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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

- - - - - x
MYLAN PHARMACEUTICALS :
INC., :
Petitioner, : Case No. IPR2023-007244
v. : U.S. Patent No.
NOVO NORDISK A/S, : 10,335,462
Patent Owner. :
- - - - - X

Deposition of
ARTHUR Z. SCHWARTZBARD, M.D., F.A.C.C.
Conducted Virtually
Tuesday, July 9, 2024
10:01 a.m. EDT

Job No.: 542784
Pages 1 - 60
Reported by: Debra A. Whitehead

1 Deposition of ARTHUR Z. SCHWARTZBARD, M.D.,
2 F.A.C.C., conducted virtually.

3

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5 Pursuant to notice, before Debra Ann Whitehead,
6 E-Notary Public in and for the State of Maryland.

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1 A P P E A R A N C E S

2 ON BEHALF OF PETITIONER:

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1 A P P E A R A N C E S C O N T I N U E D

2 ALSO PRESENT:

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C O N T E N T S

EXAMINATION OF ARTHUR Z. SCHWARTZBARD, M.D. PAGE

By Mr. May 6

EXHIBITS MARKED IN TODAY'S SESSION

(Attached to the Transcript)

EXHIBIT PAGE

Exhibit 2601 Article, "Diabetic Agents, From 38
Metformin to SGLT2 Inhibitors
and GLP1 Receptor Agonists,"
by Wilcox, et al.

Exhibit 2602 Article, "The Changing Landscape 51
of Diabetes Therapy for
Cardiovascular Risk Reduction,"
by Newman, et al.

EXHIBITS MARKED IN PRIOR SESSIONS

(Not attached)

EXHIBIT PAGE

Exhibit 1304 Declaration of Arthur Z. 17
Schwartzbard, M.D., F.A.C.C.

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

2 ARTHUR Z. SCHWARTZBARD, M.D., F.A.C.C.,
3 having been duly sworn, testified as follows:

4 EXAMINATION BY COUNSEL FOR PETITIONER

5 BY MR. MAY:

6 Q Good morning, Dr. Schwartzbard.

7 Can you please state your name and spell
8 it, for the record.

9 A Arthur Schwartzbard. A-R-T-H-U-R
10 S-C-H-W-A-R-T-Z-B-A-R-D.

11 Q Where are you currently employed?

12 A I am a cardiologist at NYU Medical Center
13 in Manhattan.

14 Q And what is your business address?

15 A 530 First Avenue, Suite 5, New York, New
16 York, 10016.

17 Q Dr. Schwartzbard, have you ever sat for a
18 deposition like this before?

19 A When you say "like this," Philip -- it's
20 okay to call you Philip?

21 Q That's fine.

22 A Not in patent. I don't recall sitting in

1 a patent litigation deposition like this before.

2 Q Have you had a deposition in another kind
3 of case before?

4 A Yes.

5 Q What kind of case were those depositions
6 in before?

7 A Pharmaceutical litigation.

8 Q When you say "pharmaceutical litigation,"
9 what do you mean?

10 A Litigation between companies about a
11 medication.

12 Q And what kind of claim was at issue in
13 that litigation?

14 A Infringements and things like that. But
15 it's a little different from this.

16 Q So it was a patent case, though.

17 Is that right?

18 A I would say patent-related maybe, but not
19 patent like this. I mean, different. This is
20 different.

21 Q Do you remember the name -- our when that
22 case occurred that you had that deposition in

1 previously in the pharmaceutical litigation
2 patent-related case?

3 A Within the last few years. I don't
4 remember exact date.

5 Q Was it within the last four years?

6 A Yes.

7 Q All right.

8 MR. MAY: Counsel, I don't think we've
9 received notice of that previous deposition
10 testimony in Dr. Schwartzbard's declaration or his
11 CV.

12 A It may be beyond four years, Phil, I'm
13 not sure of dates. Forgive me, I'm not exact on
14 dates. I don't know exactly when that case was.

15 Q Dr. Schwartzbard, do you know what
16 medication that was about?

17 A It was a medication called Exforge.

18 Q E-X-F-O-R-G-E?

19 A Yes.

20 Q And what was that medication for?

21 A It's a blood pressure medication.

22 Q Who were you testifying on behalf of in

1 that litigation?

2 A Again, I don't remember the exact firms,
3 but it was on behalf of pharmacies.

4 Q So not the specific law firm, but do you
5 know what company retained you to testify in that
6 litigation?

7 A There were several pharmaceutical
8 companies like pharmacy chains like Walgreens, CVS
9 type of pharmacies.

10 Q So you were testifying --

11 A I don't know, I don't recall if it was
12 within four years or not.

13 Q So you were testifying on behalf of
14 different pharmacies.

15 Is that right?

16 A Correct.

17 Q And what kinds of opinions were you
18 providing on behalf of those pharmacies?

19 A I was really just retained to discuss the
20 medication.

21 Q When you say "to discuss the medication,"
22 what do you mean?

1 A How it worked, what the data showed for
2 that medication, what is similar or different
3 about that medication, that medical opinion.

4 Q Similar or different to that medication
5 in what way?

6 A What's the degree of blood pressure
7 lowering, what's the trial evidence for the drug,
8 et cetera.

9 Q Did you testify only in deposition, or
10 did you ultimately testify in trial as well?

11 A Only in deposition.

12 Q Do you know if that case ultimately went
13 to trial?

14 A I do not.

15 Q Besides the litigation regarding Exforge,
16 have you ever had your deposition taken in any
17 other context?

18 A Are we again within the four year, or are
19 we going way further back or -- I'm not sure what
20 you mean.

21 Q Yeah, this is at any point. Besides that
22 pharmaceutical litigation, at any point have you

1 had your deposition taken?

2 A I have.

3 Q And has it ever been for a patent case?

4 A Not that I'm aware.

5 Q What kinds of cases have you had your
6 deposition taken in, besides the Exforge case?

7 A So many years ago I -- this is many years
8 ago, this is maybe 14 or 15 years ago, I testified
9 about a drug called fenofibrate.

10 Q And again when you say testified about
11 the drug, in what context?

12 A I had a deposition taken. I think that
13 was your question.

14 Q Right. And what kind of litigation was
15 that in?

16 A Again, I was retained just as a medical
17 expert to discuss the medication, to discuss
18 cholesterol and the disease state.

19 Q And on whose behalf were you retained?

20 A This is so many years ago, I don't
21 remember the names of the firms.

22 Q Do you remember was it a pharmaceutical

1 company, or was it again on behalf of different
2 pharmacies?

3 A Again, I don't recall. It's many years
4 ago.

5 Q So you've been doing great so far on
6 this, but I just want to go over a few ground
7 rules on a deposition before we continue.

8 Is that okay?

9 A Fine.

10 Q So as you see, today we have a court
11 reporter who is taking down all the testimony we
12 give. So I please just ask that we don't speak
13 over each other, and that you give full yes-no
14 answers, no nods or shaking of your head.

15 Is that okay?

16 A Yes.

17 Q I'm going to do my best today to ask
18 clear questions. You've done great so far seeking
19 clarification as needed. But if there is a
20 question that you don't understand, please ask for
21 clarification. Okay?

22 A Okay.

1 Q And if you don't ask for clarification,
2 I'll assume that you have understood the question
3 as I've asked it. Okay?

4 A Okay.

5 Q Is there anything that would prevent you
6 from giving full and truthful testimony today?

7 A No.

8 Q Do you have any applications open on your
9 computer besides this Zoom meeting?

10 A No.

11 Q If for some reason that changes, you
12 suddenly get a pop-up from an e-mail, just let me
13 know and just close out of whatever else may be
14 open. I understand these remote depositions can
15 be a little weird in that context.

16 A Thank you.

17 Q Is there anyone else in the room with
18 you?

19 A No.

20 Q Again, if that changes, please just tell
21 us and let us know.

22 A Will do.

1 Q And then do you have anything with you
2 for the deposition, paper copies of your
3 declaration possibly?

4 A With me in the room, besides a cup of
5 coffee and some water and snacks, is copies of my
6 report and exhibits that were submitted as part of
7 that report.

8 Q And are there any -- sorry.

9 A I'm sorry. I also have a folder that has
10 Dr. Blaha's declaration and exhibits as well.

11 Q Are there any notes or anything like that
12 on any of the papers that you have with you?

13 A No notes.

14 Q All right. Have you ever prescribed
15 Ozempic to a patient?

16 A I have.

17 Q When did you first start prescribing
18 Ozempic?

19 A I don't recall an exact year.

20 Q Do you have an approximate year?

21 A I've been prescribing it for several
22 years.

1 Q More than five?

2 A Yes.

3 Q Have you been prescribing it since it was
4 first approved?

5 A Yes and no. I would say after a drug is
6 first approved, it's often hard to get it
7 approved. So, yes, some prescriptions for that;
8 but often guided by what the patient's insurance
9 will okay.

10 Q When you say "hard to get it approved,"
11 do you mean by the insurance company?

12 A Yes.

13 Q Approximately what percentage of your
14 patients do you prescribe Ozempic to?

15 A I prescribe Ozempic only for diabetics,
16 and I prescribe it along with other GLP-1
17 agonists. So I couldn't quote you an exact
18 percentage. Don't know.

19 Q Approximately what percentage of your
20 patients have type 2 diabetes?

21 A A fair number. In cardiology, as you
22 might expect, diabetics get plenty of heart

1 disease. So I would say probably at least a third
2 of my practice has type 2 diabetes.

3 Q Somewhere between a third and a half?

4 Is that a fair estimate?

5 A I don't know that it's a half. But I
6 would say at least a third have type 2 diabetes.

7 Q And then of that third, approximately how
8 many of those patients are you prescribing Ozempic
9 to?

10 A Again, as part of my prescribing GLP-1s I
11 do prescribe Ozempic. It's not the only GLP-1
12 agonist that I write, so I couldn't give you a
13 percentage.

14 Q What other GLP-1s do you write
15 prescriptions for?

16 A I've written for many; including
17 Trulicity, Victoza, Mounjaro, multiple GLP-1s.
18 Again, in part governed by what the patient's
19 insurance will support.

20 Q And approximately how many patients do
21 you see, so that we can turn these percentages
22 into numbers?

1 A If you're referring to how many patients
2 I see in a day?

3 Q Sorry, no. Thank you for the
4 clarification. We've been talking about a third
5 of your patients have type 2 diabetes. So kind of
6 what's that number that we're talking about in
7 round numbers?

8 A So to give context to my week, I probably
9 see in an office practice somewhere between 20 and
10 25 each day, plus another five to ten on the wards
11 every day. So I'm thinking about 30 to 35 people
12 a day. So it's a busy clinical practice. So
13 applying your numbers, the numbers we're just
14 talking about, at least a third, talking about a
15 lot of diabetics being seen every week.

16 I may just add, Phil, I'm a consultative
17 cardiologist, so I see not only patients in my own
18 practice but also patients on the wards.

19 Q Okay. If you can turn to Exhibit 1304,
20 which is your declaration that you provided in
21 this case.

22 (Exhibit 1304, previously marked, not

1 attached.)

2 A Bear with me. One more time. Exhibit
3 1304 you said?

4 Q Yeah. And that should be your
5 declaration.

6 MR. WHITE: And, Dr. Schwartzbard, that's
7 your declaration, we pulled that out separately.

8 THE WITNESS: Oh, you're referring to my
9 report.

10 MR. WHITE: Yes.

11 Q Yes.

12 A Okay. Sorry. I have that out. Thank
13 you.

14 Q It's technically a declaration, so I'll
15 apologize if I refer to it as a declaration. But
16 declaration, report, same thing.

17 A Okay. Sorry. I have that out. I'm with
18 you.

19 Q All right. If you can turn to Paragraph
20 12 of your declaration, which you can find it on
21 Page 18.

22 A Yes.

1 Q In the first sentence you say that "In
2 2012, before the priority date of the '462 patent,
3 clinicians treating patients with T2D had several
4 options," and then you list a few.

5 Do you see that?

6 A I do.

7 Q Were the clinicians who were treating
8 patients with type 2 diabetes that you are
9 referring to there cardiologists or
10 endocrinologists?

11 A I'm going to say endocrinologist more
12 often on the insulin, but cardiologists, many that
13 I work with also prescribe sulfonylureas and
14 metformin there as well.

15 Q What was your personal prescribing
16 practice in 2012 with respect to your patients
17 that had diabetes?

18 A Drugs like these listed and others,
19 including pioglitazone, TZD that's mentioned
20 elsewhere in the report. But these were some of
21 the most common medicines used at that time.

22 Q All right. If you could turn to

1 Paragraph 14.

2 A Yes, sir.

3 Q In the final sentence there you refer to
4 comparison to the closest prior art. What do you
5 understand the closest prior art to mean?

6 A So I'm referring to what was available,
7 what was available to physicians prior to the
8 patent that we're discussing.

9 Q Was semaglutide available to physicians
10 prior to July 1st, 2012?

11 MR. WHITE: Objection to form.

12 A I don't recall the entry date, the exact
13 entry date for semaglutide, but GPL-1s were
14 available to physicians.

15 Q Was semaglutide specifically available
16 prior to July 1st, 2012?

17 MR. WHITE: Objection to form.

18 A Again, Philip, I'm not testifying here
19 today the exact clinical date of when semaglutide
20 was clinically available to physicians.

21 Q Do you know when semaglutide was first
22 available to physicians in general?

1 A I may have cited that elsewhere in the
2 report. I don't remember the date.

3 Q But it's your opinion that semaglutide
4 qualifies as the closest prior art?

5 A There were certainly publications about
6 semaglutide in other doses other than 1 milligram
7 prior to the approval date.

8 Q Was there any data available for any
9 doses of semaglutide prior to July 1st, 2012?

10 MR. WHITE: Objection. Form. Scope.

11 A So maybe you could clarify what you mean
12 by "data." There certainly was a lot of basic
13 science, Phase 1, Phase 2, et cetera. If that
14 counts as data, yes, there was data available
15 prior to the approval date.

16 Q And sorry, I'm speaking not generally
17 about the approval date but I'm speaking
18 specifically about prior to July 1st, 2012.

19 A And I thought I answered you, but I'll
20 try again. There was plenty of publications
21 referring to semaglutide in other doses before the
22 priority date.

1 Q And did those publications include
2 information about any cardio-protective benefits
3 of semaglutide?

4 A So elsewhere in the report I go over some
5 of the basic science of GLP-1s and what was
6 already available in the -- in the literature.
7 And again, not sure about what you're driving at.
8 But maybe I can clarify as I understand your
9 question.

10 Was there already preliminary data in
11 basic science and preclinical data for semaglutide
12 beforehand, the answer is yes.

13 Q Was there clinical data for semaglutide
14 prior to July 1st, 2012, with respect to
15 cardio-protective benefits?

16 A If you mean was there a cardiovascular
17 outcome trial prior to 2012, no.

18 Q Was there any other clinical data for
19 semaglutide prior to July 1st, 2012, with respect
20 to cardio-protective benefits or cardiovascular
21 data points?

22 A Again, elsewhere in the report I listed

1 multiple paragraphs of some of the data that was
2 already known in the literature about GLP-1
3 agonists and cardiovascular protection. In fact,
4 I spent about 25 paragraphs on that. So I would
5 rather not answer that as a yes or no.

6 Q Yeah, and I'm asking specifically about
7 semaglutide, not GLP-1s in general.

8 A So we say "cardiovascular effect," does
9 cardiovascular effect include weight loss? Does
10 it include data on reduction of A1C? I would
11 argue it does. And there was already data in the
12 literature about those benefits.

13 Q Prior to July 1st, 2012, was there any
14 clinical data regarding a 0.8-milligram
15 once-weekly dosage of semaglutide?

16 A There was a prior clinical protocol using
17 the .8, a national clinical trial I think in the
18 database using the .8-milligram dosage. And
19 that's actually also referred to in the report.

20 Q So there was a protocol. But were there
21 any outcomes from that clinical trial protocol
22 prior to July 1st, 2012?

1 A Again, so if I can just clarify, Philip,
2 what you mean by "outcomes."

3 In my report I distinguish between
4 effects on cardiovascular risk factors, A1C,
5 weight, sugar control, lipid effect, and what is a
6 cardiovascular outcome trial.

7 Q All right. So let's actually talk about
8 that for a minute.

9 So you spent a lot of time in your report
10 talking about different risk factors. I think you
11 mentioned a lot of them. A1C, weight, sugar
12 control, lipid effects, blood pressure.

13 Is that right?

14 A Those are some of the many effects that
15 GLP-1 agonists have, correct.

16 Q And then you're distinguishing those from
17 cardiovascular outcome trials. I guess what do
18 you consider to be an outcome of a cardiovascular
19 outcome trial?

20 A Well, there's a lot of ways to look at
21 cardiovascular outcomes. You can -- clinicians
22 can look at a large database and review a large

1 database and see if patients that got a drug had
2 better outcomes.

3 You can look at an insurance database,
4 you can look at a pharmaceutical company's
5 database. There's a lot of ways to review
6 cardiovascular data. And you can also do what I'm
7 referring to as a cardiovascular outcome trial,
8 where you randomize, placebo control a patient or
9 a group of people to placebo versus drug and
10 say -- follow them over a couple of years and say
11 does this group of patients have less heart
12 attack, less stroke, less death, et cetera.

13 That's what in my report I'm referring to
14 as a cardiovascular outcome trial.

15 Q And so do you consider things like
16 reduction in three point MACE, reduction in heart
17 failure, reduction in myocardial infarction, those
18 are cardiovascular outcomes?

19 A Those are cardiovascular outcomes but can
20 be found multiple ways. You can -- as I mentioned
21 earlier.

22 Q Prior to July 1st, 2012, was there any

1 cardiovascular outcome data for semaglutide?

2 A The cardiovascular outcome trial, as I
3 defined it earlier, for semaglutide came out I
4 think approximately 2016.

5 Q Was there any other cardiovascular
6 outcome data for semaglutide prior to July 1st,
7 2012, outside of the cardiovascular outcome trial?

8 A Again, there was, as I mentioned already,
9 there was in the literature a lot of data looking
10 at GLP-1 agonists, not just semaglutide but others
11 in the class, looking at some of those effects
12 that I mentioned already, reductions in A1C,
13 effects on weight, effects on sugar, effects on
14 lipids, database reviews, tons of this in the
15 literature for years prior to the publication of
16 SUSTAIN 6.

17 Q And just to redirect you back to my
18 question, though, was there any other
19 cardiovascular outcome data for semaglutide prior
20 to July 1st, 2012, outside of the cardiovascular
21 outcome trial?

22 A Again, there was dosing trials looking at

1 the effects on sugar and these markers that I've
2 referred to earlier, but not the cardiovascular
3 outcome trial as we've defined it so far. That
4 one came out in 2016.

5 Q Can you please turn to Paragraph 15 of
6 your declaration. And I'm looking at Page 22,
7 about halfway down the paragraph.

8 A I have the page open.

9 Q All right. The sentence that reads, "The
10 1.0 milligram once-weekly dose of semaglutide
11 demonstrated no cardiovascular benefits that were
12 of a different kind, rather than a different
13 degree, than seen with other drugs in the GLP-1
14 receptor agonist class that showed cardiovascular
15 benefit in other doses of Ozempic."

16 Do you see that?

17 A I do.

18 Q When you talk about "a different kind
19 rather than a different degree," what do you
20 understand that to mean?

21 A So if you ask me were there -- are there
22 cardiovascular outcome trials and benefits seen

1 with other GLP-1 agonists, the answer is there
2 are.

3 And so if I'm distinguishing between
4 Ozempic and other GLP-1 agonist outcome trials,
5 and I say, well, two trials, or three in this
6 particular case, three drugs have shown
7 cardiovascular outcome trial benefits, semaglutide
8 being one of them, Ozempic being one of the three,
9 but the other two trials also show reductions in
10 MACE, reductions in nonfatal MI, reductions in
11 stroke, et cetera.

12 And so if I'm comparing multiple drugs in
13 the class, what I mean by a difference in kind
14 versus a difference in degree is if all three
15 trials show things like a reduction in stroke, but
16 one trial shows a little more stroke reduction
17 than another, that I would call a difference in
18 degree rather than a difference in kind.

19 Q What do you categorize as a difference in
20 kind?

21 A Effects that are seen with only one drug
22 from the class, and not with others.

1 So, for example, if no other GLP-1
2 agonist had shown a reduction in stroke, and only
3 one drug did, that would imply a difference in
4 kind to me.

5 When multiple drugs in the class show a
6 reduction in stroke, that's a difference in
7 degree, not in kind.

8 Q Prior to this case, had you ever looked
9 at a patent before?

10 A I'm not sure what you mean by that. We
11 see package inserts that I guess refer to
12 patent as clinicians, but no, I've never reviewed
13 patent details before, no.

14 Q And did you review the patent at issue in
15 this case?

16 A As need to prepare this report.

17 Q What do you mean by "as needed"?

18 A Only as discussed in my report. I'm not
19 an attorney, so I'm not a patent expert, let me
20 testify to that clearly.

21 Q No, I appreciate that.

22 Prior to 2012 had you ever prescribed any

1 GLP-1 receptor agonist?

2 A I had. My -- again, I don't remember the
3 exact dates, I've testified to that already. But
4 the first GLP-1 that I had written was a drug
5 called Byetta. It was, I should say, known
6 commercially as Byetta, also known as exenatide,
7 and it was a multiple-time-a-day drug. It wasn't
8 a once-a-week drug.

9 Q Did exenatide have -- strike that. Was
10 exenatide shown to have improvements in
11 cardiovascular outcomes?

12 A Again, let's take you back to my earlier
13 answer on that, what you consider cardiovascular
14 outcomes.

15 So exenatide did have published data
16 looking at a huge database, and I commented on
17 this in the report, on almost 40,000 people,
18 showing less cardiovascular events when the
19 database was reviewed.

20 It also had well-known effects on sugar
21 and weight loss and lipids and cardiovascular risk
22 factors that were known to play a role in diabetic

1 and cardiovascular disease in diabetics.

2 Q So I understand that there were data on
3 the risk factors, but what about data specifically
4 on cardiovascular outcomes?

5 MR. WHITE: Objection to form.

6 Q Let me actually rephrase that question.
7 Was there data specifically on
8 cardiovascular outcomes of exenatide as contrasted
9 to data on cardiovascular risk factors?

10 A So again, I referred you to a point in my
11 report that looked at a large database of
12 patient -- a patient database of almost 40,000
13 people that showed that exenatide had less
14 cardiovascular -- better cardiovascular outcomes,
15 less events.

16 But if your question is was there
17 subsequently a large cardiovascular outcome trial
18 showing benefit for exenatide, the answer is no.

19 Q All right. If you can please turn to
20 Paragraph 59 of your declaration.

21 A Yes, sir.

22 Q All right. You reference that in your

1 opinion clinical evidence demonstrated the value
2 of lowering blood glucose in patients with T2D and
3 the associated reduction in both microvascular and
4 macrovascular risk.

5 Do you see that?

6 A I do.

7 Q When you say "the associated reduction,"
8 is that a causal relationship or just a -- or
9 something else?

10 MR. WHITE: Objection. Form.

11 A This paragraph is following an earlier
12 discussion, so I don't really want too much taken
13 out of context. But it's following an earlier
14 discussion that's referring to data as said in the
15 paragraph beforehand that looked at long-term
16 outcomes of people who had blood sugar lowered in
17 the UKPDS and a couple of the other trials, and
18 also referred to an ADA guideline in 2010 that
19 cited a quotation saying that lowering of blood
20 sugar is associated with a reduction in
21 microvascular and macrovascular risk.

22 So if it's okay with you, Philip, I don't

1 want to take the sentence too much out of context.
2 I'd like it connected to what preceded it, which
3 is ADA guidelines in 2010 talking about the UKPDS
4 and DCCT trials and so on, showing long-term
5 outcomes of glucose lowering.

6 Q All right. So if you want to turn to
7 Paragraph 58, which is discussing those ADA 2010
8 guidelines, the first citation in Paragraph 58
9 says that lowering A1C to below or around 7
10 percent has been shown to reduce microvascular and
11 neuropathic complications of type 1 and type 2
12 diabetes.

13 Do you see that?

14 A I do.

15 Q So is it your understanding that that's a
16 causal relationship?

17 MR. WHITE: Objection to form.

18 A Again, I'm not sure what you mean by
19 "causal." But it was shown in the UKPDS trial
20 that patients that were randomized to early -- so
21 let me just rephrase.

22 That early onset diabetics who were

1 randomized to glucose control had reductions in
2 microvascular and neuropathic complications. And
3 by microvascular for our purposes today I mean
4 eyes, nerves, kidney disease.

5 Q So is it your understanding that the
6 lowering of the A1C to below or around 7 percent
7 caused a reduction of microvascular and
8 neuropathic complications or was just correlated
9 with that reduction?

10 MR. WHITE: Objection to form.

11 A I would say as I said in the sentence,
12 it's been shown to reduce. I mean, there are many
13 effects of drugs. But that's what the trial
14 showed.

15 Q And so shown to reduce, is that a causal
16 relationship or just a correlative relationship?

17 MR. WHITE: Objection. Form.

18 A So if you look at the subscript on the
19 paper, Number 7 on Page 40, the quote from DCCT
20 showed -- I'm looking at sentence 3. Showed
21 definitively that improved glycemic control is
22 associated with significantly decreased rates of

1 microvascular as well as neuropathic complication.

2 So at least in DCCT, they were
3 attributing it to the improved glycemic control.

4 Q Okay. Can you turn to Paragraph 65 in
5 your declaration on Page 45.

6 A I'm with you.

7 Q About halfway down the paragraph you
8 write that, "In randomized clinical trials, DPP-4
9 inhibitors were not associated with a reduction in
10 cardiovascular risk."

11 Do you see that?

12 A I do.

13 Q Can you explain to me what you mean by
14 that?

15 A So let's take a particular drug, a
16 particular DPP-4, one of which I mention later in
17 the paragraph, and that's a drug called Januvia,
18 also known as sitagliptin. So their outcome trial
19 was a trial called TECOS, that's a cardiovascular
20 outcome trial as we discussed before, randomized
21 drug versus placebo, does using the drug lead to
22 less cardiovascular events or is it associated

1 with less cardiovascular events. The answer was
2 it was not. It was safe.

3 It was well-tolerated, but it did not
4 lead to less cardiovascular events. And that's
5 what I mean in that earlier sentence, was not
6 associated with a reduction in cardiovascular
7 risk. For our purposes today, you can think of
8 cardiovascular as fatal or nonfatal heart attack,
9 stroke, and the like.

10 Q So were DPP-4 inhibitors associated with
11 reduction in cardiovascular risk factors at all?

12 A They had a weak effect on hemoglobin A1C,
13 they had no effect on weight, unlike GLP-1s. Very
14 different drug class from GLP-1s. No effect on
15 weight, no effect on lipids, no effect on blood
16 pressure. And so very different class from GLP-1.

17 And so no, if I was comparing them as I
18 do in this paper to GLP-1s, a very different drug
19 class.

20 Q Was the data on the Januvia
21 cardiovascular outcomes available prior to July
22 1st, 2012?

1 A Again, I don't remember the date TECOS
2 was published. It's -- I'm sure it's in the
3 public domain. I just don't know the exact date
4 of the publication. I don't think it was prior to
5 2012.

6 Q Can you go to Paragraph 79 of your
7 declaration.

8 A Yes, sir.

9 Q In Paragraph 79 you're discussing a study
10 regarding exendin-4.

11 Is that the same or different as
12 exenatide?

13 A There are a number of different
14 formulations of exenatide. It's part of a similar
15 compound. Many of the GLP-1s went through sort of
16 an evolution in terms of development and once
17 daily, once weekly, et cetera. But it was a GLP-1
18 agonist.

19 Q Can you go to Paragraph 113 in your
20 declaration, please.

21 A Yes, sir.

22 Q You say that there was no data in the

1 prior art, and you have seen none in the
2 literature you reviewed in preparing this
3 declaration, that GLP-1 receptor agonists were
4 known or believed to cause cardiovascular injury
5 in diabetic patients.

6 Do you see that?

7 A I do. It's the last sentence in the
8 paragraph.

9 Q Was there any concern that Liraglutide
10 could potentially cause cardiovascular injury in
11 diabetic patients prior to July 1st, 2012?

12 A No, none that I've seen. No.

13 Q All right.

14 MR. MAY: Sedrick, if we could please
15 pull up Tab D and mark that as Exhibit 2601,
16 please.

17 (Exhibit 2601 marked for identification
18 and is attached to the transcript.)

19 Q Dr. Schwartzbard, what's on the screen in
20 front of you is an article entitled Diabetic
21 Agents, From Metformin to SGLT2 Inhibitors and
22 GLP1 Receptor Agonists, and it includes several

1 authors, including yourself.

2 Do you see that?

3 A I do.

4 MR. WHITE: And, Philip, can we just
5 reserve our right to object to this document?

6 MR. MAY: Sure.

7 Q This is an article that you co-authored.
8 Is that correct?

9 A Correct.

10 Q And do you recall this article?

11 A Yes. In broad sense, yes. I haven't
12 looked at it for this deposition.

13 Q If we could please turn to -- I'm sorry,
14 in this article, if you scroll down to the bottom
15 of the page, it says that this article was,
16 manuscript received January 24, 2020, revised
17 manuscript received February 25th, 2020, and
18 accepted February 28, 2020.

19 Do you see that?

20 A Yes. Last sentence --

21 MR. WHITE: I'm sorry. Go ahead.

22 Sedrick, can you drop the PDF into the

1 chat, if that's possible.

2 A/V TECHNICIAN: No problem.

3 MR. MAY: And then, Sedrick, can you
4 please turn to Page 13 of Exhibit 2601 once you've
5 dropped it into the chat.

6 Q All right. So turning to Page 13 of
7 Exhibit 2601.

8 MR. MAY: And, Sedrick, if you can scroll
9 down to the bottom of the paragraph on the
10 left-hand column.

11 A I'm looking only at my screen what you're
12 showing. I'm not opening any separate files, if
13 that's okay with you.

14 Q That's fine with me.

15 A Okay.

16 Q So looking at that.

17 MR. MAY: And, Sedrick, maybe just zoom
18 in a little bit more, just to give even my
19 eyeballs the benefit of the doubt here. Thank
20 you.

21 Q That left-hand column, the final
22 paragraph starts to say that "HF was an initial

1 concern with GLP-1 RA use."

2 Do you see that?

3 A I see the paragraph.

4 Q And HF stands for heart failure?

5 A Yes, sir.

6 Q And GLP-1 RA is GLP-1 receptor agonists?

7 A Correct.

8 Q It says that "The signal, however, was
9 not confirmed in the FIGHT trial which showed
10 nonsignificant increases in death or HF
11 hospitalization with liraglutide compared with
12 placebo for patients with HF with reduced ejection
13 fraction."

14 Do you see that?

15 A I see that.

16 Q Was the FIGHT trial published before or
17 after July 1st, 2012?

18 A The reference is there. I don't know the
19 date of the publication.

20 MR. MAY: Sedrick, if you can go down to
21 Page -- so the reference there is Reference Number
22 67.

1 Q Agreed?

2 A Agreed.

3 MR. MAY: And then, Sedrick, if you can
4 go down to Page 19 for me, please.

5 A Before you skip ahead, just make sure
6 that it's understood that this is nonsignificant.
7 We're referring to something nonsignificant. By
8 nonsignificant -- significant means it's an effect
9 that's statistically meaningful. Nonsignificant
10 means it's not. It's an effect that very likely
11 due to chance, et cetera.

12 MR. MAY: And, Sedrick, can you please go
13 to Page 19 for me. And if you go to Number 67 in
14 that list.

15 Q It says that it was published in 2016.
16 You would agree with me on that?

17 A Yes.

18 Q Okay.

19 MR. MAY: All right. Sedrick, you can
20 take this down. And I think that we can take a
21 quick break.

22 MR. WHITE: Sure.

1 (A recess was taken.)

2 BY MR. MAY:

3 Q Dr. Schwartzbard, if you could please --
4 actually, so earlier we were discussing whether or
5 not there was any data on cardiovascular outcomes
6 for semaglutide available prior to July 1st, 2012,
7 as compared to just GLP-1s in general.

8 Do you recall that?

9 A I do.

10 Q Is there anywhere in your report that you
11 can point me to that would include data on
12 cardiovascular outcomes for semaglutide prior to
13 July 1st, 2012?

14 A Again, so just distinguishing for today's
15 purposes, "outcomes." It's a broad term. So if
16 you're referring to cardiovascular outcome trial,
17 we didn't have that until SUSTAIN 6 in 2016. We
18 did have earlier data on weight loss, sugar
19 effect, blood pressure effect, cholesterol effect,
20 et cetera, in a lot of the preclinical data.

21 Q And those were all the things you
22 referred to as cardiovascular risk factors, as

1 contrasted to cardiovascular outcomes. Correct?

2 A Correct. In a broad sense, correct. I
3 would say that those are associated with better
4 cardiovascular outcomes and drugs that are able to
5 lower pressure and improve cholesterol and cause
6 weight loss in diabetics are generally quite
7 favorable, or would be expected, would have been
8 expected to be quite favorable.

9 Q But again, those are cardiovascular risk
10 factors and not cardiovascular outcomes. Correct?

11 A Cardiovascular outcome trial is referring
12 to those randomized, double-blind,
13 placebo-controlled, this drug versus placebo, and
14 does this lead to over several years less heart
15 attack, stroke, death, et cetera.

16 Q So you said that there were data on
17 cardiovascular risk factors for semaglutide,
18 however. Did that data exist as of July 1st,
19 2012?

20 A So again, there was a lot of dosing data
21 for other doses of semaglutide prior to 2012.

22 Q When you say "dosing data," did that

1 include data on cardiovascular risk factors prior
2 to July 1st, 2012?

3 A Again, in -- like in Phase 1, Phase 2,
4 earlier stages of a drug's development, definitely
5 include effects on weight and sugar, et cetera.

6 Q And do you reference that anywhere in
7 your report specifically?

8 A I did not.

9 Q If you can turn to Paragraph 122 of your
10 report. Sorry, Paragraphs 121 and 122, actually.

11 A I'm with you.

12 Q So you're discussing a criticism you have
13 of Dr. Blaha and what you allege is a failure to
14 compare against .8-milligram once-weekly dosage of
15 semaglutide.

16 Do you see that?

17 A I do.

18 Q So how would you compare against
19 the .8-milligram once-weekly dosage of semaglutide
20 based on what was known in the art as of July 1st,
21 2012?

22 A Well, an obvious question to ask is

1 what's different about a 1-milligram dose that
2 isn't seen at a .8-milligram dose, is there a
3 difference in effect on sugar, is there a
4 difference in effect on blood pressure, is there a
5 difference in effect on weight, is there a
6 difference in anything. And so it's very
7 important to know information.

8 Q And what data would you have compared
9 against that was known as of July 1st, 2012?

10 A The point is that there are other -- the
11 point of this paragraph, again I don't want to
12 take it too out of context, but the point of this
13 paragraph is there was, as in the exhibit,
14 evidence of using semaglutide in other doses other
15 than 1 milligram.

16 Q And what --

17 A In fact, quite a few references of doses
18 other than 1 milligram.

19 This paragraph is citing a .8-milligram
20 reference, but the point is there is actually
21 quite a bit of predata on looking at semaglutide
22 in other -- in doses other than 1 milligram.

1 Q And you haven't --

2 A I'm sorry. Go ahead. I'm sorry. I'm
3 sorry if I interrupted you, Philip.

4 Q No. I apologize. I believe I
5 interrupted you.

6 A So back to your question. I believe your
7 question was what comparisons would I have done.
8 I mean, again, it's not for me to have done. But
9 comparisons as referenced in this paragraph, you
10 can't just talk about a single dose, a single
11 1-milligram dose out of context. You have to talk
12 about it in a context of how, if at all, is that
13 different from any other doses available for
14 semaglutide, or previously disclosed for
15 semaglutide.

16 Q And so what data was available as of July
17 1st, 2012, to compare against for cardiovascular
18 outcomes?

19 A Again, we're blurring subjects. But just
20 to reiterate so we're on the same page, the
21 cardiovascular outcome trial doesn't come out
22 until 2016. So if your question is was there a

1 cardiovascular outcome trial as we defined it
2 earlier for the .8-milligram dose, there was not.

3 Q If you can turn to Paragraph 124 for me,
4 please.

5 A I'm with you.

6 Q In Paragraph 124 you're discussing your
7 understanding of the legal concept of nexus.

8 Right?

9 A Correct.

10 Q So you say that you understand the nexus
11 inquiry is looking to determine whether the
12 secondary consideration, which here is generally
13 the allegedly unexpected cardiovascular benefits
14 and industry praise associated with the use of the
15 claimed invention, *parens*, i.e., a 1.0 milligram
16 once-weekly dose of semaglutide to treat T2D,
17 *close parens*, and not something that was already
18 known in the prior art or something that is not
19 claimed in the '462 patent.

20 Is that an accurate reflection of your
21 understanding of what the nexus inquiry looks at?

22 A Yes.

1 Q So is it your understanding that for
2 there to be nexus, the benefit must be claimed in
3 the patent?

4 A Just going back to the paragraph. There
5 needs to be a connection there, not just -- so in
6 this particular case we're discussing a
7 1-milligram weekly dose of semaglutide to treat
8 type 2 diabetes, and there has to be a connection
9 between what's seen with that dose and in here the
10 secondary consideration, which is either
11 unexpected cardiovascular benefits or industry
12 praise.

13 Q So is it your understanding that the
14 nexus for the cardiovascular benefit means that
15 the cardiovascular benefit must be claimed in the
16 patent?

17 A It's not necessarily that it has to be
18 claimed in the patent, but it has to be -- because
19 I cited later in this report that Novo Nordisk
20 filed a separate patent for the cardiovascular
21 claim. But it should be here that the secondary
22 consideration is that this is some unexpected

1 benefit, something unexpected and a surprise
2 benefit not seen with -- and uniquely linked to
3 the 1-milligram weekly dose.

4 Q So to make sure I understand, your point
5 about being claimed in the '462 patent is -- are
6 you saying that that's because in your opinion
7 Novo Nordisk's later patent application related to
8 some cardiovascular benefit means that there can't
9 be unexpected results here related to
10 cardiovascular benefit?

11 A Not that there can't be. I spent some
12 time in this paper saying that it was not
13 unexpected result. There can be. But in order to
14 show nexus, they have to show that, that this is
15 an unexpected result or industry praise or both,
16 and that it's linked to the 1-milligram dose
17 uniquely.

18 Q Is it your understanding then that an
19 unexpected result does not need to be claimed in
20 the patent?

21 A Again, I'm not a lawyer, so I don't want
22 to be seen as an expert in patent law. I'm not

1 a -- I'm not a lawyer, let's put that out there
2 again, as I testified earlier.

3 But my understanding is that in order
4 to -- as I wrote in this paragraph, in order to
5 show nexus, they have to show that this secondary
6 consideration, which here is this allegedly
7 unexpected cardiovascular benefit or industry
8 praise, is associated with that dose.

9 MR. MAY: Sedrick, if you could please
10 pull up Tab C and mark that as Exhibit 2602.

11 (Exhibit 2602 marked for identification
12 and is attached to the transcript.)

13 MR. MAY: And also put that in the chat
14 for everyone's availability.

15 A And, Philip, I'll just ask, I'm not
16 opening these chats, I'm just going to read what
17 you show me for today's purposes. Okay?

18 MR. MAY: Okay.

19 Q So, Dr. Schwartzbard, what we've got on
20 the screen in front of you which we've marked as
21 Exhibit 2602 is an article titled, The Changing
22 Landscape of Diabetes Therapy For Cardiovascular

1 Risk Reduction, authored by Jonathan Newman,
2 et al., and including yourself as one of the
3 authors.

4 Do you see that?

5 A I do.

6 Q Are you familiar with this article?

7 A I didn't reread it for today's
8 deposition, but I'm familiar with the article in a
9 gross sense.

10 Q And you see in the top right corner this
11 article was published in 2018?

12 A I do.

13 MR. WHITE: Could we reserve our right to
14 object to this exhibit?

15 MR. MAY: Sure.

16 Q So if we scroll down to the abstract on
17 Page 1 of Exhibit 2602. If you scroll down to the
18 third line in the abstract, about the third
19 sentence. It is the third sentence. It reads,
20 "Until recently, however, improved glycemic
21 control has not been associated with robust
22 macrovascular benefit. The advent of two new

1 classes of antihyperglycemic agents, the
2 sodium-glucose cotransporter-2 inhibitors and the
3 glucagon-like peptide 1 receptor agonists, and
4 their respective large cardiovascular outcome
5 trials, has led to a paradigm shift in how
6 cardiologists and healthcare practitioners
7 conceptualize T2D treatment."

8 Do you see that?

9 A I do.

10 Q And you agree with that statement?

11 A I do.

12 MR. MAY: If we could please turn to Page
13 7 of Exhibit 2602.

14 Q The right-hand column, the top underneath
15 the heading The GLP-1 Receptor Agonists. Article
16 reads, "In comparison to the CV outcomes trials
17 with SGLT2-I, trial results with the GLP-1 RA have
18 been more heterogenous," and then the sentence
19 continues from there.

20 Do you see that?

21 A I do.

22 Q And do you agree with that statement?

1 A I do.

2 Q All right.

3 MR. MAY: And then if you could please
4 turn to Page 10 of Exhibit 2602. Sorry, actually
5 Page 9. I apologize.

6 Q In the right-hand column, the first full
7 paragraph.

8 MR. MAY: If you can scroll down a little
9 bit.

10 Q First sentence of the first full
11 paragraph on the right-hand column reads, Notably,
12 a third GLP-1 RA agent, lixisenatide, did not
13 demonstrate superiority in CV outcomes reduction
14 in the ELIXA defined trial.

15 Do you see that?

16 A I don't. I lost you, I'm sorry. The
17 screen was moving while you were reading.

18 Q Sure. So it's in the right-hand column.

19 A Okay.

20 Q And what's shown on the screen right now,
21 it's the third line down, which is the start of
22 the first full paragraph.

1 A In comparison sentence? Oh. I'm sorry.
2 The paragraph that is on the right starts,
3 "Notably, a third agent."

4 Q That's right. And so that's the sentence
5 I'm referring to. So it reads, "Notably, a third
6 GLP-1 RA agent, lixisenatide, did not demonstrate
7 superiority in CV outcomes reduction in the ELIXA
8 (Evaluation of Lixisenatide in Acute Coronary
9 Syndrome) trial."

10 Do you see that?

11 A I do.

12 Q And you agree with that statement?

13 A I do.

14 MR. MAY: And if we could please scroll
15 down further in that right-hand column to that
16 final paragraph that starts with the word
17 "finally."

18 Do you see that paragraph that starts
19 "finally," Dr. Schwartzbard?

20 A I do. I do.

21 Q And the sentence there reads, "Finally, a
22 fourth GLP-1 RA agent, exenatide, in the largest

1 GLP-1 RA CV outcomes trial to date, did not reach
2 superiority for a reduction in CV outcomes
3 compared with placebo."

4 Do you agree with that statement?

5 A I do.

6 MR. MAY: If we could please turn to Page
7 10 of Exhibit 2602.

8 Q Looking at the first full paragraph on
9 the left-hand column. It states, Results from the
10 long-acting GLP-1 RA trials with albiglutide,
11 parens, HARMONY outcome; NCT number, and
12 dulaglutide, parens REWIND; NCT number, will help
13 clarify whether the CV benefit demonstrated by
14 GLP-1 RA agents is a class effect, parens, namely
15 with the longer-acting, more potent agents, close
16 parens, or a drug-specific effect only seen with
17 liraglutide and semaglutide.

18 Do you see that?

19 A I see the sentence.

20 Q And do you agree with that? Do you agree
21 with that sentence as of 2018?

22 A Yeah. So this is -- this is obviously my

1 submission to the court for this case actually
2 cites the REWIND trial. So as you no doubt know,
3 the REWIND trial was favorable and granted what's
4 now known as Trulicity an indication to reduce
5 cardiovascular events even -- even in people who
6 haven't yet had events.

7 Q But you agree with the sentence as of
8 2018. Right?

9 A Yes.

10 MR. MAY: All right, Sedrick, you can
11 take this article down.

12 Why don't we go ahead and take a short
13 ten-minute break.

14 MR. WHITE: Okay. Sounds good.

15 (A recess was taken.)

16 MR. MAY: Dr. Schwartzbard, I have no
17 further questions at this time. Thank you very
18 much for your time today.

19 THE WITNESS: Thank you, Philip.
20 Appreciate it.

21 MR. WHITE: And we have nothing, Philip.

22 (Off the record at 11:42 a.m. EDT.)

ACKNOWLEDGMENT OF DEPONENT

I, ARTHUR Z. SCHWARTZBARD, M.D.,
F.A.C.C., do hereby acknowledge that I have read
and examined the foregoing testimony, and the same
is a true, correct and complete transcription of
the testimony given by me, and any corrections
appear on the attached Errata sheet signed by me.

(DATE)

(SIGNATURE)

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C E R T I F I C A T E

I, Debra Ann Whitehead, E-Notary Public in and for
the State of Maryland, do hereby certify:

That ARTHUR Z. SCHWARTZBARD, M.D.,
F.A.C.C., the witness whose deposition is
hereinbefore set forth, was duly sworn by me before
the commencement of such deposition and that such
deposition was taken virtually and is a true record
of the testimony given by such witness.

I further certify that the adverse party,
NOVO NORDISK A/S, was represented by counsel at the
deposition.

I further certify that the deposition of
ARTHUR Z. SCHWARTZBARD, M.D., F.A.C.C., occurred
virtually, on Tuesday, July 9, 2024, from 10:01
a.m. to 11:42 a.m. EDT.

1 I further certify that I am not related to
2 any of the parties to this action by blood or
3 marriage, I am not employed by or an attorney to any
4 of the parties to this action, and that I am in no
5 way interested, financially or otherwise, in the
6 outcome of this matter.

7

8 IN WITNESS WHEREOF, I have hereunto set my
9 hand this 11th day of July, 2024.

10

11 My commission expires:

12 April 30th, 2027

13

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15 E-NOTARY PUBLIC IN AND FOR THE

16 STATE OF MARYLAND

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