Great. Thank you very much.

4 All right. Plaintiff, you're up.

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

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

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

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

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

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

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

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

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