

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN INSTITUTIONAL LLC and PFIZER INC.,
Petitioner,

v.

NOVO NORDISK A/S,
Patent Owner.

IPR2020-00324
Patent 8,114,833 B2

Record of Oral Hearing
Held: March 26, 2021

Before ERICA A. FRANKLIN, JOHN G. NEW, and
SUSAN L.C. MITCHELL, *Administrative Patent Judges*.

IPR2020-00324
Patent 8,114,833 B2

APPEARANCES:

ON BEHALF OF PETITIONER MYLAN INSTITUTIONAL LLC:

BRANDON M. WHITE, ESQ.
Perkins Coie LLP
700 13th Street NW, Suite 800
Washington, DC 20005-3960
(202) 654-6206
bmwhite@perkinscoie.com

ON BEHALF OF PETITIONER PFIZER INC.:

MICHAEL JOHNSON, ESQ.
Willkie Farr & Gallagher LLP
787 Seventh Avenue
New York, NY 10019-6099
(212) 728-8137
mjohnson1@willkie.com

ON BEHALF OF PATENT OWNER:

JEFFREY OELKE, ESQ.
Fenwick & West LLP
902 Broadway
New York, NY 10010-6035
(212) 430-2747
joelke@fenwick.com

The above-entitled matter came on for hearing on Friday, March 26, 2021, commencing at 10:00 a.m. EDT, via Videoconference.

P-R-O-C-E-E-D-I-N-G-S

10:00 a.m.

JUDGE FRANKLIN: Good morning, I'm Judge Franklin and with me are Judges New and Mitchell. We welcome you to this hearing for IPR 2020-00324. IPR 2020-01252 has been joined with this proceeding, and this hearing relates to U.S. Patent 8,114,833.

We will begin with Counsel for the parties introducing yourselves and when doing so, please spell your name for the court reporter, beginning with Counsel for Petitioners?

MR. WHITE: This is Brandon White from Perkins Coie for Petitioner Mylan Institutional, B-R-A-N-D-O-N, W-H-I-T-E.

JUDGE FRANKLIN: And is there anyone else for Petitioner?

MR. JOHNSON: Good morning, Your Honor, this is Michael Johnson from Willkie Farr & Gallagher on behalf of the Petitioner Pfizer Incorporated and that's M-I-C-H-A-E-L, J-O-H-N-S-O-N.

JUDGE FRANKLIN: Thank you, and who do we have for Patent Owner?

MR. OELKE: Good morning, Your Honor, this is this is Jeff Oelke from Fenwick and West on behalf of the Patent Owner and my name is spelled J-E-F-F and the last name is O-E-L-K-E.

JUDGE FRANKLIN: And do we have anyone else for Patent Owner?

MR. OELKE: I don't believe so, Your Honor.

1 JUDGE FRANKLIN: All right, thank you. Consistent with the
2 hearing order, each party has a total of 45 minutes for its presentation.
3 Petitioners may reserve a portion of their time to respond to arguments
4 presented by Patent Owner, and Patent Owner has also been authorized to
5 reserve a portion of its time for rebuttal.

6 Please be mindful that a court reporter is transcribing this hearing and
7 there is no shared display for the demonstrative exhibits. So, when
8 referring to a particular demonstrative exhibit or slide, clearly identify it by
9 number so that we may all follow along.

10 We are in receipt of Petitioner's objections to three of Patent Owner's
11 demonstrative slides and we will reserve ruling on them. However, Patent
12 Owner, you should be prepared to address any inquiries from this hearing
13 regarding whether the slides noted in the objections contain new arguments.

14 And lastly, please remember to mute yourself when you are not
15 presenting and we will also mute ourselves until we have a question or
16 comment for you. That way, hopefully we may avoid unnecessary
17 feedback during this remote hearing. If during the hearing you encounter
18 any technical difficulties, please let us know.

19 And now, Petitioner, you may proceed after indicating any time you
20 would like to reserve for rebuttal. Mr. White?

21 MR. WHITE: Your Honors, I believe Mr. Johnson is going to be
22 making the argument today.

23 JUDGE FRANKLIN: Okay, Mr. Johnson, how much time would
24 you like to reserve?

1 MR. JOHNSON: Your Honor, I would like to reserve 15 minutes.

2 JUDGE FRANKLIN: Okay, when you're ready you may begin.

3 MR. JOHNSON: Good morning, Your Honors and may it please the
4 Board, my name, as I said, is Mike Johnson, I'm from Willkie Farr &
5 Gallagher on behalf of the Petitioner Pfizer Incorporated.

6 The crux of this matter comes down to the fundamental notion that
7 companies can't patent that which they've already disclosed to the public, but
8 that is exactly what Novo is trying to do here today with the '833 patent.

9 Novo's scientists filed the application that would become the Flink
10 reference in 2001 and 2002. And in that application they disclosed
11 formulations that match up with the '833 patent and disclose all the
12 elements. Not only that, but Novo specifically amended the Flink
13 application in order to specifically contain references and claims to the
14 propylene glycol-containing formulation.

15 To illustrate this, if you direct your attention to Slide 17, Slide 17
16 discloses the relevant text from the first four priority applications of the
17 Flink reference, Exhibits 1108, 1009, 1110, and 1111, they're the -- the
18 polyhydric alcohols mentioned only include mannitol, sorbitol, or glycerol.

19 However, in January of 2002 Novo specifically amended this
20 application to include reference to propylene glycol, or PG, which will be
21 the focus of the argument today. It was this conscious decision by Novo to
22 describe and claim propylene glycol as an isotonicity agent in Flink that
23 forms the basis of Grounds 1 and 2 of the validity challenges today.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.