

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EMBODY, INC. AND ZIMMER BIOMET HOLDINGS,
INC.,
Petitioner

V.

LIFENET HEALTH,
Patent Owner.

Case IPR2025-00248
U.S. Patent No. 10,137,223

ORAL AND VIDEOTAPED DEPOSITION OF
ANTONIOS G. MIKOS
JANUARY 21, 2026

ORAL AND VIDEOTAPED DEPOSITION of
ANTONIOS G. MIKOS, produced as a witness at
the instance of the Petitioner, and duly
sworn, was taken in the above-styled and
numbered cause on January 21, 2026, from
9:29 a.m. to 4:10 p.m., before
Mendy A. Schneider, CSR, RPR, in and for the
State of Texas, recorded by machine
shorthand, at the offices of McGuireWoods,
845 Texas Avenue, 24th Floor, Houston, Texas,
pursuant to the Federal Rules of Civil
Procedure and the provisions stated on the
record or attached hereto; that the
deposition shall be read and signed.

7048658-001

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MIKE FLORES, The Videographer

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	exhibits are reflected in the manner in which	
	they were read into the record and do not	
	necessarily denote an exact quote from the	
	document.)	

1 THE VIDEOGRAPHER: We are on
2 the record at 9:29 a.m. on January 21,
3 2026.

4 Audio and video recording will
5 continue to take place until all
6 parties agree to go off the record.

7 Please note that the
8 microphones are sensitive and may pick
9 up whispering and private
10 conversations.

11 This is the video-recorded
12 proceeding of Antonios Mikos taken by
13 counsel for the petitioners in the
14 matter of Embody, Inc., et al., versus
15 LifeNet Health filed in the United
16 States Patent Trial and Appeal Board.

17 This proceeding is being held
18 at the offices for McGuireWoods
19 located at 845 Texas Avenue, Texas
20 Tower, 24th Floor, Houston, Texas
21 77002.

22 My name is Mike Flores. I'm
23 the videographer on behalf of US Legal
24 Support. I am not related to any
25 party in this action, nor am I

1 financially interested in the outcome.

2 The court reporter is Mendy
3 Schneider on behalf of US Legal
4 Support.

5 At this time will counsel
6 please state their presence for the
7 record and followed by the swearing in
8 of the witness.

9 MR. LEVINE: This is Howard
10 Levine. I'm joined by my colleague,
11 David Feigenbaum, from Hogan Lovells,
12 representing petitioner in this
13 matter.

14 MS. WIEKER: Amanda Wieker from
15 the law firm of McGuireWoods. I'm
16 here on behalf of patent owner LifeNet
17 Health and the witness Antonios Mikos.

18 ANTONIOS G. MIKOS,
19 having been first duly sworn, testified as
20 follows:

21 EXAMINATION

22 BY MR. LEVINE:

23 Q. Good morning, Dr. Mikos.

24 A. Good morning.

25 Q. Can you state your full name

1 for the record, please.

2 A. Antonios Georgios Mikos.

3 Q. And where do you currently
4 reside?

5 A. I reside here in Houston,
6 Texas.

7 Q. And what is your current
8 address?

9 A. 2329 Wroxton Road.

10 Q. And, Dr. Mikos, have you been
11 deposed before?

12 A. Yes.

13 Q. In what context have you been
14 deposed?

15 A. In cases related to patent
16 litigations.

17 Q. And in those cases related to
18 patent litigations, were you testifying as an
19 expert witness?

20 A. Yes.

21 Q. Have you also testified as a
22 fact witness in those cases relating to
23 patent litigations?

24 A. What is a fact witness?

25 Q. Were you personally involved in

1 the merits of any of those patent litigations
2 aside from being an expert and offering
3 testimony?

4 A. No.

5 Q. Were any of those patents your
6 patents in those litigations?

7 A. No.

8 Q. Other than -- and when did
9 these patent litigations that you testified
10 as an expert take place?

11 A. Sometime the last 30 years.

12 Q. And just for the record, did
13 you say 30 years?

14 A. 3-0, 30.

15 Q. 3-0.

16 Have you -- have any of these
17 patent litigations took place in the last
18 five years?

19 A. The last litigation was before
20 the pandemic, so I think it was about six,
21 seven years.

22 Q. And who did you testify for in
23 that litigation?

24 A. I don't remember the parties
25 involved. This is information that I

1 provided to the attorneys and I can also
2 provide it to you.

3 Q. Just to be clear, so sitting
4 here today, you don't remember the parties
5 that were involved in that patent litigation
6 six to seven years ago; is that right?

7 A. One party was MiMedx.

8 The other party was -- I don't
9 remember the exact name of the party, but it
10 was a case in Atlanta. And, again, the
11 information I can provide to you.

12 Q. So you remembered one of the
13 parties.

14 Was that the party that you
15 testified for?

16 A. No. That was not the party
17 that I was retained by.

18 Q. So it was the other party that
19 retained you?

20 A. (Nodding head.)

21 Q. Did that case go to trial?

22 A. No.

23 Q. Do you recall if you testified
24 only at a deposition in that case?

25 A. In that case, I did not offer a

1 deposition.

2 Q. Okay. In that case were your
3 opinions limited to providing an expert
4 report?

5 A. Correct.

6 Q. Okay. And, again, if you don't
7 remember, you don't remember.

8 But sitting here today, do you
9 recall why you weren't deposed in that case
10 on the basis of your expert report?

11 A. My understanding is that the
12 case was settled. It's right before the time
13 that I was about to be deposed.

14 Q. And, again, sitting here today,
15 if you recall, do you recall if you were
16 representing the patentee or the party
17 accused of infringement in that case?

18 A. I don't remember.

19 Q. Okay. Do you remember the
20 general technology that was involved in that
21 case?

22 A. What I recall, it was a case
23 involving an extracellular matrix
24 biomaterial.

25 Q. So today, as the -- as the

1 court reporter mentioned to you, it is
2 important that we don't talk over each other
3 so that everything gets down on the record.

4 I will try to ask you a
5 question, then pause, and I will try to allow
6 you to answer the question before I ask
7 another question.

8 Is that acceptable?

9 A. Yes.

10 Q. Your testimony today is under
11 oath. That means you're obligated to tell
12 the truth as if it were in a court with a
13 judge present.

14 Do you understand that?

15 A. Yes.

16 Q. During the deposition, I plan
17 to take breaks probably every hour. But if
18 you need a break at any time, just indicate
19 that you need a break and we'll break.

20 The only thing that I ask is
21 that if there's a pending question, you
22 answer the question and then we can go off
23 the record.

24 Is that acceptable?

25 A. Yes.

1 Q. Dr. Mikos, is there anything
2 that would prevent you from testifying
3 truthfully and accurately today?

4 A. No.

5 Q. Did you bring any documents
6 with you to the deposition today?

7 A. No.

8 Q. Did you prepare for this
9 deposition today?

10 A. Yes.

11 Q. And how did you prepare for
12 this deposition?

13 A. I reviewed my expert reports.
14 I reviewed my exhibits. And I met yesterday
15 with the attorneys.

16 Q. Did you meet with counsel for
17 more than one day in preparation for your
18 deposition today?

19 A. No.

20 Q. Is it true that you met with
21 counsel, in preparation of your deposition
22 today, yesterday?

23 A. Yes.

24 MS. WIEKER: Objection to form.

25

1 (BY MR. LEVINE)

2 Q. And who were the counsel that
3 you met with?

4 A. I met here in this office with
5 Ms. Amanda Wieker.

6 Q. Anyone else present?

7 A. There was another attorney who
8 joined briefly via Zoom.

9 Q. And do you recall who that was?

10 A. David, Davis. I'm not a
11 hundred percent sure if this is the name.

12 Q. George Davis?

13 A. George Davis, yeah.

14 Q. And approximately how many
15 hours did you meet with counsel yesterday in
16 preparation for your deposition today?

17 A. We started around 9 o'clock.
18 We had to break for lunch and we finished
19 around 4 o'clock.

20 Q. Other than counsel, did you
21 speak with anyone in preparation for your
22 deposition today?

23 A. Yesterday?

24 Q. At any time.

25 A. No. I only spoke with counsel.

1 Q. And is it correct that you are
2 offering opinions in this case on behalf of
3 LifeNet; is that right?

4 A. That's correct.

5 Q. Okay. If I refer to LifeNet as
6 the patent owner, is that acceptable to you?
7 Will you understand what I'm referring to?

8 A. Yes.

9 Q. In preparation for your
10 deposition today, did you discuss -- strike
11 that.

12 In preparation for your
13 deposition today, did you have any
14 discussions with individuals employed by
15 LifeNet?

16 A. No.

17 Q. When were you first retained by
18 LifeNet to offer opinions in this case?

19 MS. WIEKER: Objection to form.

20 A. I was retained by the attorneys
21 to offer expert opinions for this case
22 sometime the summer of '25. Last summer.

23 (BY MR. LEVINE)

24 Q. And do you recall who
25 approached you?

1 A. It was an expert witness search
2 firm called IMS Legal Strategies.

3 Q. And do you have a relationship
4 with that expert search firm, IMS Legal
5 Strategies?

6 A. No.
7 Excuse me. I have an agreement
8 with them but I didn't have any previous
9 relationship with them.

10 Q. So when you say you have an
11 agreement with them, did you have an
12 agreement with them before they contacted you
13 in connection with this case?

14 A. No. The agreement is to be
15 retained as an expert for this particular
16 case.

17 Q. Had you been contacted by
18 IMS Legal Strategies to work as an expert in
19 any other case?

20 A. Not that I recall.

21 Q. Do you know how IMS Legal
22 Strategies identified you as a potential
23 expert in this case?

24 A. No.

25 Q. So after they contacted you

1 about potentially working on this case, what
2 was the next contact you had with either
3 LifeNet or the attorneys representing
4 LifeNet?

5 A. Can you repeat the question,
6 please.

7 Q. Sure. After you were contacted
8 by IMS Legal Strategies, what was your next
9 contact with either individuals employed by
10 LifeNet or the attorneys representing LifeNet
11 in this litigation?

12 A. As I discussed earlier, I never
13 had any discussion with anyone employed by
14 LifeNet.

15 The only discussion that I had
16 after I'd been contacted initially by
17 IMS Legal Strategies was by the attorneys
18 working on this case.

19 Q. So just -- so just to be clear,
20 since you were retained in the summer of 2025
21 through today, you have not had any contacts
22 with any individuals employed by LifeNet
23 regarding your opinions in this case; is that
24 correct?

25 MS. WIEKER: Objection; asked

1 and answered.

2 A. That is correct. I never had
3 any contact with anyone working at --
4 employee of LifeNet during that time.
5 (BY MR. LEVINE)

6 Q. So after IMS Legal Strategies
7 contacted you, your next contact in
8 connection with this case was with the
9 attorneys representing LifeNet in this
10 action; is that right?

11 MS. WIEKER: Objection to form.

12 A. I don't remember if the first
13 contact with the attorneys was before the
14 signing of the agreement or after the signing
15 of the agreement but was approximately at
16 that time.

17 (BY MR. LEVINE)

18 Q. Okay. And which attorney was
19 that who contacted you of the ones who are
20 representing LifeNet in this litigation?

21 MS. WIEKER: Objection to form.

22 A. Again, we're talking about
23 being contacted during the time of the
24 retention time, that was Ms. Wieker.

25

1 (BY MR. LEVINE)

2 Q. Okay. And after that time, did
3 there come a time when you prepared your
4 expert report in this case?

5 A. We had several discussions
6 about the case and at some point there was
7 a -- I realize that I needed to submit expert
8 report for this case.

9 Q. And do you understand that your
10 opinions here are offered in connection with
11 two proceedings before the Patent Trial and
12 Appeals Board?

13 A. That's my understanding. It's
14 '248 and '249 case.

15 Q. And if I refer to the Patent
16 Trial and Appeal Board as the PTAB, is
17 that -- will you know what I'm referring to?

18 A. Yes.

19 Q. Okay. Have you been retained
20 as an expert before in any proceedings before
21 the PTAB?

22 A. Yes, I did.

23 Q. And when -- and when was that?

24 A. That was one or two of the
25 cases that I served as an expert witness in

1 the past.

2 Q. Okay. And how long ago were
3 those cases?

4 A. I don't recall.

5 Q. Was it outside the five-year
6 period we were discussing before?

7 A. It was before the five-year
8 period -- before five -- five-year period,
9 yes.

10 Q. And do you recall generally the
11 parties in those cases?

12 A. No.

13 Q. And do you recall the general
14 subject matter of those cases, to the best of
15 your recollection?

16 MS. WIEKER: Objection to form.

17 A. Most of the cases that I served
18 as an expert witness, I would say all the
19 cases that I serve as an expert witness
20 involve biomaterials-related technologies.

21 (BY MR. LEVINE)

22 Q. Let me mark as Exhibit 1 a
23 document entitled "Declaration of
24 Dr. Antonios G. Mikos, Ph.D.," in support of
25 patent owner's response, Case

1 No. IPR2025-00248.

2 (Marked Mikos Exhibit No. 1.)

3 MS. WIEKER: Thank you.

4 THE WITNESS: Thank you.

5 (BY MR. LEVINE)

6 Q. Let me mark as Mikos Exhibit 2
7 document entitled "Declaration of
8 Dr. Antonios G. Mikos, Ph.D.," in support of
9 patent owner's response, Case
10 No. IPR2025-00249.

11 (Marked Mikos Exhibit No. 2.)

12 THE WITNESS: Thank you.

13 MS. WIEKER: Thank you.

14 (BY MR. LEVINE)

15 Q. If I could turn you to
16 Exhibit 1, is it correct that this is the
17 declaration that you prepared in connection
18 with the IPR proceeding that has the last
19 three digits 248?

20 A. Yes.

21 Q. Okay. And if you turn to
22 Page 61 of the report, is that your
23 signature?

24 A. Yes.

25 Q. And it was dated October 28,

1 2025?

2 A. Yes.

3 Q. And do you recall how this
4 document was prepared?

5 A. It was prepared by me in
6 collaboration with the attorneys in this
7 case. This is the report that expresses all
8 my opinions for this particular case, the 248
9 case.

10 Q. And in terms of how the
11 document was prepared, I assume you didn't
12 type this yourself, correct?

13 MS. WIEKER: Objection to form.
14 (BY MR. LEVINE)

15 Q. You can answer.

16 A. I typed certain parts of the
17 report. Again, the report followed extensive
18 discussions that I had with the attorneys and
19 it clearly reflects all my opinions.

20 Q. So certain portions of the
21 report you -- you actually entered into the
22 word processor yourself; is that correct?

23 A. We exchanged a lot of e-mails
24 with the attorneys and, yes, I have typed
25 several parts of the reports myself.

1 Q. Okay. And do you recall which
2 ones?

3 A. No, but I would say there was
4 extensive text that I entered into the
5 report.

6 Q. And about how long -- strike
7 that.

8 About how many hours did you
9 spend in preparing this report?

10 A. I don't recall the exact number
11 of hours.

12 Q. Ballpark number.

13 Was it more than 50 hours,
14 would you say?

15 A. Based on the invoices that I
16 submitted to IMS, I don't think it was more
17 than 50 hours.

18 Q. Okay. Would it have been more
19 than 40 hours?

20 A. I cannot say.

21 Q. Again, I'm just probing your
22 memory.

23 Would it be more than
24 ten hours?

25 A. Probably more than ten hours

1 taking into consideration also the literature
2 review that I conducted to -- for the
3 opinions that I expressed in the report.

4 Q. And you said you did a
5 literature review.

6 What do you mean by that?

7 A. Try to support my opinions with
8 existing literature at the time of the
9 invention, something that the person of skill
10 in the art would have been aware of.

11 Q. And in your answer now, you
12 referred to a person of skill in the art. If
13 I use the abbreviation POSA, is that
14 acceptable?

15 Will you understand what I'm
16 referring to?

17 A. Yes.

18 Q. If I can turn you to Page 62 of
19 your Exhibit 1 --

20 A. Yes.

21 Q. -- and looking at the
22 references considered, can you tell me which
23 one of those references you identified in
24 your literature search?

25 MS. WIEKER: Objection to form.

1 (BY MR. LEVINE)

2 Q. You can answer.

3 A. I would say -- I mean, if --
4 when I look, the exhibits -- the different
5 exhibits on Page 63 are, going from the
6 bottom, the references by Zeugolis,
7 Z-E-U-G-O-L-I-S, the reference by Woodruff,
8 W-O-O-D-R-U-F-F, the reference by Shoulders,
9 S-H-O-U-L-D-E-R-S, and Raines, R-A-I-N-S
10 [verbatim].

11 These are some of the
12 references so that I identified myself. Also
13 I think I mentioned a last reference by
14 Barnes, B-A-R-N-E-S.

15 But there may be others. I
16 also reviewed a lot of the references that
17 the attorneys provided, so it's very hard, as
18 I sit here, to say definitely which reference
19 I identify myself and which reference was
20 provided by the attorneys.

21 But clearly these are all the
22 references that I used in -- to support the
23 opinions that are expressed in this report.

24 Q. Okay. Shoulders and Raines,
25 that's identified as Exhibit 1017 in the

1 table that's on Page 63; is that right?

2 A. Correct.

3 Q. And Zeugolis is Exhibit 2019;
4 is that right?

5 A. I'm sorry, what is your
6 question?

7 Q. Zeugolis that you referred to
8 in your answer --

9 A. Yes.

10 Q. -- that's Exhibit 2019?

11 A. This is the Exhibit 2019, yes.

12 Q. And Woodruff is Exhibit 2018?

13 A. That is correct.

14 Q. And in terms of preparation,
15 was Exhibit 2 prepared the same way as
16 Exhibit 1?

17 MS. WIEKER: Objection to form.

18 A. Like Exhibit 1, some of the
19 references are -- were provided by the
20 attorneys.

21 Some of the references, I
22 discovered them following literature searches
23 at the time of the invention and before the
24 time to support the opinions that I express
25 in the report, in this report.

1 (BY MR. LEVINE)

2 Q. And if you can turn to Page 76
3 of this document --

4 A. Yes.

5 Q. -- is that your signature on
6 Page 76?

7 A. Yes.

8 Q. And it was dated October 28,
9 2025, as well; is that right?

10 A. Yes.

11 Q. And if you could turn to
12 Page 77 through 80 of your expert report, can
13 you identify those references that you recall
14 sitting here today that you identified in
15 connection with your literature review?

16 MS. WIEKER: Objection to form.

17 A. Again, some of the references
18 that I identified myself following literature
19 searches in connection with this case were
20 Exhibit 2035 by Lustig, L-U-S-T-I-G.

21 Exhibit 2034 by Crisan,
22 C-R-I-S-A-N.

23 Exhibit 2031 by Ni Annaidh, N-I
24 A-N-N-A-I-D-H.

25 Exhibit 2030 by Ma, M-A.

1 Exhibit 2029 by Butler,
2 B-U-T-L-E-R.

3 Exhibit 2028 by Butler,
4 B-U-T-L-E-R.

5 Exhibit 2027 by Hashemi,
6 H-A-S-H-E-M-I.

7 Exhibit 2026 by Johnson,
8 J-O-H-N-S-O-N.

9 Exhibit 2025 by Gennison,
10 G-E-N-N-I-S-O-N.

11 Exhibit 2024 by Engler,
12 E-N-G-L-E-R.

13 Exhibit 2023 by Sikavidsas,
14 S-I-K-A-V-I-D-S-A-S.

15 Exhibit 2021 by Rothamel,
16 R-O-T-H-A-M-E-L.

17 Exhibit 2019 by Zeugolis,
18 Z-E-U-G-O-L-I-S.

19 Exhibit 2018 by Woodruff,
20 W-O-O-D-R-U-F-F.

21 There are some that I'm not a
22 hundred percent sure. I mean, like I said,
23 earlier, the exhibit by -- 2020 by Barnes,
24 that I may have identified it myself or the
25 attorneys may have provided.

1 I am not a hundred percent sure
2 about that.

3 Yeah, I think this is some of
4 the reference that I think I identified
5 myself because these are the references that
6 were included to support the tables and the
7 figures that I included in my expert reports.

8 (Marked Mikos Exhibit No. 3.)

9 (BY MR. LEVINE)

10 Q. Let me mark as the next
11 exhibit, Mikos Exhibit 3, U.S. Patent
12 No. 10,137,223 to Francis, et al.

13 A. Thank you.

14 MS. WIEKER: Thank you.

15 (BY MR. LEVINE)

16 Q. And, Dr. Mikos, did you review
17 Exhibit 3 in connection with your opinions in
18 this case?

19 A. Yes.

20 Q. And is Exhibit 3 the patent
21 that is the subject of your declaration that
22 is Exhibit 1?

23 A. Yes.

24 Q. And how long, if you recall,
25 did you spend time reviewing Exhibit 3?

1 MS. WIEKER: Objection to form.

2 (BY MR. LEVINE)

3 Q. You can answer.

4 A. How long total time that I
5 spent reviewing?

6 Q. Yes.

7 A. I don't recall how long the
8 exact time, but I review it very carefully.

9 Q. And if I refer to Exhibit 3 as
10 the '223 patent, is that acceptable? You'll
11 understand what I'm referring to?

12 A. Yes.

13 (Marked Mikos Exhibit No. 4.)

14 (BY MR. LEVINE)

15 Q. Let me mark as the next exhibit
16 as Mikos Exhibit 4 a document, U.S.
17 11,318,227, a U.S. patent to Francis, et al.

18 MS. WIEKER: Thank you.

19 MR. LEVINE: Oh, shoot. It was
20 only a matter of time before I did
21 that.

22 (BY MR. LEVINE)

23 Q. Here we go, Dr. Mikos.

24 Dr. Mikos, is Exhibit 4 the
25 patent that is the subject of your

1 declaration that is Exhibit 2?

2 A. Yes.

3 Q. And if I refer to this patent
4 as the '227 patent, is that acceptable?
5 You'll understand what I'm referring to?

6 A. Yes.

7 Q. Okay. And do you recall how
8 long you spent reviewing the '227 patent,
9 which is Exhibit 4?

10 MS. WIEKER: Objection to form.

11 A. I don't recall how long. I
12 studied this patent very carefully.

13 (BY MR. LEVINE)

14 Q. If I could turn you back to
15 Exhibit 1, which is your declaration
16 concerning the '223 patent.

17 If I can turn you to exhibit --
18 sorry, strike that.

19 If I could turn you to
20 Paragraph 45.

21 A. Yes.

22 Q. That paragraph says: "To
23 measure alignment of the scaffold's fibers,
24 the '223 patent employs a fast Fourier
25 transform ('FFT') analysis, which is

1 described in a 2008 publication authored by
2 Dr. Simpson, Petitioner's expert witness, and
3 which the patent incorporates by reference."

4 Do you see that paragraph?

5 A. Yes.

6 Q. And if I refer to a fast
7 Fourier transform analysis as "FFT," will you
8 understand what I'm referring to?

9 A. Yes.

10 Q. And have you performed an FFT
11 analysis yourself?

12 MS. WIEKER: Objection to form.

13 (BY MR. LEVINE)

14 Q. You can answer.

15 A. An FFT analysis in connection
16 to this case or an FFT analysis in general?

17 Q. An FFT analysis in general.

18 A. Yes. Myself and my students
19 have conducted FFT analysis as part of our
20 research. It's a tool that is commonly used
21 for image analysis.

22 Q. And you, yourself, conducted
23 the FFT analysis?

24 A. As a professor I supervise
25 students who do all the experiments. I'm

1 responsible for all the experiments. They
2 explain to me all the steps.

3 I may not have been in front of
4 the computer pressing -- pressing the buttons
5 but I supervise the students who did all the
6 analysis and I discuss with them all the
7 results.

8 Q. So the students actually
9 perform the FFT analysis but you supervise
10 them in connection as their professor.

11 Is that true?

12 MS. WIEKER: Objection to form.

13 (BY MR. LEVINE)

14 Q. You can answer.

15 A. As relates to specific research
16 projects, yes, that the students will conduct
17 an FFT analysis and they will discuss with me
18 the analysis itself, the suitability of the
19 technique, and the tools employed, as well as
20 the analysis of the data.

21 Q. And in what context did your
22 students perform an FFT analysis?

23 MS. WIEKER: Objection to form.

24 (BY MR. LEVINE)

25 Q. You can answer.

1 A. If they thought that the
2 FFT analysis would be suitable for the -- for
3 their research, that would be fine. I mean,
4 and I don't recall, I mean, the specific
5 instances but we have conducted FFT analysis
6 and we have reported the results of
7 FFT analysis in the literature.

8 I should also mention that as a
9 professor I teach different classes. One of
10 the classes that I taught for a number of
11 years was mathematics for engineers, and FFT
12 is a tool that is used that in -- to process
13 data and I'm sure that we had discussions
14 about FFT also there.

15 Q. Do you recall actually
16 discussing FFT in those courses?

17 A. I don't recall discussing FFT
18 in that course, but I'm sure it was something
19 that was part of the curriculum and part of
20 the topic that was discussed with the
21 students.

22 Q. But sitting here today, you
23 don't remember actually teaching FFT in that
24 particular course to engineers that you're
25 referring to?

1 MS. WIEKER: Objection to form.

2 (BY MR. LEVINE)

3 Q. Is that true?

4 MS. WIEKER: Sorry.

5 A. No, I recall teaching FFT. I
6 don't recall in what context the FFT was
7 taught. Again, if you see my CV, I list the
8 courses that I taught as professor at Rice
9 University and one of the courses that I
10 taught is mathematics, and that was more than
11 20 or 25 years ago.

12 (BY MR. LEVINE)

13 Q. So -- so when was the first
14 time that -- strike that.

15 So in that course, were you
16 teaching using FFT to determine the alignment
17 of electrospun fibers?

18 MS. WIEKER: Objection to form.

19 A. I don't recall in what context
20 the -- the teaching of FFT was about. One
21 thing that I might say is that FFT is a
22 standard mathematical tool that the theory of
23 which can be taught.

24 (BY MR. LEVINE)

25 Q. And do you recall if either --

1 strike that.

2 When you testified about your
3 students using FFT analysis in their work,
4 did that concern the analyzing the alignment
5 of electrospun fibers?

6 A. Yes. Among other things.

7 Q. And was that work published?

8 A. Yes.

9 (Marked Mikos Exhibit No. 5.)

10 MR. LEVINE: Let me mark as
11 Mikos Exhibit 5 the CV of
12 Antonios G. Mikos.

13 Here you go.

14 MS. WIEKER: Thank you.

15 (Discussion off the record.)

16 (BY MR. LEVINE)

17 Q. Dr. Mikos, is this a copy of
18 your -- your CV?

19 A. Yes.

20 Q. Can you identify the paper that
21 you're referring to where your students
22 published using FFT to analyze the alignment
23 of electrospun fibers?

24 A. If you go to Page 45 of my CV,
25 one example of a publication that uses FFT to

1 characterize the alignment of electrospun
2 fibers and also the alignment of myotubes
3 that are formed is reference 537 by Smoak,
4 S-M-O-K [verbatim]; Hogan, H-O-G-A-N;
5 Grande-Allen, G-R-A-N-D-E-A-L-L-E-N; and
6 Mikos, M-I-K-O-S.

7 Q. All right. Are there any other
8 publications on your CV in which FFT was used
9 to determine the alignment of electrospun
10 fibers?

11 MS. WIEKER: Objection to form.

12 A. There may be others. I don't
13 recall now, I mean, others, but this
14 particular one is representative that clearly
15 shows how FFT analysis and ImageJ were used
16 to characterize the alignment of electrospun
17 fibers.

18 (BY MR. LEVINE)

19 Q. And that was -- that paper was
20 published in 2021, correct?

21 A. That is correct.

22 Q. And when was the approximately
23 the work done that led to the publication of
24 this paper?

25 MS. WIEKER: Objection to form.

1 (BY MR. LEVINE)

2 Q. You can answer.

3 A. I would have to check the lab
4 books of that particular student but if I
5 need to guess, I would say 2020 or 2019.

6 There is a related paper by the
7 student that I can identify that deals with
8 electrospun fibers but I'm not certain
9 whether that paper has an FFT analysis.

10 So this is a 2019 article on
11 Page 43 of my CV. The name -- the
12 publication -- the number of the publication
13 is 496. It's by the same first author,
14 Smoak, S-M-O-A-K; Han, H-A-N; Watson,
15 W-A-T-S-O-N; Kishan, K-I-S-H-A-N,
16 Grande-Allen, G-R-A-N-D-E-A-L-L-E-N;
17 Cosgriff-Hernandez,
18 C-O-S-G-R-I-F-F-H-E-R-A-N-D -- I'm sorry,
19 Hernandez, H-E-R-N-A-N-D-E-Z; and Mikos,
20 M-I-K-O-S.

21 That was a paper published in
22 Tissue Engineering Part C: Methods in 2019,
23 again, that involves electrospun fibers but
24 I'm not certain if that particular
25 publication includes an FFT analysis.

1 The previous one that I
2 mentioned I'm a hundred percent positive that
3 it included the FFT analysis.

4 Q. And just as approximation, the
5 work underlying the publication listed on
6 your CV as 496, that would have taken place
7 in the 2018-to-2019 time frame?

8 MS. WIEKER: Objection to form.

9 A. If I go back to the back of my
10 CV and see the years that the particular
11 student was in my lab -- so we're talking
12 about Mollie Smoak, so she was in my lab but
13 from 2016 to 2021. I'm looking at the
14 Page 167 of my CV, somewhere at the bottom it
15 says Mollie M. Smoak, M-O-L-L-I-E M.
16 S-M-O-A-K, Ph.D. 2016-2021. This was the
17 time that she was in my lab so that would be
18 an accurate period that the work that's
19 reported in this publication was conducted.

20 (BY MR. LEVINE)

21 Q. Other than Mollie Smoak, do you
22 recall any other students performing FFT to
23 determine the alignment of electrospun
24 fibers?

25 A. I don't recall but I can check

1 if needed and tell you, I mean, what other
2 students use FFT as part of their research.

3 Q. Looking at your CV, does it
4 refresh your recollection as to whether any
5 other publications, other than 537 and
6 potentially 496, involved using FFT to
7 determine the alignment of electrospun
8 fibers?

9 MS. WIEKER: Objection to form.
10 (BY MR. LEVINE)

11 Q. You can answer.

12 A. Looking at my CV, I mean, you
13 will recognize that I have published over 700
14 publications. It's very hard to remember
15 which ones also involve the FFT, and one of
16 the reasons that I remember the ones by Smoak
17 is Mollie Smoak is because these are the most
18 recent ones and these are some of the results
19 that I may present in scientific conferences
20 so I recall them. But I've been a
21 professional for over 30 years and FFT is not
22 a new technique.

23 Q. What -- who is the first -- to
24 your understanding, who is the first research
25 group to use FFT to assess the alignment of

1 electrospun fibers?

2 MS. WIEKER: Objection to form.

3 A. I don't know.

4 (BY MR. LEVINE)

5 Q. Is it your understanding that
6 there was a research group before
7 Dr. Simpson's group that used FFT to
8 determine the alignment of electrospun
9 fibers?

10 MS. WIEKER: Objection to form.

11 A. So the question is whether
12 there was any group before Dr. Simpson who
13 used FFT to characterize the alignment of
14 electrospun fibers?

15 (BY MR. LEVINE)

16 Q. Yes.

17 A. I don't know. I would have to
18 check.

19 Q. For your opinions in this case,
20 you were opining on the techniques in
21 performing FFT analysis, correct?

22 A. I provide some technical
23 opinions about different aspects of the cases
24 including the FFT analysis.

25 Q. In forming those opinions, did

1 you look back at any of your papers that you
2 say you used or your students used FFT to
3 analyze the alignment of electrospun fibers?

4 A. I don't recall. I would have
5 used back any of these papers if I thought it
6 was necessary but I don't recall looking back
7 at any of the papers. I would have relied on
8 my memory knowing how FFT works.

9 Q. So just to be clear, so you
10 didn't look book at, for example, the 537
11 paper by Ms. Smoak?

12 MS. WIEKER: Objection to form.

13 A. What do you mean I didn't look
14 back? I may have checked that paper but...
15 (BY MR. LEVINE)

16 Q. And you said you may have
17 checked that paper.

18 Do you recall if you did or did
19 not check that paper?

20 MS. WIEKER: Objection to form.

21 A. I may have checked that paper
22 and I may have confirmed that indeed that FFT
23 was used as part of this paper, but I don't
24 recall anything else more than that. This is
25 a paper that came out of my lab.

1 I was the corresponding author
2 of that paper, so -- and this was a recent
3 paper, so I was aware of the details of that
4 paper.

5 (BY MR. LEVINE)

6 Q. And, again, I'm asking -- if
7 you don't remember, you don't remember -- but
8 do you recall checking any other papers on
9 your CV in connection with forming your
10 opinion on FFT -- FFT techniques to analyze
11 the alignment of electrospun fibers?

12 MS. WIEKER: Objection to form.

13 A. I may have checked other
14 papers, but I don't remember.

15 (BY MR. LEVINE)

16 Q. Okay. Let me...

17 MR. LEVINE: Huh.

18 (BY MR. LEVINE)

19 Q. Dr. Mikos, are -- are you
20 certain testifying here today that Paper 537
21 reports an FFT analysis of electrospun
22 fibers?

23 MS. WIEKER: Objection to form.

24 A. Yes. 537 reports an FFT
25 analysis that was part of the ImageJ software

1 tool characterized the alignment of -- of
2 fibers that were produced by an
3 electrospinning technique.

4 (BY MR. LEVINE)

5 Q. And does it have a -- a graph
6 that has different peaks in it, to the best
7 of your recollection?

8 MS. WIEKER: Objection to form.

9 A. I'm not sure what you refer by
10 a graph with different peaks. What I recall
11 it has, it has histograms that were the
12 result of the FFT analysis that show the
13 number of fibers that were aligned at
14 specific angles with respect to a reference
15 that documents the extent of the alignment of
16 the electrospun fibers.

17 (Marked Mikos Exhibit No. 6.)

18 (BY MR. LEVINE)

19 Q. Let me show you the next
20 exhibit as Mikos Exhibit 6, a document
21 entitled "Modulation of anisotropy and
22 electrospun tissue-engineering scaffolds:
23 Analysis of fiber alignment by the fast
24 Fourier transform."

25 Dr. Mikos, have you seen this

1 document before?

2 A. I have not seen this document
3 in this format.

4 Q. When you say "in this format,"
5 I'm not sure I understand what you're saying.

6 A. This is a part of the copy
7 that's deposited to the NIH to be -- to show
8 that the receptors can have access to that
9 for free.

10 However, the same publication
11 is published in the general -- was submitted
12 in this particular case biomaterials. So
13 I've seen this, I mean, in the format of the
14 general.

15 Q. But you have seen the -- the
16 substance of this article, correct, just not
17 in this particular format?

18 A. Correct.

19 Q. And this is one of the articles
20 you reviewed for this case; is that right?

21 A. Let me check my...

22 Yes, it is the Exhibit No. 1013
23 of the '223 patent.

24 Q. And do you understand that this
25 is an article that came out of Dr. Simpson's

1 research group?

2 MS. WIEKER: Objection to form.

3 A. Dr. Simpson is a coauthor in
4 this publication and he's also listed as a
5 correspondent author.

6 (BY MR. LEVINE)

7 Q. Are you aware of any research
8 group analyzing the alignment of electrospun
9 tissue using FFT before Dr. Simpson's paper
10 in 2006?

11 MS. WIEKER: Objection to form.

12 A. I don't know.

13 (BY MR. LEVINE)

14 Q. Did you examine that question
15 in formulation of your opinions in this case?

16 MS. WIEKER: Objection to form.

17 A. No.

18 (BY MR. LEVINE)

19 Q. Would you consider Dr. Simpson
20 an expert in the analysis of electrospun
21 fibers for alignment using the FFT technique?

22 A. He certainly published articles
23 using FFT. Whether I would consider him an
24 expert or not, that's another issue.

25 Q. And why is that another issue?

1 A. What qualifies someone as an
2 expert?

3 Q. What qualifies someone as an
4 expert in your mind?

5 A. Extensive research in the
6 particular topic that's impacted the field.

7 Q. And would you agree that
8 Dr. Simpson has performed extensive research
9 on this topic in the field and therefore
10 he's -- would be considered an expert under
11 your own definition?

12 MS. WIEKER: Objection to form.

13 A. As I said earlier, he has
14 published some papers and obviously he's
15 aware of the technique.

16 Whether I would describe
17 someone as an expert, this is not something
18 that I was asked to opine. But I can
19 certainly say that he has published papers in
20 that area.

21 (BY MR. LEVINE)

22 Q. And do you recall if you,
23 yourself, have -- have cited Dr. Simpson in
24 any of your papers?

25 MS. WIEKER: Objection to form.

1 A. I don't recall. We might, "we"
2 meaning the students. And I may have cited
3 Dr. Simpson, but I don't recall.

4 MR. LEVINE: Okay. We've been
5 going for more than an hour. Is this
6 a good time for a break?

7 MS. WIEKER: Good by me.

8 THE WITNESS: Sure. Sure.
9 Thank you.

10 MR. LEVINE: Great.

11 THE VIDEOGRAPHER: Off the
12 record at 10:38 a.m.

13 (Break from 10:38 a.m. to 10:46 a.m.)

14 THE VIDEOGRAPHER: Back on the
15 record 10:46 a.m. Beginning Tape 2.

16 (BY MR. LEVINE)

17 Q. Dr. Mikos, at Paragraph 48 of
18 your declaration for the '223 patent,
19 Exhibit 1 --

20 A. What is the paragraph number
21 again?

22 Q. 48.

23 A. Yes.

24 Q. And do you see those graphs
25 that you've included in your expert report?

1 MS. WIEKER: Objection to form.

2 (BY MR. LEVINE)

3 Q. Under Paragraph 48.

4 A. Yes. I see those graphs, the
5 two graphs in Paragraph 48.

6 Q. Okay. How would you refer to
7 those graphs?

8 A. These were graphs that were
9 taken from one of the exhibits. This was a
10 paper by Ayres published in Journal
11 Biomaterial Science, Polymer Edition.

12 Q. And would you refer to them as
13 FFT alignment plots?

14 MS. WIEKER: Objection to form.

15 A. Again, Graphs F and I under
16 Paragraph 48, these would be the FFT
17 alignment plots.

18 (BY MR. LEVINE)

19 Q. And in Paragraph 50, you
20 have -- you incorporated figures 8A and 8B
21 from the '223 patent.

22 Do you see that?

23 A. Yeah. I see it's Figure 8A and
24 8B from the '223 patent under Paragraph 50.

25 Q. And would you refer to those as

1 FFT alignment plots as well?

2 A. Yes and no.

3 Q. Why -- why no?

4 A. Figure -- Figure 8A and

5 Figure 8B, at the bottom of each figure they
6 have a plot that is the FFT alignment plots.

7 However, at the top they have a
8 picture of the fibers themselves to the left.

9 And to the right they have what
10 is called the FFT frequency plot.

11 Q. So the graphs themselves in
12 Paragraph 50, would those be referred to as
13 FFT alignment plots?

14 MS. WIEKER: Objection to form.

15 A. Again, the graphs at the bottom
16 that refer to gray scale is a function of
17 degrees, these would be what I would call the
18 FFT alignment plots.

19 (BY MR. LEVINE)

20 Q. And do you recall in the
21 publication we were referring to early,
22 No. 537, do you recall if you had an FFT
23 alignment plot in that publication?

24 MS. WIEKER: Objection to form.

25 A. Which publication are you

1 referring to?

2 (BY MR. LEVINE)

3 Q. 537 in your CV, which was

4 Exhibit 5.

5 A. Yeah, let me make sure we refer

6 to the same publication. Yeah.

7 And your question is again?

8 Q. Is in that paper, did you have

9 an FFT alignment plot?

10 A. Similar to the one that appears

11 at the bottom of Figure 8A and Figure 8B?

12 Q. Yes, or the one that is under

13 Paragraph 48?

14 MS. WIEKER: Objection to form.

15 A. In that publication we had a

16 plot that was another way of presenting the

17 results of the FFT analysis. That was

18 essentially a histogram that presented the

19 alignment of fibers at different degrees from

20 the principal axis of alignment.

21 (BY MR. LEVINE)

22 Q. But you did not have an FFT

23 alignment plot of the sort under Paragraph 48

24 of your report or under graph -- under

25 Paragraph 50 of your report; is that correct?

1 A. We included another way that is
2 very well accepted in the literature of
3 presenting the alignment of fibers, something
4 that has been used also in the literature.

5 Q. You used -- you used a
6 histogram, correct?

7 A. It's an FFT histogram.

8 Q. Right. But not an alignment
9 plot, correct?

10 MS. WIEKER: Objection to form.

11 A. It depends what you call an
12 alignment form. One can call that histogram
13 also an alignment form plot.

14 (BY MR. LEVINE)

15 Q. But it -- but it is a different
16 form of showing alignment than the plots that
17 are, for example, under Paragraph 48 and
18 Paragraph 50 of your expert report, correct?

19 MS. WIEKER: Objection to form.

20 A. What we presented in the
21 article by Smoak, et al., was the results of
22 the FFT analysis in the form -- in the format
23 of a histogram that convey the information of
24 the alignment of fibers.

25

1 (BY MR. LEVINE)

2 Q. Okay. And do you recall if any
3 of your publications, ever, you provided an
4 alignment plot for the FFT that was of the
5 sort that is in paragraphs either 48 or
6 Paragraph 50 of your report?

7 MS. WIEKER: Objection to form.

8 A. I don't recall.

9 (BY MR. LEVINE)

10 Q. Let me ask you to turn to
11 exhibit --

12 MR. LEVINE: What exhibit was
13 this?

14 (Discussion off the record.)

15 (BY MR. LEVINE)

16 Q. -- Exhibit 6 which was the --
17 the paper by Dr. Simpson.

18 And if you can turn to Page 2
19 of that document, the last paragraph -- the
20 last paragraph before the section that says
21 "Materials and Methods" and the last two
22 sentences.

23 In this -- it says: "In this
24 study we used digital Bright-field and
25 cono -- confocal microscopy to capture images

1 of electrospun scaffolds and demonstrate the
2 use of the fast Fourier transform (FFT) to
3 measure fiber alignment in the scaffolds.
4 Our approach has several advantages. It is
5 rapid, nondestructive, and can be used to
6 rapidly integrate alignment data over a
7 relatively large area."

8 Do you agree with Dr. Simpson's
9 conclusion in this sentence that the
10 technique they described in this paper is
11 rapid, nondestructive, and can be used to
12 rapidly integrate alignment data over a
13 relatively large area?

14 MS. WIEKER: Objection to form.
15 (BY MR. LEVINE)

16 Q. You can answer.

17 A. I disagree with his statement
18 "nondestructive."

19 Q. And why do you disagree with
20 that statement?

21 A. The FFT analysis relies on an
22 image that is captured and analyzed. That
23 capture of the image is a destructive
24 technique.

25 Q. Why is it a destructive

1 technique?

2 A. So let's consider the case that
3 the image is from a sample that is examined
4 under scanning electron microscopy.

5 To examine a sample, a polymer
6 sample with scanning electron microscopy, one
7 would have to call to the sample with gold.
8 That process is destructive. It makes the
9 sample not usable for anything else after the
10 SEM analysis or the FFT analysis.

11 Q. Thank you for that answer.

12 So this sentence they're
13 talking about using a digital Bright-field
14 image.

15 Do you agree that capturing the
16 digital Bright-field image is not
17 destructive?

18 MS. WIEKER: Objection to form.
19 (BY MR. LEVINE)

20 Q. You can answer.

21 A. It uses digital Bright-field
22 and confocal microscopy. Confocal microscopy
23 may be destructive.

24 Q. When you say "may be
25 destructive," why do you -- why do you say

1 that?

2 A. It depends on the kind of
3 fluoro force [phonetic] that one is using to
4 image with confocal microscopy.

5 Q. Okay. Do you agree that using
6 a Bright-field image without using confocal
7 microscopy would not be destructive?

8 MS. WIEKER: Objection to form.
9 (BY MR. LEVINE)

10 Q. You can answer.

11 A. Using digital Bright-field
12 microscopy in the context of what, in the
13 context of capturing an image?

14 Q. Yes.

15 A. Unless contrast agents are
16 used, the optical -- the digital Bright-field
17 microscopy may be nondestructive.

18 (Discussion off the record.)

19 (BY MR. LEVINE)

20 Q. And can FFT analysis be done on
21 a Bright-field image?

22 A. It can. The question is how
23 accurate it is.

24 Q. So do you have an understanding
25 why Dr. Simpson wrote in his paper that the

1 approach described herein is nondestructive?

2 MS. WIEKER: Objection to form.

3 (BY MR. LEVINE)

4 Q. You can answer.

5 A. I have no idea.

6 Q. Again, sitting here today, you
7 disagree with that statement that he wrote in
8 his paper?

9 MS. WIEKER: Objection to form.

10 A. I disagree that this statement
11 cannot be applied in all circumstances.

12 (BY MR. LEVINE)

13 Q. And you testified that an
14 electron, to generate an electron scanning --
15 scanning microscopy image, that is
16 destructive because it's the -- you use gold
17 to coat the sample; is that right?

18 MS. WIEKER: Objection to form.

19 A. Scanning electron microscopy in
20 principle examines surfaces that are
21 electrically conductive.

22 If the material is not
23 electrically conductive, which is the case of
24 polymers, the specimen is coated by a
25 material that is electrically conductive.

1 Gold is the most common
2 material that is used for coating. Platinum
3 is another type of material, et cetera, but
4 gold is the most common one.

5 (BY MR. LEVINE)

6 Q. All right. And that results in
7 the sample not being usable afterwards,
8 correct?

9 A. Correct.

10 (Marked Mikos Exhibit No. 7.)

11 (BY MR. LEVINE)

12 Q. Let me show you what has been
13 marked as Mikos Exhibit 7, a document bearing
14 the title "Measuring fiber alignment in
15 electrospun scaffolds: A user guide to the 2D
16 fast Fourier transform approach."

17 MS. WIEKER: Thank you.

18 (BY MR. LEVINE)

19 Q. Dr. Mikos, have you reviewed
20 this paper before?

21 A. Yes, I did.

22 Q. Okay. When is the first time
23 you reviewed this paper?

24 A. I reviewed this paper obviously
25 for this case. I don't recall if I have

1 seen -- if I have reviewed this paper before.
2 I should say, as stated in my CV, that I'm
3 part of the editorial board of the Journal of
4 Biomaterials Science, Polymer Edition.

5 (Discussion off the record.)

6 A. I am part of the editorial
7 board of the Journal of Biomaterials Science,
8 Polymer Edition.

9 And being a member of the
10 editorial board, I receive copies of the
11 journals when they are published. It's my
12 habit, whenever I get these issues, to go
13 through them and read the title in the
14 abstract.

15 So I may have seen it before,
16 but I reviewed it extensively for this case.

17 (BY MR. LEVINE)

18 Q. And is -- if you can turn to
19 Exhibit 1, which is your declaration on the
20 '223 patent, Paragraph 45, which we were
21 discussing before.

22 MS. WIEKER: Howard, you said
23 Paragraph 45?

24 MR. LEVINE: Paragraph 45.

25 MS. WIEKER: Thank you.

1 (BY MR. LEVINE)

2 Q. Is this the paper that you
3 refer to in Paragraph 45?

4 A. Yes.

5 Q. And if you can turn to
6 Exhibit 3, which is the '223 patent, and if
7 you can turn to Column 13, Line 18, is this
8 the paper that you refer to as being
9 incorporated by the '223 patent?

10 A. Yes.

11 Q. And I -- I think you testified,
12 and correct me if I'm wrong, that you
13 reviewed this paper extensively in connection
14 with your opinions in this case; is that
15 right?

16 A. I reviewed this paper very
17 carefully, yes.

18 Q. Let me ask you just -- I'm
19 going to ask you some more questions about
20 Exhibit 7, but if I could go back to
21 Exhibit 1, which is your declaration. In
22 Paragraph 54, you say pendant -- strike that.

23 You say: "Independent claim 1
24 recites a fast Fourier transform (FFT)
25 analysis results of the fibers have adjacent

1 peaks -- have adjacent major peaks with about
2 180 degrees apart from each other.

3 "A POSITA would understand the
4 definition and meaning of the term 'major
5 peaks' is provided in the '223 patent
6 itself."

7 And then you have a quote:

8 "The major peaks herein refers -- refer to
9 peaks higher than the average of the peaks in
10 the result."

11 Do you see that?

12 A. Yes.

13 Q. Okay. And is it correct, then,
14 in Paragraph 56 of your report, you determine
15 what the average of the peaks is reported in
16 Figure 8A; is that correct?

17 A. Yes.

18 Q. And you do that to determine
19 whether there are major peaks in Figure 8A
20 that are about 180 degrees apart from each
21 other; is that correct?

22 A. Yes.

23 Q. And you determine -- strike
24 that.

25 In Figure 8A, can you identify

1 the peaks that you relied on in making your
2 calculation in Paragraph 56?

3 MS. WIEKER: Objection to form.

4 A. In Figure 8A, at the bottom of
5 the figure, we have a graph of gray value
6 versus degrees. Degrees spanning from 0 to
7 360 degrees.

8 In that interval, I identify
9 four peaks: one at 0 degrees, one at
10 90 degrees, one at 180 degrees, and one at
11 270 degrees.

12 The peaks at 90 and
13 270 degrees, as stated in my report, have
14 heights approximately 95,000 units and,
15 again, according to the report, the peak's at
16 0 and 180 degrees with heights approximately
17 75,000. Therefore, the average of the four
18 is 85,000.

19 (BY MR. LEVINE)

20 Q. And is it all right if I refer
21 to the peak at 0 as Peak 1, the peak at 90 as
22 Peak 2, the peak at 180 as Peak 3, and the
23 peak at 270 as Peak 4?

24 A. They are not identified like
25 that in the report. But I think you may.

3 At around Line 36 -- at around
4 360 degrees, you see how the line at the end
5 of the -- of the alignment plot starts to go
6 up.

7 Is there a reason you didn't
8 include that as a peak?

9 MS. WIEKER: Objection to form.

10 A. Again, we're looking at
11 Figure 8A at the bottom --

12 (BY MR. LEVINE)

13	Q.	Yes.
----	----	------

14 A. -- of the graph of gray value
15 versus degrees?

16 It is my understanding and my
17 experience that what appears at 0 degrees
18 would appear at 360 degrees. So this is
19 considered the same peak that I refer to at
20 0 degrees.

21 Q. That calculation that you just
22 performed, is that calculation in the
23 '223 patent itself, which is Exhibit 3?

24 A. I would have to refresh my
25 memory.

1 I would have to read the patent
2 if you want a definite answer.

3 Do you want to do that?

4 Q. Yes. Yes.

5 A. This was my calculation.

6 Q. So it's not in the patent?

7 A. The calculation is not in the
8 patent, but based on the information included
9 in the patent, I calculated the average.

10 Q. And does the patent actually
11 assign values to the -- to four peaks?

12 A. It's very easy to get the
13 values for the four peaks based on the graph.
14 The graph is very clear. We're talking about
15 the bottom of Figure 8A.

16 So one can easily determine
17 approximate values of the gray value for the
18 different degrees.

19 Q. Okay. But the patent itself in
20 the text doesn't say what those peaks are,
21 correct?

22 MS. WIEKER: Objection to form.

23 A. Figure 8A, again, the bottom of
24 that figure, is the result of the FFT
25 analysis.

1 A person of skill in the art
2 would be able to -- by seeing the graph to
3 determine those values and do those
4 calculations.

5 (BY MR. LEVINE)

6 Q. But -- but to the extent that
7 you carefully reviewed the patent and just
8 looked at it again, you didn't see those
9 calculations in the patent itself, correct?

10 MS. WIEKER: Objection; asked
11 and answered.

12 A. Again, as I said earlier, a
13 person of skill in the art would have been
14 able by seeing these values in Figure 8A in
15 the bottom of the '223 patent to come up with
16 these numbers and calculate this average over
17 the four peaks shown here.

18 (BY MR. LEVINE)

19 Q. And in terms of Figure 8B,
20 which I think you're looking at on
21 Paragraph 50, did you assign values to those
22 peaks as well?

23 MS. WIEKER: Objection to form.

24 A. I don't think I assigned values
25 or calculated the average of the four peaks

1 shown at the bottom of Figure 8B. I may be
2 wrong, but, looking at the report, I don't
3 see those values.

4 (Reporter clarification.)

5 (BY MR. LEVINE)

6 Q. Okay. Do you agree that there
7 are also four peaks in Figure 8B?

8 A. Again, looking at Figure 8B at
9 the bottom, gray value versus degrees from 0
10 to 360 degrees, I see four peaks.

11 Q. Okay. And is it correct that
12 that first peak is about 90,000?

13 MS. WIEKER: Objection to form.

14 (BY MR. LEVINE)

15 Q. You can answer.

16 A. First peak would be between
17 nine -- 90,000 and ninety- -- to 93000.

18 Q. Does it extend beyond the
19 90,000 line?

20 MS. WIEKER: Objection to form.

21 A. The image is not very crisp.
22 So I can see it goes to 90,000. Whether it
23 goes to 92,000 or 93,000, I cannot say with
24 certainty. But clearly it goes up to 90,000.

25

1 (BY MR. LEVINE)

2 Q. And consistent with your
3 opinions in Paragraph 56, would Peak 2 and 4
4 be approximately 95,000 units?

5 MS. WIEKER: Objection to form.

6 (BY MR. LEVINE)

7 Q. You can answer.

8 A. Again, peaks at approximately
9 90 degrees and peak approximately 270 degrees
10 would be about 94,000, 95,000 gray value,
11 again, looking at the bottom of Figure 8B.

12 Q. And the third peak that goes
13 about halfway, would you say that one is
14 about 92,500?

15 MS. WIEKER: Objection to form.

16 (BY MR. LEVINE)

17 Q. You can answer.

18 A. I cannot clearly see where it
19 goes, because I wanted to see it at
20 360 degrees. But the line, I think, is cut
21 at 350, so I'm not sure where it ends at
22 300 degrees -- 360 degrees.

23 Q. So I was referring to the --
24 the peak between Peaks 2 and 4 at around
25 180 degrees.

1 And would you agree that peak
2 goes to about 92,500 --

3 MS. WIEKER: Objection to form.

4 (BY MR. LEVINE)

5 Q. -- on the gray -- the gray
6 value?

7 MS. WIEKER: Howard, just for
8 clarity, I think you established the
9 Peaks 1, 2, 3, and 4 on Figure 8A.

10 Are you intending those to also
11 apply to Figure 8B?

12 MR. LEVINE: Sure.

13 MS. WIEKER: Do you want to
14 just maybe identify --

15 MR. LEVINE: Yeah, if that's
16 helpful.

17 MS. WIEKER: -- what each one
18 is?

19 MR. LEVINE: Yeah.

20 (BY MR. LEVINE)

21 Q. So I think we referred to the
22 Peak 1 as 90,000. Peak 2 --

23 MS. WIEKER: In terms of the
24 degrees on the X-AXIS, that might be
25 the most clear way to identify it.

1 MR. LEVINE: Okay.

2 (BY MR. LEVINE)

3 Q. So Peak 1 is at 0 degrees.

4 And, Dr. Mikos, correct me if I'm wrong about
5 that.

6 A. I suggest that since I don't
7 have it marked right here, can we refer to
8 the degrees of the peaks?

9 Q. Sure.

10 A. Those degrees.

11 Q. Sure. That's easy.

12 So the peak at 0 degrees we
13 refer to as 90,000.

14 MS. WIEKER: Objection to form.

15 Mischaracterizes.

16 (BY MR. LEVINE)

17 Q. The peak at -- at 90 degrees we
18 referred to between 94- and 95,000 and the
19 same thing with the peak --

20 MS. WIEKER: Objection to form.

21 (BY MR. LEVINE)

22 Q. -- at 270 degrees.

23 MS. WIEKER: Objection to form.

24 (BY MR. LEVINE)

25 Q. So my -- I guess so those are

1 three of the four peaks.

2 And my last question was: The
3 peak at 180 degrees, is that about -- it
4 looks to be about halfway, about 92,500, on
5 the -- on the gray value?

6 MS. WIEKER: Objection to form.

7 A. Again, looking at Figure 8B, at
8 the bottom of Figure 8B, the graph of gray
9 value versus degrees, when I look at
10 180 degrees, the peak value is about 92,000,
11 93,000.

12 Again, without measuring that,
13 it's hard to say. But with my eyes, it's
14 about 92,500. That's my estimate.

15 The peak at 0 degrees, it's --
16 I can clearly say it's above 90,000. Whether
17 it's 91,000, 92,000, 93,000, I cannot tell
18 because it's -- the reproduction does not
19 allow me to do so.

20 The peaks at 90 degrees, again,
21 the same figure, it's below 95,000.

22 The one at nine -- 270 degrees,
23 it's about 95,000.

24 (BY MR. LEVINE)

25 Q. Okay. So there is some

1 difficulty in peaking -- picking the exact
2 values of these peaks, correct?

3 A. Just by looking at the graph as
4 it appears in the patent, again, recognizing
5 that it's -- the reproduction is not very
6 clear, the best that one can do is
7 guesstimate.

8 Q. And presumably the inventors
9 had a better image than the reproduction in
10 the patent, correct?

11 MS. WIEKER: Objection to form.

12 A. I assume the -- that's a valid
13 assumption. I cannot speak for the
14 inventors, but I would say yes.

15 (BY MR. LEVINE)

16 Q. So it would have been somewhat
17 easier for them to assign peaks looking at
18 the original image, right?

19 MS. WIEKER: Objection to form.

20 A. It's very hypothetical.

21 (BY MR. LEVINE)

22 Q. And just to be clear, you did
23 not perform your analysis in which you
24 averaged, assigned numerical values to the
25 peak and created an average to Figure 8B, you

1 only did it to Figure 8A, correct?

2 A. That is correct.

3 Q. And if we can turn to -- back
4 to the Ayres paper Exhibit 7.

5 Dr. Mikos, is it acceptable if
6 I refer to this as Ayres 2008? Will you know
7 what I'm referring to?

8 A. Yes.

9 Q. And as I understand it, you
10 reviewed this paper very carefully in
11 preparation for your opinions in this case;
12 is that right?

13 A. Yes.

14 Q. In the Ayres 2008 paper, do
15 they assign numerical values to peaks to
16 calculate an average to then determine
17 whether peaks are major peaks above that
18 average?

19 MS. WIEKER: Objection to form.

20 A. Assign values to peaks, which
21 peak are you referring to?

22 (BY MR. LEVINE)

23 Q. I'm just asking if in the
24 entirety of the paper that you reviewed, do
25 they essentially do the analysis that you

1 describe doing in Paragraph 56 of your
2 report?

3 A. Again, you're referring to
4 peaks that appear in Figure 1 in Images C, F,
5 and I?

6 Q. Or in Figures M and N in
7 Figure 3.

8 A. I don't recall that.

9 I think they make a statement
10 about peaks being higher when they compare
11 the F and I, but I don't recall assigning
12 values.

13 Q. Let me ask you to turn to
14 Page 614 of the Ayres 2008.

15 A. 6004?

16 Q. 614.

17 A. 1-4. Yes.

18 Q. And do you see there is a --
19 a -- alignment plot for exhibit -- for
20 Figure M [verbatim]?

21 MS. WIEKER: Objection to form.

22 A. Figure 3M?

23 (BY MR. LEVINE)

24 Q. Figure 3M.

25 Is it correct that's an

1 alignment plot?

2 A. That's an alignment plot, yes.

3 Q. And do you see there in that
4 Figure 3M alignment plot there is a -- a blue
5 trace and a red trace right under that.

6 Do you see that?

7 A. Can you repeat, I'm sorry?

8 Q. Sure. In Figure 3M --

9 A. Yes.

10 Q. -- do you see there is a -- a
11 blue trace?

12 A. I cannot hear you. What trace?

13 Q. A blue.

14 A. A blue. Okay, yes.

15 Q. Color blue.

16 A. The one at the bottom, yes.

17 Q. And there's also -- and that
18 blue trace refers to in the legend vertical
19 aligned fibers FFT peaks at 90 and 270.

20 Do you see that?

21 A. Yes.

22 Q. Okay. And right below that
23 blue trace, there is a red trace that says
24 vertical aligned wavy PPT [verbatim] peaks at
25 90 and 270.

1 Do you see that?

2 A. Yes.

3 Q. And do you have an
4 understanding that the blue trace corresponds
5 to Figure 3G and that the red trace
6 corresponds to Figure 3E?

7 MS. WIEKER: Objection to form.

8 A. Again, we are in 3M?

9 (BY MR. LEVINE)

10 Q. Yes.

11 A. And you're asking whether the
12 blue corresponds to 3G?

13 Q. Yes.

14 A. And the red corresponds to?

15 Q. 3E.

16 A. Yes. Okay.

17 Q. Okay. And if you turn to
18 the -- the -- the bottom of that page, the
19 last sentence where they're describing a --
20 some of these figures, it says: "A field of
21 aligned slightly undulating fibers which more
22 closely resembles the fibers of an aligned
23 electron scaffold (Figure 3E) produces high
24 frequency pixels that are preferentially
25 distributed along the vertical axis of the

1 frequency plot once the plot has been rotated
2 90 degrees (Figure 3F)."

3 Then it says: "The 3D FFT
4 alignment plot of this scaffold (Figure 3M)
5 vertical aligned wavy plot contains distinct
6 peaks at 90 and 270 degrees 2D, FFT alignment
7 value of 0.06 units, and much smaller peaks
8 at 180 and 360 2D, FFT alignment value of
9 0.02 units."

10 Then it says: "The larger
11 peaks report the principal axis of alignment
12 while the smaller peaks correspond to
13 background information, noise, and edge
14 effects."

15 Sitting here today, do you have
16 any reason to disagree with Dr. Simpson's
17 statement that the smaller peaks correspond
18 to background information, noise, and edge
19 effects?

20 MS. WIEKER: Objection to form.

21 A. Well, these results are --
22 compares to particular types of
23 configurations. I wouldn't call them fibers.

24 My understanding is that they
25 are made of spaghetti, being some model

1 materials, and the data are what they are.

2 I would not extrapolate that
3 statement to general analysis of electrospun
4 fibers because the FFT analysis -- the FFT
5 alignment, that contains major peaks as
6 defined in the '223 patent and minor peaks.

7 My understanding is that the
8 major peaks, again, as defined in the
9 '223 patent, correspond to the alignment
10 fibers along the primary axis of alignment,
11 where the minor peaks correspond to
12 another -- a secondary axis of alignment.

13 I would not classify them in
14 general as noise or edge effects.

15 (BY MR. LEVINE)

16 Q. So -- so --

17 A. Which exhibit are we now?

18 Q. I haven't asked a question yet.

19 If we could look back at
20 exhibit -- I'm -- I'm going to go back to
21 Ayres but let's go to Exhibit 1, which is
22 your expert declaration, Paragraph 55.

23 And I -- and I'm doing this
24 because I think you just offered some
25 testimony about this figure and I just -- I

1 want to make sure I understand it.

2 So we had identified the peaks
3 before as 1, 2, 3, 4.

4 So Peaks 1 and 3, the peaks at
5 0 and 180, is it your understanding that
6 those peaks represent fibers of a different
7 alignment than the peaks at 2 and 4?

8 MS. WIEKER: Objection to form.

9 A. Again, for clarification we're
10 comparing peaks at 0 degrees and 180 degrees
11 in Figure 8A the bottom gray value versus
12 degrees to the peaks at 90 degrees and
13 270 degrees.

14 So my opinion, as stated in the
15 report, is that the peaks at 90 and 270 are
16 what are defined in the '223 patent as the
17 major peaks, and the peaks at 0 and
18 180 degrees would be peaks of lower height or
19 minor peaks.

20 (BY MR. LEVINE)

21 Q. Okay. And so in Ayres 2008,
22 when we were reading, Dr. Simpson said that
23 those smaller peaks correspond to background
24 information, noise, and edge effects and
25 I'm -- my question is, are those peaks that

1 you just identified at 0 and 180, do you
2 agree or disagree that those peaks correspond
3 to background information, noise, and/or edge
4 effects?

5 A. I disagree.

6 Q. Okay. And why do you disagree?

7 A. Because these peaks may
8 represent a secondary axis of alignment of
9 fibers and I would not call aligned fibers
10 along a secondary axis of alignment as noise
11 or edge effects.

12 Q. Could the -- could those peaks
13 represent noise or edge effects?

14 MS. WIEKER: Objection to form.

15 A. This is very hypothetical.

16 (BY MR. LEVINE)

17 Q. But your opinion, sitting here
18 today, looking at all the -- the data that
19 you reviewed, is that the peaks at 0 and 180,
20 you believe represent a secondary axis of
21 alignment; is that correct?

22 A. Yes, especially when I see the
23 top left image of the figures, Figure 8A top
24 left.

25 Q. So let me -- let me ask you a

1 question.

2 If the fibers were perfectly
3 aligned and those two peaks were not there
4 because the fibers were perfectly aligned and
5 you just had the peaks at 90 degrees and
6 270 degrees, would you consider those two
7 peaks major peaks?

8 MS. WIEKER: Objection to form.

9 A. If I had two peaks between 0
10 and 360 degrees and the two peaks had the
11 same height, I would not consider those as
12 major peaks, according to the definition of
13 major peaks in the '223 patent.

14 (BY MR. LEVINE)

15 Q. So in your opinion, the
16 definition of major peaks in a '223 patent
17 requires the presence of fibers that have a
18 secondary alignment from the major peaks; is
19 that correct?

20 MS. WIEKER: Objection to form.

21 A. Not necessarily. This is not
22 part of the definition.

23 (BY MR. LEVINE)

24 Q. But if those peaks weren't
25 there, it would not fall within your

1 definition, correct?

2 MS. WIEKER: Objection to form.

3 A. Can you clarify which peaks

4 were not there?

5 (BY MR. LEVINE)

6 Q. If the peaks representing

7 secondary alignment were not present in the

8 alignment plot, then that would not meet your

9 definition, correct?

10 MS. WIEKER: Objection to form.

11 A. Again, as I said earlier, if

12 there were only two peaks between 0 and

13 360 degrees and the two peaks had the same

14 height, I wouldn't classify them as major

15 peaks according to the definition of the

16 major peaks.

17 (BY MR. LEVINE)

18 Q. And hypothetical, if that

19 alignment plot had two -- only two major

20 peaks of the same height but also had some

21 smaller noise peaks, then, as I understand

22 it, under your definition, that could be --

23 those two peaks could be considered major

24 peaks because there would be other smaller

25 peaks that would lower the average and those

1 major peaks would be above the average; is
2 that right?

3 MS. WIEKER: Objection to form.

4 Mischaracterizes.

5 (BY MR. LEVINE)

6 Q. You can answer.

7 A. Yeah, that's a question that
8 includes statements that are not accurate.

9 First statement, any spikes
10 that are part of noise, I would not consider
11 those peaks.

12 Q. And how would you know if those
13 spikes were due to noise or due to the
14 presence of a secondary alignment?

15 MS. WIEKER: Objection to form.

16 A. In any signal, I can understand
17 what constitutes noise and what constitutes a
18 real signal by simply examining the
19 signal-to-noise ratio.

20 (BY MR. LEVINE)

21 Q. So let me -- let me -- let me
22 ask you a question that's a little less
23 hypothetical. If you look at Ayres Page 614
24 that we were looking at before, and I would
25 like to ask you to take a look at Figure N,

1 as in "Nancy."

2 A. Yes, Figure 3N.

3 Q. Figure 3N.

4 A. Yes.

5 Q. On Page 1 -- on Page 614.

6 And do you understand that the
7 blue and the red traces in Figure 3N
8 correspond to the images at Figures 3I and
9 Figures 3K?

10 A. That's my understanding.

11 Q. And if you look at the
12 description under Figure 3, the
13 second-to-last sentence says: "2D FFT
14 alignment plots before and after removing
15 edge effects from the image depicted in
16 Panels I to L, arrows denote edge noise
17 effects. This figure is published in color."
18 And it gives a web address.

19 I guess my first question is:
20 Do you agree with Dr. Simpson that the peaks
21 identified by the arrows are -- in the blue
22 trace are noise effects?

23 MS. WIEKER: Objection to form.

24 A. Again, if I see the blue line
25 in isolation, what appears to be a peak that

1 an arrow points to, I would not consider that
2 noise.

3 For me, the noise is that
4 movement of the line up and down with equal
5 probability going up and down.

6 This, to me, at the arrow
7 points appears to be a peak.

8 (BY MR. LEVINE)

9 Q. Okay. And if you -- you look
10 at the Images 3I and 3K, does that help
11 inform your opinion as to whether the -- the
12 shapes identified by the arrows are peaks or
13 noise?

14 MS. WIEKER: Objection to form.

15 A. Looking at the Images I and K
16 of Figure 3, the only thing that I can see is
17 some aligned fibers with the presence of a
18 mask in K compared to I. That's the only
19 thing I see.

20 (BY MR. LEVINE)

21 Q. Okay. Is it correct that the
22 blue trace, the blue line, would fall within
23 your definition of having two major peaks?

24 MS. WIEKER: Objection to form.

25

1 (BY MR. LEVINE)

2 Q. You can answer.

3 A. I would have to calculate how
4 much is the average. And if the peaks at
5 45 degrees and 225 degrees are above the
6 average, they will be classified as major
7 peaks.

8 Q. Okay. And is it correct that
9 under your analysis, the red trace would not
10 have two major peaks?

11 MS. WIEKER: Objection to form.

12 (BY MR. LEVINE)

13 Q. You can answer.

14 A. If the heights at 45 degrees
15 and 225 degrees of the red trace are the
16 same, these would not be classified as major
17 peaks.

18 Q. But isn't it correct that
19 it's -- that both the red and the blue are
20 analyzing the same scaffold?

21 MS. WIEKER: Objection to form.

22 A. The scaffold is the same. The
23 analysis is different.

24 (BY MR. LEVINE)

25 Q. Can you turn back to Exhibit 6,

1 which is the other Ayres-Simpson paper.

2 And I understand that you
3 reviewed this paper very carefully as well,
4 correct?

5 A. Yes, in a different format.

6 Q. A different format.

7 Did this paper assign numerical
8 values to peaks in an alignment plot and then
9 calculate an average to determine if there
10 were major peaks?

11 MS. WIEKER: Objection to form.

12 A. I don't recall, but I will be
13 glad to review the paper again and answer
14 your question.

15 (BY MR. LEVINE)

16 Q. Sure.

17 A. Okay.

18 I see here in Section 3.3 of
19 the results titled "Fiber alignment in
20 scaffold anisotropy is judged by FFT," the
21 authors assign values to the peaks that are
22 reported in the -- in Figure 3.

23 Q. So the authors assign values to
24 the peaks, but do they calculate an average
25 to determine whether peaks are major or not

1 major?

2 MS. WIEKER: Objection to form.

3 A. I didn't see, again, in
4 Section 3.3, the calculation of any average
5 of peaks any peaks.

6 (BY MR. LEVINE)

7 Q. You can put that down. I have
8 no more questions about it.

9 When we were discussing FFT
10 analysis, have you done any FFT analysis in
11 connection with this case?

12 A. No.

13 Q. Have any of people working at
14 your direction performed any FFT analysis in
15 connection with this case?

16 MS. WIEKER: Objection to form.

17 A. In connection with this case,
18 no.

19 (BY MR. LEVINE)

20 Q. Is there a reason why you
21 didn't perform your own FFT analysis on some
22 of the issues that have arisen in this case?

23 A. I was not asked to do an FFT
24 analysis. I was asked to offer technical
25 opinion about some of the results in some of

1 the documents that were presented to me.

2 (Marked Mikos Exhibit No. 8.)

3 MS. WIEKER: Howard, we've been
4 getting -- we've been about an
5 hour-15. If there's a good lunch
6 foreseeable --

7 MR. LEVINE: Yeah, this is a
8 good time for a break.

9 MS. WIEKER: -- well, it -- I'm
10 not trying to rush you.

11 MR. LEVINE: No, no, not all.

12 MS. WIEKER: I'm just saying if
13 there's a good window.

14 MR. LEVINE: Is this a good
15 time for a break for you, Dr. Mikos?

16 THE WITNESS: That's fine.

17 MR. LEVINE: Yeah, let's --
18 let's break for lunch. That's fine.

19 MS. WIEKER: Okay.

20 THE VIDEOGRAPHER: Off the
21 record at 11:59 a.m.

22 (Break from 11:59 a.m. to 12:31 p.m.)

23 THE VIDEOGRAPHER: Back on the
24 record 12:31 p.m. Beginning Tape 3.

1 (BY MR. LEVINE)

2 Q. Good afternoon, Dr. Mikos.

3 A. Good afternoon.

4 Q. Let me show you what's been
5 marked as Mikos Exhibit 8, a document with a
6 title "Electrospun collagen-chitosan-TPU
7 nanofibrous scaffolds for tissue-engineered
8 tubular grafts."

9 Oh, could I have that one back?

10 I did it again.

11 (Discussion off the record.)

12 MR. LEVINE: There you go.

13 MS. WIEKER: Thank you.

14 (BY MR. LEVINE)

15 Q. Dr. Mikos, have you reviewed
16 this paper before?

17 A. Yes.

18 Q. Is this one of the papers you
19 reviewed in forming your opinions in this
20 case?

21 A. Yes.

22 Q. If I can turn you to Page 309
23 of the paper, there's a paragraph on the
24 right-hand column before the section that
25 says 3.2, Fourier transform infrared

1 spectroscopy. Starts with "The aim of..."

2 Do you see that?

3 A. No.

4 Q. Sure.

5 A. Page 309?

6 Q. 309. Right-hand column.

7 A. Which paragraph?

8 Q. It's the paragraph right before

9 Section 3.2. Starts with --

10 A. Okay. Yes.

11 Q. It says: "With the aim of
12 measuring fiber alignment, a two-dimensional
13 fast Fourier transform (2D FFT) approach
14 described by Ayres, et al. [25] was adapted."

15 And if you look at
16 Reference 25, is that the Ayres 2008 paper
17 that we were discussing earlier in the
18 deposition?

19 A. Yes. The one published in the
20 Journal of Biomaterial Science, Polymer
21 Edition.

22 Q. I think you said you were an
23 editor on the Journal of Biomaterial Science;
24 is that right?

25 A. No. I'm a member of the

1 editorial board of the Journal of Biomaterial
2 Science, Polymer Edition.

3 (Reporter clarification.)

4 A. I'm a member of the editorial
5 board of the Journal of Biomaterials Science,
6 Polymer Edition.

7 (BY MR. LEVINE)

8 Q. And what's the difference
9 between -- between being an editor on the
10 journal and being a member of the editorial
11 board?

12 A. The editor of the journal is
13 responsible for the peer review of
14 manuscripts submitted to the journal.

15 The editorial board assists the
16 editor with peer review of manuscripts and
17 other issues that the editor may seek
18 guidance.

19 Q. Is that journal considered a
20 highly reputable journal in the field?

21 A. It is one of the high reputable
22 journals in the field.

23 Q. Okay. If we you go back to
24 Page 309, it says: "In brief, quadrate
25 region was captured from SEM images Figures

1 4A and B."

2 Do you understand SEM refers to
3 scanning electron microscopy?

4 A. Yes.

5 Q. "And then analyzed with Image J
6 software to create corresponding frequency
7 plots and 2D FFT alignment plots. The two
8 peaks at 175 and 355 degrees in Figure 4E
9 show that with a rotation speed of 4,000
10 rotations per minute, pure TPU nanofibers
11 were highly arrayed along one direction."

12 And if you can turn to the next
13 page -- well, actually Page 311, under
14 Figure 4E, is it your understanding that's
15 the figure that was referred to in the text I
16 just read?

17 A. Yes.

18 Q. And the authors concluded that
19 those nanofibers were highly arrayed along
20 one direction; is that right?

21 A. What are you reading?

22 Q. The text on 309 in Figure 4E
23 show that with a rotation speed of 4,000
24 revolutions per minute, pure TPU nanofibers
25 were highly arrayed along one direction.

1 A. Yes.

2 Q. And is it correct that in
3 Figure 4E the authors identify two peaks, one
4 at 175 and one at 355?

5 A. Again, that's in Figure 4E, the
6 FFT alignment shows three peaks -- I'm
7 sorry -- shows two peaks between 0 and
8 360 degrees.

9 Q. And is that because the peak at
10 around 0 is the same as the peak around 355
11 for the reasons you discussed before in your
12 testimony?

13 MS. WIEKER: Objection to form.
14 (BY MR. LEVINE)

15 Q. You can answer.

16 A. Yes, there are two peaks
17 between 0 and 360.

18 Q. Under your definition of major
19 peaks, would there be two major peaks
20 180 degrees in Figure 4E?

21 MS. WIEKER: Objection to form.
22 (BY MR. LEVINE)

23 Q. You can answer.

24 A. Again, based on the definition
25 of major peaks in the '223 patent that is the

1 height of the peak should be higher than the
2 average of all peaks.

3 I would not classify these two
4 peaks as major peaks because the height of
5 the peaks is the same, so the average would
6 be equal to the value of the height of the
7 peaks.

8 So the peaks -- the height of
9 these peaks would not be higher than that of
10 the average.

11 Q. So is it correct that although
12 the authors of this paper found that the
13 fibers were highly aligned, it would not
14 satisfy your definition of having two major
15 peaks?

16 MS. WIEKER: Objection to form.

17 A. The result of the FFT analysis
18 can produce two peaks or four peaks between 0
19 and 360 degrees.

20 Having two peaks of the same
21 height is the result of highly aligned fibers
22 even though the peaks -- the two peaks of the
23 same height may not qualify as major peaks.

24 In the case of four peaks
25 between 0 and 360 degrees, again, I'm

1 referring to the result of the FFT analysis,
2 if two peaks have height higher than that of
3 the average of the four peaks, that would
4 designate that the fibers are highly aligned.

5 (BY MR. LEVINE)

6 Q. In -- in your understanding
7 of -- of this paper, did the authors assign
8 numerical values to the two peaks and perform
9 an average?

10 MS. WIEKER: Objection to form.

11 (BY MR. LEVINE)

12 Q. You can answer.

13 A. I don't recall this being the
14 case, but I'll be glad to review the
15 manuscript and tell you if they assign
16 numbers and calculated the average.

17 Q. Yes, please.

18 A. I don't see any values assigned
19 to those two peaks in the Figure 4E.

20 Q. Okay. Sitting -- sitting here
21 today, do you recall any of the publications
22 you reviewed in preparation for opinions in
23 this case that conducted the analysis you
24 have in Paragraph 56 of your declaration?

25 MS. WIEKER: Objection to form.

1 A. The analysis you refer to
2 calculating the average of the peaks, I do
3 not recall and I don't cite in my report any
4 other publications.

5 I may have seen it, but as I'm
6 sitting here I don't recall any other
7 publication.

8 (BY MR. LEVINE)

9 Q. You can put that one down,
10 the -- well, you already did. It's okay.

11 Let me mark as the next exhibit
12 Mikos Exhibit 9.

13 (Marked Mikos Exhibit No. 9.)

14 (BY MR. LEVINE)

15 Q. Paper entitled "The Involvement
16 of Integrin Beta 1 Signaling and the
17 Migration and Myofibroblastic Differentiation
18 of Skin Fiber Blasts on Anisotropic
19 Collagen-Containing Nanofibers."

20 MS. WIEKER: Thank you.

21 (BY MR. LEVINE)

22 Q. Dr. Mikos, have you reviewed
23 this paper in preparation of your opinions in
24 this case?

25 A. Yes.

1 Q. And is this the paper that's
2 referred to as Huang2 in your declaration,
3 for example, at Paragraphs 61 through 68, for
4 example?

5 A. Yeah, this is the Huang2
6 reference.

7 Q. At Paragraph 64 of your report
8 in Exhibit 1, you state that Huang2 discloses
9 that FFT analysis was performed on aligned
10 and random fibers.

11 Do you see that?

12 A. Yes.

13 Q. Is it your opinion that Huang2
14 was able to get aligned electrospun fibers?

15 A. Yes.

16 Q. And what's your basis for your
17 opinion that Huang2 was actually able to
18 obtain aligned electrospun fibers?

19 MS. WIEKER: Objection to form.

20 (BY MR. LEVINE)

21 Q. You can answer.

22 A. Looking at Exhibit 9, Page 1793
23 looking at Figure 1B, I see a scanning
24 electromicrograph for what is referred to as
25 anisotropic electrospun nanofibers matrices

1 and in my opinion this would be the result
2 for aligned electrospun fibers.

3 Q. And is it correct that Huang --
4 Huang2's electrospun fibers contained a blend
5 solution of collagen and PCL?

6 MS. WIEKER: Objection to form.

7 A. Again, the material that was
8 used in the publication by Huang, et al.,
9 that's Exhibit 9, it uses a blend of PCL and
10 collagen.

11 (BY MR. LEVINE)

12 Q. In your testimony before you
13 mentioned the terms "isotropic" and
14 "anisotropic."

15 Do you have an understanding
16 what those terms mean in the context of
17 Exhibit 9?

18 MS. WIEKER: Objection to form.

19 A. In general, the term
20 "isotropic" refers to a material with
21 properties being the same in all directions,
22 in three dimensions.

23 "Anisotropic" refers to
24 material that has properties that are not the
25 same in all directions, in three dimensions.

1 In the context of the Huang2
2 paper, my understanding of the term
3 "isotropic" refers to a material that is --
4 is made of electrospun fibers with properties
5 the same in two directions, in all
6 directions -- two dimensions, in all
7 directions.

8 Anisotropic would mean a
9 material that has properties that are
10 different in different directions, in two
11 dimensions.

12 (BY MR. LEVINE)

13 Q. And how does that relate to the
14 alignment of the electrospun fibers as you
15 understand it?

16 MS. WIEKER: Objection to form.

17 A. Again, referring to isotropic
18 versus anisotropic materials, I understand
19 the isotropic 2D -- let me rephrase, the
20 isotropic electrospun scaffold to have random
21 fiber alignment.

22 (BY MR. LEVINE)

23 Q. Okay.

24 A. That will make the properties
25 the same in all directions, again, in the

1 case of random alignment.

2 In the case of a material with
3 aligned fibers, that will make the material
4 anisotropic in 2D, again, in the context of
5 the Huang2 article.

6 Q. Okay. If -- if I turn you to
7 Section 3.1 of Huang -- of Huang2 on
8 Page 1794, on the -- the last sentence in
9 3.1, does that refer to material testing of
10 the fibers that he obtained described in this
11 paper?

12 MS. WIEKER: Objection to form.

13 A. It refers to mechanical
14 properties, not of the fibers but of the
15 matrices comprised of the fibers.

16 (BY MR. LEVINE)

17 Q. Thank you for that
18 clarification.

19 Okay. And in the second
20 sentence in that same section, it says: "A
21 majority of the fibers (approximately
22 90 percent) collected on the rotating mandrel
23 aligned in the same direction as the
24 rotation. To better analyze the fiber
25 alignment, FFT analysis was performed on the

1 SEM images of randomly selected areas N
2 equals 5 to characterize the anisotropy and
3 assign a numerical value to fiber
4 orientation."

5 Do you see that?

6 A. Yes.

7 Q. When it says N equals 5, is it
8 your understanding that they took images of
9 five different places of the scaffold?

10 MS. WIEKER: Objection to form.

11 (BY MR. LEVINE)

12 Q. You can answer.

13 A. It was FFT analysis on five
14 images taken from different areas of the
15 scaffold.

16 Q. And if you turn to the page
17 before that you mention in your testimony,
18 Figure 1, Figure 1C, there is a graph, an
19 alignment plot, and there is a dark line with
20 a caption ANISO.

21 Do you understand that line to
22 represent the average of the FFTs conducted
23 on those five images?

24 MS. WIEKER: Objection to form.

25

1 (BY MR. LEVINE)

2 Q. You can answer.

3 A. I don't -- I don't see
4 information in the figure caption to identify
5 this line as the average. It may be the
6 average of the five measurements but it may
7 be a representative of the five measurements.

8 Q. When you say "representative of
9 the five measurements," what do you mean by
10 that?

11 A. If all five measurements look
12 alike, the authors can only present one of
13 them as a representative of the five
14 measurements.

15 Q. The next sentence states: "The
16 narrow peak of the normalized intensity
17 values in any anisotropic" --

18 A. Which column are you?

19 Q. I'm sorry. Figure -- Page 1794
20 under Section 3.1, the sentence right after
21 the one that talks about the SEM images of
22 randomly selected area N equals 5.

23 A. Yes.

24 Q. The next sentence.

25 A. Yes.

1 Q. It says: "The narrow peak of
2 the normalized intensity values in
3 anisotropic matrices (Figure 1C) indicate --
4 indicated that the PCL/collagen nanofibers
5 aligned along a single axis?"

6 And then they cite Figure 1B.

7 Sitting here today, do you
8 disagree with that statement of the authors?

9 MS. WIEKER: Objection to form.

10 A. The question is if I agree or
11 disagree?

12 (BY MR. LEVINE)

13 Q. Correct.

14 A. Agree or disagree?

15 Q. Either one.

16 A. I agree with the statement.

17 Q. Okay. In your -- in your
18 understanding, what is the -- strike that.

19 In your understanding, what is
20 being investigated in the Huang2 paper?

21 MS. WIEKER: Objection to form.

22 A. You're asking me what is
23 investigated in this paper?

24 (BY MR. LEVINE)

25 Q. What -- what is the purpose of

1 this paper?

2 What are the authors
3 investigating, as you understand it?

4 A. Give me one second.

5 Q. Sure.

6 A. I think it's clearly stated.

7 The objective in the second line of the
8 abstract, I read: "It becomes highly desired
9 to understand how various nanofibrous
10 matrices regulate skin cell behaviors and
11 intracellular signaling pathways, important
12 to tuning the functionality of
13 tissue-engineered skin grafts and affecting
14 the wound healing process."

15 Q. And in connection with that,
16 are they also investigating the hypothesis of
17 how fiber alignment affects fibroblast to
18 myofibroblast differentiation?

19 A. This is clearly stated in the
20 next sentence, of the abstract that is "In
21 this study, the phenotypic expressions of
22 normal human dermal fibroblasts (NHDFs) on
23 the collagen-containing nanofibrous matrices
24 with either isotropic (i.e., fibers collected
25 randomly with no alignment) or anisotropic,

1 (i.e., fibers collected with alignment) fiber
2 organizations were studied by immunostaining,
3 migration assay and molecular analysis."

4 Q. Okay.

5 A. Period.

6 Q. And a little further down in
7 that abstract, it says: "Moreover, the
8 fibroblast-to-myofibroblast differentiation
9 was greatly enhanced for the NHDFs cultured
10 on anisotropic nanofibrous matrices over a
11 period of 48 hours."

12 Do you see that?

13 A. In the abstract, yes.

14 Q. So are the authors concluding
15 that in the presence of aligned nanofibrous
16 matrices the differentiation of fibroblast to
17 myofibroblast are greatly enhanced?

18 MS. WIEKER: Objection to form.

19 A. They report the result of the
20 study over a period of 48 hours. That's how
21 I read it.

22 (BY MR. LEVINE)

23 Q. And in -- in that 48-hour
24 period, on the aligned fibers as opposed to
25 the random fibers, the differentiation of

1 fibroblast to myofibroblast was enhanced.

2 Is that fair to say?

3 MS. WIEKER: Objection to form.

4 A. That's how -- how I read this
5 statement. When the authors compared the two
6 types of fiber -- nanofibrous matrices
7 anisotropic versus isotropic when they
8 culture the NHDF cells and studied the
9 fibroblast to myofibroblast differentiation
10 over a period of 48 hours.

11 (BY MR. LEVINE)

12 Q. And are -- is the
13 differentiation of fibroblast to -- to
14 myofibroblast important in the healing of any
15 particular tissues in the body?

16 MS. WIEKER: Objection to form.

17 (BY MR. LEVINE)

18 Q. You can answer.

19 A. It may be important depending
20 on many other parameters.

21 (Reporter clarification.)

22 (BY MR. LEVINE)

23 Q. For example, if you know
24 sitting here today, in healing a tendon
25 injury, is there a differentiation of

1 fibroblast to myofibroblast?

2 MS. WIEKER: Objection to form.

3 (BY MR. LEVINE)

4 Q. You can answer.

5 A. It is one of the cellular
6 processes that's important. It's not the
7 only cellular process, but it's one of them.

8 Q. Okay. Let me turn you to --
9 back to Exhibit 1, which is your declaration
10 on the '223 patent. And if I can direct your
11 attention to Paragraph 69.

12 And in Paragraph 69, you have
13 two -- strike that.

14 In -- in Paragraph 69, you
15 include two alignment plots; is that correct?

16 A. There are two alignment plots
17 from different sources.

18 Q. And is it correct that one
19 source, the alignment plot on the left, is
20 from Dr. Simpson's testing and one source on
21 the right is from the Huang2 article that we
22 were just discussing?

23 A. That's correct.

24 Q. Okay. And taking a look at the
25 FFT alignment plot on the left from

1 Dr. Simpson's testing, do you agree that this
2 plot meets your definition of having two
3 major peaks 180 degrees apart?

4 MS. WIEKER: Objection to form.
5 (BY MR. LEVINE)

6 Q. You can answer.

7 A. Can you repeat the question,
8 please.

9 Q. Sure. For the alignment plot
10 on the left from Dr. Simpson's testing, do
11 you agree that this plot meets your
12 definition of having two major peaks?

13 MS. WIEKER: Same objection.

14 A. As I stated in -- extensively
15 in the report, I don't feel that the results
16 of Dr. Simpson -- Simpson's analysis as shown
17 here in Paragraph 69 are reliable for a
18 number of reasons that I elaborated
19 extensively in my report.

20 So I cannot take this figure in
21 isolation and express an opinion.

22 I have to take into
23 consideration that this figure was produced
24 under conditions which are not scientifically
25 rigorous and reproducible.

1 And for this reason the only
2 opinion that I would express about this
3 result is that it's different from the one
4 that's reported here in Paragraph 69 to the
5 right that was produced by Huang2 under
6 conditions clearly stated in his article.

7 (BY MR. LEVINE)

8 Q. You're an expert. I can ask
9 you a hypothetical question.

10 I want you to assume for me
11 that Dr. -- I know you disagree. I want you
12 to assume for me that Dr. Simpson knew how to
13 correctly perform his own method. I want you
14 to assume that. And the results are what is
15 obtained in the left alignment plot under
16 Exhibit 69 [verbatim].

17 Assuming those results are
18 scientifically valid, would this alignment
19 plot show two major peaks under your
20 definition of major peaks that we were
21 discussing earlier this morning?

22 MS. WIEKER: Objection to form.

23 Objection; improper hypothetical.

24 (BY MR. LEVINE)

25 Q. You can answer.

1 A. Again, this is purely
2 hypothetical. What I -- the opinion that I
3 form about his analysis, it's clearly stated
4 in my report repeatedly identifying what were
5 the shortcomings and the issues -- the
6 scientific issues that I had with his
7 scientific analysis.

8 And based on those opinions I
9 cannot answer these purely hypothetical
10 questions.

11 Q. Okay. Can you identify peaks
12 in Dr. Simpson's testing that's reproduced in
13 Paragraph 69 of your paper?

14 MS. WIEKER: Objection to form.

15 A. If I see the graph on Page 69
16 [verbatim], again, reiterating as I stated
17 earlier that this graph was produced under
18 conditions that are not scientifically
19 rigorous and I see one care of in isolation,
20 I can see that, yes, there are peaks.

21 (BY MR. LEVINE)

22 Q. Okay. And consistent with what
23 we've done with the other graphs that you
24 identified, can you tell me what the peaks
25 that you see in this graph are?

1 MS. WIEKER: Objection to form.

2 (BY MR. LEVINE)

3 Q. You can answer.

4 A. Again, as I stated earlier and
5 I reiterate that this is the result of a test
6 that was under conditions that are not
7 scientifically rigorous, as I very
8 methodically stated in my expert report.

9 And seeing this graph in
10 isolation, I see four peaks, one at 90, one
11 at 180, one at 270, and one at 360.

12 I'm sorry, the one at 360 is
13 the same as the one at 0, so four peaks
14 total.

15 Q. And if we wanted to do your
16 calculation, you would assign a numerical
17 value to each of those peaks, calculate an
18 average, and then determine if the peaks at
19 90 and 270 are greater than that average; is
20 that correct?

21 MS. WIEKER: Objection to form.

22 Mischaracterizes.

23 A. Again, as I stated earlier,
24 I -- this is purely hypothetical. This is
25 the result that I don't trust. This is a

1 result that over study that was conducted
2 under conditions that I did not consider
3 scientifically rigorous and I prefer not to
4 continue this hypothetical discussion.

5 (BY MR. LEVINE)

6 Q. Well, I -- I understand that
7 you might prefer not to continue the
8 hypothetical discussion, but I -- I think I
9 am entitled to ask my questions.

10 And my question is merely: If
11 you wanted to do your calculation that you
12 have in Paragraph 56 of your report on these
13 four peaks, is it correct that you would
14 assign a numerical value to each of those
15 four peaks, calculate an average, and
16 determine if the peaks at 90 and 270 are
17 greater than the average?

18 MS. WIEKER: Objection to form.

19 A. Well, again, if we take any
20 result of an FFT analysis, not looking at
21 Dr. Simpson's result and we identify peaks in
22 that analysis, then, yes, I mean, in that
23 hypothetical case of a result on an FFT
24 analysis, again, purely theoretical, I would
25 follow the same methodology that I followed

1 earlier to calculate the average of the
2 heights and determine whether some peaks will
3 be classified as major peaks based, again, on
4 the definition of the major peaks as stated
5 in the '223 patent.

6 (BY MR. LEVINE)

7 Q. And based on your testimony
8 today, I assume you did not do that analysis
9 on the Dr. Simpson's assignment plot that's
10 reproduced in Paragraph 69?

11 MS. WIEKER: Objection to form.

12 A. In my expert report, I clearly
13 identify the issues and the problems with
14 Dr. Simpson's analysis. And I don't think
15 that I -- I did not conduct any analysis to
16 calculate the average.

17 (BY MR. LEVINE)

18 Q. Let me turn you to Paragraph 81
19 of Exhibit 1, your report. In the first
20 sentence you say: "Unlike Huang2,
21 Dr. Simpson did not test images of five
22 randomly selected areas."

23 You see that?

24 A. Yes.

25 Q. Looking back at the Exhibit 3,

1 which is the '223 patent, does the patent say
2 how many areas of the scaffold they analyzed?

3 A. Figure 8, the figure caption
4 states: "Figure 8 depicts exemplary FFT
5 analysis, the results (A) of the fibers
6 described herein and (B) a control sample."

7 So the way that I read the
8 exemplary is that this is a representative
9 result of the FFT analysis.

10 Q. Okay. And does it say how many
11 images they -- they analyzed?

12 A. I don't recall but I can check
13 the methods in the examples of the patent to
14 make sure that I'm not mistaken.

15 Q. Okay.

16 A. Do you want me to do that?

17 Q. Yes, please.

18 A. Yes.

19 In Column 13 of Page 19 of
20 the -- of 24 of the Exhibit 3, I read that in
21 some embodiments FFT results of the fibers
22 described herein may have adjacent major peak
23 with about 180 degrees apart from each other
24 as shown in Figure 8.

25 Although it doesn't say what

1 the N [phonetic] value is, I see that
2 multiple embodiments were tested, and that
3 what appears in Figure 8 is a representative
4 FFT analysis result.

5 Q. Where it says in some
6 embodiments the FFT analysis result of the
7 fibers have adjacent major peaks with about
8 180 degrees apart from each other, couldn't
9 that also be referring to the fact that they
10 also have 8B which is an embodiment in which
11 the peak are not --

12 MS. WIEKER: Objection.

13 (BY MR. LEVINE)

14 Q. -- 180 degrees?

15 MS. WIEKER: Objection.

16 (BY MR. LEVINE)

17 Q. Do not have major peaks
18 180 degrees apart from each other?

19 MS. WIEKER: Object to form.

20 A. That's not -- that's not how I
21 read it. The way that I read is that in some
22 embodiments the FFT result of the fibers
23 described herein may have adjacent major peak
24 180 degrees apart.

25 Having said that, they also

1 investigated here in Figure 8B some
2 embodiments that didn't have any major peaks.

3 (BY MR. LEVINE)

4 Q. Okay. But they don't give the
5 number, correct, of how many embodiments, as
6 you understand it?

7 MS. WIEKER: Objection to form.

8 A. Again, referring to the
9 embodiments where the FFT results of the
10 fibers described herein may have adjacent
11 major peaks, they don't -- with about
12 180 degrees apart from each other, they don't
13 give a number.

14 (BY MR. LEVINE)

15 Q. Okay. In Paragraph 95 of your
16 expert report, you say: "Here Dr. Simpson
17 did not report where or how he applied the
18 circular projection in the ImageJ software."

19 Based on your review and your
20 previous review of the patent, does the
21 patent show how the circular projection was
22 applied in the ImageJ software?

23 MS. WIEKER: Objection to form.

24 A. Can you repeat the question.
25

1 (BY MR. LEVINE)

2 Q. Yeah. Does the patent show how
3 the circular projection was applied in the
4 ImageJ software?

5 MS. WIEKER: Objection to form.

6 A. The circular projection --
7 again, I didn't find any information about
8 the circular projection as I was reading this
9 patent now. The only thing that -- relative
10 that I read was that they followed the FFT
11 analysis that was described in the
12 publication by Ayres.

13 So I would assume that they
14 follow the exact same methodology as what is
15 described in the Ayres.

16 (BY MR. LEVINE)

17 Q. And didn't Dr. Simpson in his
18 testing also say that he followed the
19 procedures set forth in Ayres?

20 MS. WIEKER: Objection to form.

21 A. The procedures to do what? I
22 mean, to do the selection -- the circular
23 selection? How to do the image analysis? To
24 vary the illumination? It's not clear.

25

1 (BY MR. LEVINE)

2 Q. Okay. Does the patent say --
3 in the next sentence it says: "For example,
4 Dr. Simpson's 2008 paper explains that images
5 should be stored and analyzes uncompressed
6 TIFF files to preserve image integrity.
7 Dr. Simpson does not address how Huang2's
8 images were stored and/or the impact on his
9 testing."

10 Does the patent say how the
11 images were stored that they had ran their
12 FFT analysis on?

13 A. Again, I rely on my previous
14 statement of what's stated in the patents
15 that the inventors followed the exact
16 procedure as described in the Ayres paper.

17 Q. And in Paragraph 97, you say:
18 "Dr. Simpson does not address the
19 illumination of the reproduction of Huang2
20 image that Dr. Simpson tested."

21 Other than relying on the Ayres
22 publication, does the patent talk about the
23 illumination that it used in generating its
24 FFT analysis?

25 A. What is your question?

1 Q. Other than the description of
2 the Ayres paper, does the patent have any
3 other language about how it used illumination
4 in generating the FFT alignment plots in
5 Figures 8A and 8B?

6 A. My understanding is that they
7 followed the protocol as described in the
8 Ayres paper. As I'm sitting here, I mean, I
9 don't recall seeing any information about the
10 illumination, how it was.

11 One thing that I might state --
12 state is that my understanding of reading
13 this patent that is the '223 patent is that
14 the analysis was done in samples that were
15 appropriate for analysis as indicated in the
16 Ayres paper.

17 However, when reading
18 Dr. Simpson's declaration, the way he did the
19 analysis on reproduction or photocopies of
20 images, my conclusion, as stated in the
21 report, is that he didn't follow the
22 guidelines that he himself stated in his own
23 paper.

24 And that was the basis for my
25 disagreement concerning the scientific rigor

1 of his analysis.

2 Q. But you agree that the results
3 in the patent, the '223 patent, are
4 scientifically valid based on the description
5 of following the Ayres 2008 technique; is
6 that correct?

7 MS. WIEKER: Objection to form.

8 A. Again, we're talking about the
9 alignment.

10 (BY MR. LEVINE)

11 Q. Alignment plots.

12 A. The alignment plots presented
13 in Figure 8A and 8B at the bottom of those
14 figures.

15 And take into consideration the
16 statements included in the specification of
17 this patent, my conclusion is that these are
18 valid results.

19 Q. Because they follow the
20 technique set forth in Ayres 2008?

21 MS. WIEKER: Objection to form.

22 A. Again, as stated in the
23 specification of this patent, the '223
24 patent.

25

1 (BY MR. LEVINE)

2 Q. Is it your testimony -- strike
3 that.

4 As you understand it,
5 Dr. Simpson was performing an FFT analysis on
6 the image set forth in the Huang2 paper; is
7 that right?

8 MS. WIEKER: Objection to form.

9 A. Not of the actual image, on the
10 reproduction of that image.

11 (BY MR. LEVINE)

12 Q. And when you say "a
13 reproduction of the image," what do you mean?

14 A. As stated his deposition, my
15 understanding is that Dr. Simpson used a PDF
16 copy of that image that he downloaded from
17 the journal web page to conduct his analysis.

18 So this is what I call a
19 reproduction of the image. So Dr. Simpson
20 did not use the raw data, the raw SEM data.

21 Q. So in your opinion, unless --
22 unless you use the original raw data SEM
23 image, then the subsequent FFT analysis is
24 not valid.

25 Is that what you're saying?

1 MS. WIEKER: Objection to form.

2 (BY MR. LEVINE)

3 Q. You may answer.

4 A. Again, as Dr. Simpson clearly
5 stated in his Ayres 2008 article, the use of
6 compressed data may not result in accurate
7 results of the FFT analysis.

8 So clearly the use of the PDF
9 file involves the use of compressed data. So
10 according to his own words and guidelines,
11 the resulting analysis is not accurate.

12 Q. So -- so for his ac- -- his
13 analysis to be accurate, he would have to
14 have the original image that Huang2 did his
15 analysis on; is that correct?

16 MS. WIEKER: Objection to form.

17 A. The original data in the proper
18 format that is in a TIFF uncompressed format,
19 that will allow him do a correct and accurate
20 analysis of the data.

21 (BY MR. LEVINE)

22 Q. Okay. Let me turn you to
23 Paragraph 106 of your report.

24 A. Which one?

25 Q. Your Exhibit 1.

1 A. Okay.

2 Q. You're talking about claim 2 of
3 the '223 patent. And you say: "Claim 2
4 depends on claim 1 and recites that 'the
5 fibers comprise type I collagen in its native
6 triple helical structure."

7 Do you see that?

8 A. Yes.

9 Q. Do you agree that Huang2
10 started with Type I collagen in its native
11 triple helical structure?

12 MS. WIEKER: Objection to form.

13 A. Based on the information that's
14 included in the methods -- materials and
15 methods of the Huang2 article, the type of
16 collagen is designated. The source is
17 designated.

18 There is no information whether
19 this collagen Type I scaffold is in its
20 native triple helical structure.

21 (BY MR. LEVINE)

22 Q. And in Paragraph 107, you state
23 that in the second sentence: "Huang2 states
24 that it dissolved type I collagen and
25 polycaprolactone ('PCL') in a

1 11,1,3,3,3-hexafluoro-2-propanol ('HFIP')
2 solution for electrospinning, but does not
3 specify the structure of the collagen that is
4 present in the resulting electro [verbatim]
5 fibers themselves, as the claim requires."

6 Do you see that?

7 A. Yes.

8 Q. Is it correct that the examples
9 in the patent also use HFIP as a solvent?

10 And I can refer you specifically to Example 1
11 of Exhibit 3 at Column 19 at Lines 40 to 41.

12 MS. WIEKER: Objection to form.

13 A. Again, Example 1 lists
14 1,1,1,3,3,3-hexafluoro-2-propanol as the
15 solvent that was used.

16 However, I would like to draw
17 your attention to the fact that the
18 '223 patent uses heart basement membrane as a
19 starting material that was dissolved in that
20 particular solvent.

21 (BY MR. LEVINE)

22 Q. So is it correct that the '223
23 patent did not spin electro [verbatim] fibers
24 with collagen, as you understand it?

25 MS. WIEKER: Objection to form.

1 A. The '223 patent spun fibers --
2 electrospun fibers made of a blend of
3 polycaprolactone and heart basement membrane
4 that contains collagen Type I.

5 (BY MR. LEVINE)

6 Q. So it's your understanding that
7 in -- in this context that heart base
8 [verbatim] membrane is synonymous with Type I
9 collagen?

10 MS. WIEKER: Objection to form.

11 A. First, it's heart basement.

12 (BY MR. LEVINE)

13 Q. Basement membrane.

14 A. It's not synonymous. Heart
15 basement membrane contains many other
16 biomolecules besides collagen Type I.

17 Q. And what percentage of
18 collagen -- Type I collagen is in heart
19 basement membranes, if you know?

20 MS. WIEKER: Objection to form.

21 A. I don't recall the specific
22 percentage of collagen Type I. But this is
23 something that a person of skill in the art
24 would easily find.

25

1 (BY MR. LEVINE)

2 Q. And -- and it true that --
3 well, strike that. Sorry.

4 In Example 1, the -- the
5 solvent that we just read is referred to HFP.
6 And an example, Paragraph 107 on your report,
7 it refers to HFIP.

8 Do you agree that that is the
9 same solvent even though it uses a different
10 abbreviation?

11 A. HFP and HFIP are the same
12 solvent.

13 Q. Okay.

14 A. The reason for the I is because
15 the solvent is also called
16 hexafluoroisopropanol.

17 Q. And does the patent assess
18 whether the collagen in the heart basement
19 membrane remains Type I after
20 electrospinning?

21 MS. WIEKER: Objection to form.

22 A. I did not express an opinion
23 about the '223 patent. My reports are
24 focused mainly on the issues on the grounds
25 as identified in the expert reports.

1 extensively in my report. And I supported my
2 opinion based on references at the time of
3 the invention that a person of skill in the
4 art would have been aware on how the
5 hexafluoroisopropanol can break down the
6 hydrogen bonding that is responsible for the
7 triple helical structure of collagen Type I
8 through both hydrophilic and hydrophobic
9 interactions.

10 (BY MR. LEVINE)

11 Q. And given that the patent uses
12 the same solvent, wouldn't the HFP used in
13 the examples also denature the collagen
14 Type I that is contained in heart basement
15 membrane?

16 MS. WIEKER: Objection to form.

17 A. As I said earlier, it is well
18 known that several biomolecules can protect
19 the bioactivity of other biomolecules.

20 So knowing that the collagen
21 Type I in the heart basement membrane was in
22 the presence of other biomolecules, such as
23 glycoproteins and proteoglycans, these other
24 biomolecules may have helped preserve the
25 bioactivity of collagen Type I present in the

1 heart basement membrane.

2 (BY MR. LEVINE)

3 Q. And is that reported in the

4 '223 patent?

5 A. I don't recall that being

6 reported.

7 Q. To your recollection, does the

8 '223 patent report on the structure of Type I

9 collagen after the fibers have been

10 electrospun?

11 MS. WIEKER: Objection to form.

12 A. I don't recall seeing that in

13 this particular document. That's in

14 Exhibit 3. That is the '223 patent. I may

15 have missed it when I read it again -- this,

16 but I don't think seeing that...

17 (BY MR. LEVINE)

18 Q. In Paragraph 111 of your -- of

19 Exhibit 1, your declaration...

20 (Discussion off the record.)

21 (BY MR. LEVINE)

22 Q. On Paragraph 111, it says:

23 "Huang2 also utilizes fetal bovine serum in

24 its cell culture process."

25 Do you see that?

1 A. Yes.

2 Q. If you turn to claim 2 of the
3 '223 patent.

4 A. Claim 2?

5 Q. Claim 2.

6 A. Yes.

7 Q. Is it -- is it your
8 understanding as a POSA that claim 2 requires
9 cell culture?

10 MS. WIEKER: Objection to form.

11 (BY MR. LEVINE)

12 Q. You can answer.

13 A. Claim 2, as claim 1 to which
14 claim 2 depends on, refers to scaffold.

15 So the question here is that
16 the scaffold in which environment, is it in a
17 cell culture environment? Is it in the body?
18 Is it sitting in the air?

19 Obviously, if it's in cell
20 culture or in a biological environment, then,
21 yes, I mean, then, I mean, fetal bovine
22 serum, I mean, will be in contact with the
23 scaffold.

24 Q. But there is no requirement,
25 for example, that cells are cultured on the

1 scaffold in claim 2 unlike, for example,
2 claim 11?

3 MS. WIEKER: Objection to form.

4 A. Again, as I said earlier I
5 consider the scaffold in any environment.
6 The claim 1 or claim 2 doesn't say scaffold
7 that's sitting on the shelf in -- not in
8 contact with fetal bovine serum.

9 (BY MR. LEVINE)

10 Q. But temporally after you can
11 make the scaffold before you culture cells on
12 it, correct?

13 MS. WIEKER: Objection to form.

14 A. Yes and no. There are
15 techniques that involve also cell culture
16 during the fabrication of the scaffold.

17 (BY MR. LEVINE)

18 Q. There can be?

19 A. There can be.

20 Q. And there also cannot be?

21 MS. WIEKER: Objection to form.

22 (BY MR. LEVINE)

23 Q. Correct?

24 A. Yes.

25 Q. And is it correct that you

1 could also implant a scaffold without
2 culturing cells in the body and have
3 naturally occurring cells use that matrix to
4 repopulate the scaffold after implanted --
5 after implantation?

6 MS. WIEKER: Objection to form.

7 A. You're referring to any
8 scaffold that is fabricated by any technique
9 that is implanted in the body.

10 Yes, there have been
11 biomaterials implanted in the body. But,
12 again, the biomaterials will be in contact
13 with the biological environment that may
14 include fetal bovine serum or other enzymes
15 present in that milieu.

16 (BY MR. LEVINE)

17 Q. For -- for a scaffold that's
18 implanted in a human without cells cultured
19 on it, that there is no fetal bovine serum in
20 the human, correct?

21 A. There's no bovine serum --

22 Q. Correct.

23 A. -- but there is human serum.

24 (Discussion off the record.)
25

1 (BY MR. LEVINE)

2 Q. For claim 4 it says: "The
3 scaffold according to claim 1 where the
4 scaffold has an average porosity from about
5 60 percent to about 90 percent."

6 Do you see that?

7 A. Yes, that's claim 4 of the '223
8 patent.

9 Q. And that is referring back to
10 claim 1 which covers an -- a scaffold with
11 aligned fibers, as you understand it,
12 correct?

13 A. Correct. It's a dependent
14 claim.

15 Q. Does the patentee try to obtain
16 60 to 90 percent porosity in an aligned
17 scaffold?

18 MS. WIEKER: Objection to form.

19 A. This is something that I was
20 not asked specifically to opine, I mean,
21 about the teachings from the '223 patent. I
22 tried to focus on the invalidity of the '223
23 patent in view of the documents that was
24 presented to the PTAB.

25

1 (BY MR. LEVINE)

2 Q. Is there any discussion of
3 porosity in the patent other than at
4 Column 14, Lines 21 to 27, based on your
5 reviews of the patent?

6 MS. WIEKER: Objection to form.

7 Asked and answered.

8 A. Again, since I was not asked to
9 focus on that, I mean, I cannot really
10 comment. I didn't focus on that particular
11 aspect of the '223 patent.

12 (BY MR. LEVINE)

13 Q. Does this text at Column 14,
14 Line 21 to 26 teach how to obtain a porosity
15 of 60 to 90 percent in an aligned scaffold?

16 MS. WIEKER: Objection to form.

17 A. Again, I cannot take that in
18 isolation. I mean, I didn't focus my report
19 on that so I cannot really say anything.

20 (BY MR. LEVINE)

21 Q. Would a POSA understand how to
22 obtain a aligned scaffold with 60 to
23 90 percent porosity?

24 MS. WIEKER: Objection to form.

25 A. Again, as I said earlier, I

1 mean, this is not the focus of my report.

2 (BY MR. LEVINE)

3 Q. But in your -- in your reviews
4 of the patent, sitting here today, you don't
5 recall any other language in the patent
6 discussing porosity other than what's in
7 Column 14; is that right?

8 MS. WIEKER: Objection; form.

9 Again, asked and answered.

10 A. Again, I don't want to rely on
11 my memory. As I said, I didn't focus on the
12 patent itself.

13 MR. LEVINE: Let's -- I think
14 we've been going for more than an
15 hour. Is it a good time for a break?

16 MS. WIEKER: I think that's
17 great.

18 MR. LEVINE: Okay.

19 THE VIDEOGRAPHER: Off the
20 record at 1:55 p.m.

21 (Break from 1:55 p.m. to 2:18 p.m.)

22 THE VIDEOGRAPHER: Back on the
23 record 2:18 p.m. Beginning of Tape 4.

24 (BY MR. LEVINE)

25 Q. Dr. Mikos, let me --

1 (Discussion off the record.)

2 (BY MR. LEVINE)

3 Q. Let me mark as the next exhibit
4 Mikos Exhibit 10.

5 (Marked Mikos Exhibit No. 10.)

6 (BY MR. LEVINE)

7 Q. A document entitled
8 "Electrospinning of Polymeric Nanofibers for
9 Tissue Engineering Applications: A Review."

10 MS. WIEKER: Thank you.

11 (BY MR. LEVINE)

12 Q. Dr. Mikos, is this one of your
13 papers?

14 A. Yes.

15 Q. And what was the purpose of
16 this article?

17 MS. WIEKER: Objection to form.

18 A. This is a review article and
19 the objectives of the review are clearly
20 stated in the abstract. It's the last
21 sentence: "In this review we examine
22 electrospinning by providing a brief
23 description of the theory behind the process,
24 examining the effect of charging" -- take
25 back -- "the effect of changing the process

1 parameters on the fiber morphology and
2 discussing the potential applications and
3 impacts of electrospinning on the field of
4 tissue engineering."

5 (BY MR. LEVINE)

6 Q. And are the first two authors
7 of the paper students of yours?

8 A. The first author, Quynh Pham,
9 P-H-A-M, was a graduate student at that time.
10 The second author, Upma Sharma, S-H-A-R-M-A,
11 was a postdoctoral fellow at that time.

12 Q. So starting at Page 1198, is it
13 correct that you're discussing parameters of
14 electrospinning process?

15 A. That's correct, under the
16 section "Parameters of Electrospinning
17 Process."

18 Q. On the right-hand column on the
19 same page, 1198, the bottom right paragraph,
20 the first sentence says: "The diameter of
21 the fibers produced by electrospinning has
22 been found to increase with increasing
23 solution concentration."

24 So is that correct that the
25 higher solution concentration, the higher the

1 diameters of the fibers?

2 MS. WIEKER: Objection to form.

3 A. In the case of electrospinning,
4 yes.

5 (BY MR. LEVINE)

6 Q. And if you could turn to
7 Page 1201 under "Collector Composition and
8 Geometry" --

9 A. Yes.

10 Q. -- in the middle of that
11 paragraph it says: "It was found that
12 packing density was influenced by the
13 conductivity of the collectors. The more
14 conductive collectors dissipated the charge
15 of the fibers. When this charge was not
16 dissipated, non -- nonconductive collectors,
17 the fibers repelled one another yielding a
18 more porous structure."

19 So are you stating that if you
20 want a more porous scaffold, you would use a
21 less conductive collector?

22 MS. WIEKER: Objection to form.

23 Objection; incomplete hypothetical.

24 (BY MR. LEVINE)

25 Q. You can answer.

1 A. This is a statement based on
2 the result of Reference 36. The sentence
3 states what it states.

4 One will have to get to
5 Reference 36 to see under which conditions,
6 which electrospinning conditions this
7 statement would apply.

8 Q. But the statement is -- is
9 referring to the conductivity of the
10 collectors and its relationship on packing
11 density.

12 And I thought you were saying
13 is that the -- the less conductive the
14 collector, you would obtain a more porous
15 scaffold because of the fibers would repel
16 each other.

17 Is that not right? If it's
18 not, please correct me.

19 MS. WIEKER: Objection to form.

20 A. Again, this is a statement.
21 It's very clear stated; however, one will
22 need to get Reference 36 to see in what
23 context, what materials, what conditions this
24 statement applies.

25 But the statement is true as

1 stated.

2 (BY MR. LEVINE)

3 Q. And if you could turn to
4 Page 1205, and on the left-hand column
5 towards the bottom there's a paragraph that
6 starts with Lee, et al.

7 Do you see that?

8 A. Yes.

9 Q. And is that text in that
10 paragraph referring to the use of aligned
11 fibers to treat a ligament injury?

12 MS. WIEKER: Objection to form.

13 A. This refers to polyurethane
14 nanofibers. Polyurethane is a synthetic
15 polymer and the tissue engineering
16 application is engineering ligament tissue.

17 (BY MR. LEVINE)

18 Q. And is the cell type they used
19 fibroblast for engineering ligament tissue?

20 MS. WIEKER: Objection to form.

21 A. They used human ligament
22 fibroblast.

23 (BY MR. LEVINE)

24 Q. And is it correct that you're
25 reporting that when the polyurethane fibers

1 were aligned they secreted more ECM than when
2 attached to a random fiber configuration?

3 MS. WIEKER: Objection to form.

4 (BY MR. LEVINE)

5 Q. You can answer.

6 A. Again, that compares the study
7 of human ligament fibroblasts and that their
8 function, how when they cultured on different
9 fiber configurations, was specifically the
10 shape and the secretion of ECM and the effect
11 that the mechanical strain had on these
12 outcomes on human ligament fibroblast.

13 Q. And it found that for the
14 aligned fibers there was more ECM secreted in
15 this particular study; is that correct?

16 A. Again, one will have to see the
17 particular reference in detail, but this
18 being a review, it summarizes the findings of
19 that particular article.

20 Q. And if you go to the same page
21 but the right column, second paragraph from
22 the bottom, it says: "A collagen nanofiber
23 mesh scaffold may have the advantage of not
24 only resembling the size, scale, but also the
25 chemical and biological function of ECM."

1 What does ECM stand for?

2 A. ECM stands for extracellular
3 matrix.

4 Q. Then it says: "The spinning of
5 collagen Types 1 and 3 is feasible using" --
6 and then it says "HFP as a solvent."

7 And that is the same solvent we
8 were discussing earlier in the context of
9 Huang2; is that correct?

10 MS. WIEKER: Objection to form.

11 A. That is correct. This is the
12 hexafluoroisopropanol.

13 (BY MR. LEVINE)

14 Q. And then it says: "Collagen
15 fiber diameters of a hundred nanometers
16 (Type I) and 250 nanometers (Type III) were
17 achieved. These fibers possessed the typical
18 67 nanometer banding pattern observed in
19 native collagen."

20 A. And there is a reference next
21 to it, Reference 10.

22 Q. 10.

23 And so is it correct that using
24 this solvent, the authors of this paper were
25 able to obtain the typical banding patterns

1 observed in native collagen?

2 A. That's what the sentence says.

3 Q. And what is Reference 10?

4 A. If you go to the references on
5 Page 1208, it's a paper by Matthews, Wnek,
6 Simpson, Bowlin.

7 And the title of the paper is
8 "Electrospinning of collagen nanofibers,"
9 published in Biomacromolecules and then it
10 has the volume number, page, and the year
11 2002.

12 Q. So that's a paper for -- from
13 Dr. Simpson's research group; is that
14 correct?

15 MS. WIEKER: Objection to form.

16 A. It has the same initials and
17 he's listed as a coauthor so whether it's
18 from his group or not, I cannot tell with
19 certainty unless I see the actual
20 publication.

21 (BY MR. LEVINE)

22 Q. And if you turn to Page 1206,
23 there's a -- there's a -- a heading called
24 "Composite Scaffolds."

25 Do you have an understanding of

1 what that means in the context of your review
2 article?

3 A. It's clearly stated in the
4 first -- first two sentences what a composite
5 scaffold is.

6 Q. So it -- the -- then let me --
7 let me just ask you the question, then.

8 Is a composite scaffold a
9 scaffold with multiple layers?

10 A. That's one type of composite
11 scaffold.

12 Q. And then it says: "Each layer
13 can be tailored for a specific cell adhesion
14 and could be potentially beneficial for zonal
15 articular cartilage or arterial vessel
16 repair. Boland, et al., have demonstrated
17 smooth muscle cell infiltration into a
18 multilayered scaffold of collagens Type I and
19 III and elastin when cultured in a rotary
20 cell system."

21 So is it correct that here
22 you're reporting that Boland, et al., made a
23 scaffold with multiple layers that had
24 collagens Type I and III and were able to get
25 smooth muscle cell infiltration into the

1 different layers of the scaffold?

2 MS. WIEKER: Objection to form.

3 A. I will have to double-check
4 what multilayer scaffold of collagen Types I
5 and III and elastin refers to, whether it's
6 distinct layers of collagen I and III and
7 elastin or whether a blend of these collagens
8 was used, because that would also qualify as
9 a composite scaffold.

10 (BY MR. LEVINE)

11 Q. But given that clarification,
12 is it correct that they were able to get
13 smooth muscle infiltration into the different
14 layers of the scaffold, at least as you
15 report here?

16 MS. WIEKER: Objection to form.

17 A. That's what the sentence says
18 in the...

19 (BY MR. LEVINE)

20 Q. And what is Reference 91?

21 A. It's Boland, Matthews,
22 Pawlowski, Simpson, Wnek, Bowlin. And the
23 title is "Electrospinning collagen elastin:
24 Preliminary vascular tissue engineering,"
25 published in Frontiers in Bioscience, volume

1 number, page, year 2004.

2 Q. And that's also a paper in
3 which Dr. Simpson was an author; is that
4 right?

5 MS. WIEKER: Objection to form.

6 A. An article, Reference 91,
7 Dr. Simpson is listed as a middle author,
8 yes.

9 (BY MR. LEVINE)

10 Q. So is it correct that in your
11 review article, you cite an article in which
12 Dr. Simpson was a coauthor at Reference 10,
13 Reference 31, Reference 91, Reference 95,
14 Reference 101, and Reference 112?

15 MS. WIEKER: Objection to form.

16 (BY MR. LEVINE)

17 Q. You can answer.

18 A. Again, referring to this review
19 article, that the co-author and corresponding
20 author, Dr. Simpson, is listed as a middle
21 author.

22 That will tell me that he may
23 not be the corresponding author of those
24 articles. So it's not clear to me whether
25 this is a work conducted in his lab or

1 whether he collaborated with his senior
2 authors of those papers to contribute to the
3 work that's presented in the articles.

4 Q. Is it correct that you cited to
5 an article in which Dr. Simpson was at least
6 a coauthor some six times in your review
7 article?

8 A. I listed as many times as I
9 thought it was necessary to have a
10 representative opinion about the topics that
11 were covered in this review.

12 (Marked Mikos Exhibit No. 11.)
13 (BY MR. LEVINE)

14 Q. Let me mark as the next exhibit
15 as Mikos Exhibit 11 an article that says
16 "Multiscale fibrous scaffolds in regenerative
17 medicine."

18 Is this another one of your
19 review articles, Dr. Mikos?

20 A. Yes. I'm listed here as
21 coauthor of these articles -- of this
22 article.

23 Q. And is there a reason why
24 you're not listed as the -- the last author
25 on this paper?

1 MS. WIEKER: Objection to form.

2 A. Yeah, this particular article
3 was conducted mainly in the laboratory of the
4 last author, Dr. Shantikumar,
5 S-H-A-N-T-I-K-U-M-A-R V. N-A-I-R.

6 (BY MR. LEVINE)

7 Q. Were any of the -- any of the
8 authors listed in this article worked in your
9 laboratory?

10 MS. WIEKER: Objection to form.

11 A. Yes. One of the authors was a
12 graduate student at that time. Erica J.
13 Levorson, L-E-V-O-R-S-O-N.

14 (BY MR. LEVINE)

15 Q. Let me turn you to Page 7 of
16 this article. And in that first and complete
17 paragraph after the citation to Article 48,
18 it says: "Mota, et al., developed dual-scale
19 scaffolds consisting of aligned PCL
20 microfilaments and PLGA nanofibers."

21 Do you have an understanding of
22 what is meant by dual-scale -- dual-scale
23 scaffolds in the context of this article?

24 A. I would have to check that
25 article, that Reference 32, to give you a

1 complete answer.

2 The -- if I need to speculate,
3 they're now -- the way that I'm understanding
4 dual scale is two types of fibers, microscale
5 fibers and nanoscale fibers.

6 But to give you a thorough and
7 complete answer, I would have to check that
8 reference.

9 Q. Let me ask you -- if you go
10 down to the first complete paragraph on that
11 same page, the third sentence, it says:
12 "Porosity and pore size in electrospun
13 scaffolds are mainly dependent on the fiber
14 diameter and their packing density."

15 Sitting here today, do you
16 agree with that statement that you published?

17 A. Yes. This is actually
18 something that I also elaborated extensively
19 in my expert report.

20 Q. A little further down, the last
21 paragraph on that page, second sentence, it
22 says: "Initially four different polymers
23 were individually electrospun, Type I
24 collagen, styrenated gelatin (ST-gelatin),
25 segmented polyurethane (SPU), and

1 polyethylene oxide. Then these individual
2 fiber meshes were deposited layer by layer to
3 form a trial layered electrospun mesh and
4 mixed electrospun fiber mesh."

5 Would this be considered a
6 multilayer scaffold, Dr. Mikos?

7 MS. WIEKER: Objection to form.

8 A. What is referred to as a
9 trilayer electrospun mesh, the word will tell
10 me that there was three layers. So that
11 would be a type of multilayer scaffold.

12 (BY MR. LEVINE)

13 Q. And is one of the reasons you
14 would make a multilayer scaffold is to
15 increase the strength of the overall
16 scaffold?

17 A. Not necessarily.

18 Q. Is that a possible reason why
19 you would make a multilayer scaffold, would
20 be to increase its strength?

21 MS. WIEKER: Objection to form.

22 A. Not really.

23 (BY MR. LEVINE)

24 Q. Okay.

25 A. In many cases multilayer

1 scaffolds are fabricated to mimic the zonal
2 organization found in anisotropic tissues.

3 That is if a particular tissue
4 has different zones. And the different zones
5 can be of materials of different mechanical
6 properties or different cells of different
7 phenotypes or different compositions of
8 extracellular matrix.

9 These would qualify -- these
10 would require the use of a multilayer
11 scaffold to mimic that zone of organization
12 found in the tissue.

13 Q. Let me -- if I could turn you
14 to Table 1 in this paper on Page 15.

15 You see the -- the first line
16 in the table refers to fiber fabrication and
17 under it says: "Aligned electrospun PGA
18 collagen fibers."

19 Does this mean that you're
20 reporting that Reference 47 has aligned
21 electrospun PGA/collagen fibers?

22 MS. WIEKER: Objection to form.

23 A. Can I check Exhibit 1 for a
24 second and Exhibit 2.

25 Yeah, this -- although I

1 recognize that this is an article I'm listed
2 as a coauthor, this is not an article that I
3 rely on my opinions. But I can take your
4 question.

5 (BY MR. LEVINE)

6 Q. Is it correct that in this
7 review article that you're a coauthor on,
8 you're reporting that Reference 47 had
9 aligned electrospun PGA collagen fibers?

10 MS. WIEKER: Objection to form.

11 A. Again, that's what I -- I
12 assume that's the case if I go to
13 Reference 47. It's a long time since I wrote
14 this article in 2012, so I cannot tell you
15 anything more than what's included in the
16 table.

17 So if you read this statement
18 in the table, I would say, yes, that's what
19 it is. But I will need to go to Reference 47
20 to give you a thorough answer about which
21 conditions, which parameters, et cetera.

22 (BY MR. LEVINE)

23 Q. And I think you said this
24 thing was -- this article was published in
25 2012.

1 A. Correct.

2 Q. Okay. It says on the cover it
3 was published online on November 3, 2011.

4 A. Yes. Both statements are
5 accurate.

6 Q. Okay.

7 A. 2012 is the date when the
8 article was included in an issue, in a
9 printed issue of the journal.

10 However, before that, an
11 article appears online. So any publication
12 released the date of where the article became
13 available to the community, but also the date
14 where the article was included in the printed
15 issue.

16 Q. And let me mark as the next
17 exhibit as Mikos Exhibit 12, a paper titled
18 "Quantitative Analysis of Cell Adhesion on
19 Aligned Micro and Nanofibers."

20 (Marked Mikos Exhibit No. 12.)

21 MR. LEVINE: Here you go.

22 MS. WIEKER: Thank you.

23 (BY MR. LEVINE)

24 Q. Is -- is this paper, to your
25 knowledge, Reference 47 that was discussed in

1 your review article that we were just talking
2 the about?

3 MS. WIEKER: Objection to form.

4 A. Yes. Again, let me
5 double-check to make sure that this article
6 was cited or not cited in my expert reports.

7 It's not one of the articles
8 that I rely in forming my opinions as stated
9 in the two expert reports.

10 Q. Is it the paper that's
11 referenced as No. 47 in your review article?

12 A. Yes, it is.

13 Q. And on Page 293 under "Results"
14 of Exhibit 12, it says: "In this study we
15 analyzed the fabrication of align nanofibers
16 composed of PGA/collagen composite materials.
17 As shown in Figure 1A, PGA collagen
18 nanofibers could be fabricated to generate
19 randomly aligned structure of PGA/collagen
20 fibers. Furthermore, the alignment of
21 nanofibers could be aligned by using a
22 spinning substrate."

23 And then it cites on the next
24 page Figure 1B where it says: "Align fibers
25 collected on PVA collecting fibers with

1 diameter of 500 nanometers."

2 And again, my question is, is
3 this the description that you're referring to
4 in -- in Table 1 where you say aligned
5 electrospun PGA/collagen fibers?

6 MS. WIEKER: Objection to form.

7 A. Again, you're referring to
8 Table 1 --

9 (BY MR. LEVINE)

10 Q. Yes.

11 A. -- of Exhibit 11 --

12 Q. Yes.

13 A. -- the first entry in that
14 table where it says align electrospun PGA
15 collagen fibers?

16 Q. Yes.

17 A. Yes, that appears to be the
18 same article.

19 Q. Okay. Let me mark as the next
20 exhibit as Mikos Exhibit 13.

21 (Marked Mikos Exhibit No. 13.)

22 (BY MR. LEVINE)

23 Q. An article entitled
24 "Electrospun Poly (caprolactone) Microfiber
25 and Multilayer Nanofiber/Microfiber

1 Scaffolds: Characterization of Scaffold and
2 Measurement of Cellular Infiltration."

3 Here you go.

4 MR. LEVINE: Here you go.

5 A. For the record, the title of
6 the paper is "poly (epsilon" --

7 (BY MR. LEVINE)

8 Q. Epsilon.

9 A. -- "caprolactone)."

10 Q. Is this another one of your
11 papers, Dr. Mikos?

12 A. Yes, it is.

13 Q. And if I can refer you to
14 Table 1 of this paper.

15 A. If you can give me one
16 second --

17 Q. Sure.

18 A. -- I want to confirm that I
19 didn't rely on this article for my expert
20 reports.

21 Yes. Yes, please.

22 Q. Can you tell me what Table 1
23 shows?

24 A. Yeah. Table 1, the title is
25 "Electrospinning Processing Conditions for

1 PCL," PCL standing for poly epsilon
2 caprolactone scaffold. It has seven columns.
3 The first column lists the targeted fiber
4 diameter in micrometers.

5 Second column, the PCL
6 concentration in what percent.

7 The third column, the solvent
8 mixture by volume.

9 The fourth one, the collector
10 distance in centimeters.

11 The fifth one, the voltage in
12 kilowatt.

13 The sixth one, the flow rate in
14 micro -- in milliliter per hour.

15 And the seventh one, the needle
16 gauge.

17 Q. And is it correct that those
18 parameters you just read are -- are designed
19 to achieve certain target fiber diameters?

20 MS. WIEKER: Objection to form.

21 A. Again, as I stated earlier,
22 what is listed in Table 1 of that article is
23 the processing parameters that were selected
24 for this targeted fiber diameters listed in
25 the first column.

1 (BY MR. LEVINE)

2 Q. So, for example, for a targeted
3 fiber diameter of 5, you had a PCL
4 concentration of 12, a solvent mixture by
5 volume of 5 to 1, a collector distance of
6 19.5, a voltage of 22, a flow rate of 8, and
7 a needle gauge of 18; is that correct?

8 A. That is correct.

9 Q. And you believed that those
10 parameters would give you a fiber diameter of
11 5 micrometers; is that correct?

12 MS. WIEKER: Objection to form.

13 A. That was the targeted diameter
14 using this processing conditions that were
15 selected the best on experimentation.

16 (BY MR. LEVINE)

17 Q. And does Table 2 on Page 2800
18 give the results of those experiments?

19 MS. WIEKER: Objection to form.

20 A. Table 2 or at least an average
21 fibro diameters from the top and bottom of
22 the microfiber PCL scaffolds fabricated using
23 the conditions described in Table 1.

24 So here we have three columns.
25 The first column lists again the targeted

1 fiber diameter, and column second and third
2 list the actual fiber diameter at the top in
3 micrometers, and the second -- and the third
4 column lists the actual fiber diameter at the
5 bottom, again in micrometers.

6 (BY MR. LEVINE)

7 Q. So based on your understanding
8 of Table 2, is it correct that you were able
9 to achieve the targeted fiber diameter that
10 you were -- that you desired based on the
11 parameters set forth in Table 1?

12 MS. WIEKER: Objection to form.

13 A. As I said earlier, these
14 parameters listed in Table 1 were selected
15 following extensive experimentation by the
16 graduate student and the postdoctoral fellow
17 involved in this particular study in my lab,
18 and the conditions were listed in Table 1
19 were the ones that resulted in actual fiber
20 diameters as close as possible to the
21 targeted values, and again, Table 2 lists
22 these actual values following the
23 characterization of the scaffolds.

24 (BY MR. LEVINE)

25 Q. So is it correct that the

1 experiments were successful in that you did
2 it [phonetic] -- in fact, achieve the
3 targeted fiber diameters that you were set --
4 that you set out to achieve in Table 1?

5 MS. WIEKER: Objection to form.

6 Asked and answered.

7 A. Again, as I said earlier,
8 selecting the appropriate parameters listed
9 in Table 1, we were able to get actual fiber
10 diameters as close to the targeted fiber
11 diameters within experimental error by using
12 the particular processing conditions as
13 listed in Table 1.

14 (Marked Mikos Exhibit No. 14.)

15 (BY MR. LEVINE)

16 Q. Let me mark as the next exhibit
17 Mikos Exhibit 14, a U.S. patent application
18 US 20110293685 to Kuo, et al.

19 MS. WIEKER: Thank you.

20 (BY MR. LEVINE)

21 Q. Dr. Mikos, have you reviewed
22 this patent application in connection with
23 your opinions in this case?

24 A. Yes.

25 Q. And I -- I'll be asking you

1 some questions about Exhibit 14.

2 But if you could turn to
3 Exhibit 2, which is your declaration
4 concerning the '227 patent. Are you there?

5 And if you could turn to
6 Paragraph 118, and in Paragraph 118 in the
7 middle of the paragraph, it says:
8 "Specifically, Kuo discloses a specific
9 method to create a three-dimensional rolled
10 scaffold for treatment of muscle, tendon,
11 ligament, or nerve tissue."

12 Do you see that?

13 A. Yes.

14 Q. And you see it cites Figure 1?

15 A. Yes.

16 Q. Is it your understanding that
17 the figure on the cover of Exhibit 14 and
18 also the next page is, in fact, Figure 1?

19 A. They appear to be the same.

20 Q. The next sentence says: "First
21 Kuo seeds appropriate cells onto a scaffold."

22 Do you see that?

23 A. Yes.

24 Q. According to Figure 1, is -- is
25 that the first step in the diagram or

1 flowchart that's at Figure 1?

2 MS. WIEKER: Objection to form.

3 A. Again, Figure 1 states as --
4 following the first arrow, a schematic that
5 includes the text add cells. Whether these
6 are the appropriate cells, it's unknown.

7 (BY MR. LEVINE)

8 Q. Well, you -- just so we're
9 using the same technology, you're referring
10 to Figure 1 as a schematic?

11 A. Figure 1 is a schematic.

12 Q. Okay. Isn't the first step of
13 the schematic in Figure 1 to prepare a
14 scaffold?

15 MS. WIEKER: Objection to form.

16 A. This is the first step but, as
17 I said earlier, the schematic after the first
18 arrow.

19 (BY MR. LEVINE)

20 Q. So add cells is the second step
21 after you prepared the scaffold, correct?

22 A. Yes.

23 Q. Okay. And is it correct that
24 Figure 1 shows preparing the scaffold as a
25 sheet?

1 MS. WIEKER: Objection to form.

2 (BY MR. LEVINE)

3 Q. You can answer.

4 A. That's my understanding. It
5 looks like it's a two-dimensional scaffold
6 that the cells are seeded onto.

7 Q. And does Kuo provide
8 explanations of how to produce a
9 two-dimensional scaffold with electrospun
10 fibers?

11 MS. WIEKER: Objection to form.

12 A. It states that roll -- that
13 aligned fibers can be part of the scaffold.

14 (BY MR. LEVINE)

15 Q. Okay. If you turn to Page 3 of
16 Kuo, Paragraphs 43 to 48.

17 A. Column 3 or Page 3?

18 Q. Page 3.

19 A. Yes.

20 Q. Paragraphs 43 to 48.

21 Does that part of Kuo explain
22 how to produce fibers to be used in the
23 scaffold?

24 MS. WIEKER: Objection to form.

25 A. What I see in Paragraph 43, it

1 says: "Fibers may be produced using any
2 method known in the art such as, melt
3 spinning, extrusion, drawing, wet spinning,
4 or electrospinning. Alternatively, as the
5 concentrated solution has gel-like
6 consistency, a fiber can be pulled directly
7 from the solution."

8 (BY MR. LEVINE)

9 Q. And in Paragraph 46, it says:
10 "Electrospinning for the formation of fine
11 fibers has been actively explored recently
12 for applications such as high performance
13 filters and biomaterial scaffolds for cell
14 growth, vascular grafts, wound dressings or
15 tissue engineering."

16 Do you see that?

17 A. Yes.

18 Q. And does Huang2 address wound
19 dressing?

20 MS. WIEKER: Objection to form.

21 A. Is what?

22 (BY MR. LEVINE)

23 Q. Does Huang2 address wound
24 dressing?

25 MS. WIEKER: Same objection.

4 A. Exhibit 9.

5 Here we have nanofibers
6 matrices for skin regeneration.

8 Q. And in Paragraph 115 of your
9 report, you say: "Huang2 discloses that its
10 scaffold is used for skin wound repair."
11 Isn't that correct?

3 Q. And isn't that the same as
4 wound dressing?

6	A. It can be different.
---	-------------------------

8 Q. But it can be the same as well?

20	A. Skin wound - -
----	-------------------

MS. WIEKER: Is there a question?

24 (BY MR. LEVINE)

25 Q. It can be the same as well?

1 MS. WIEKER: Is --

2 A. The report clearly stated that
3 the Huang² disclosed that the scaffold is
4 used for skin wound -- wound repair.

5 (BY MR. LEVINE)

6 Q. And -- and would you agree
7 that's a typo in your first line of
8 Paragraph 115? That should be "wound" and
9 not "would"?

10 MS. WIEKER: You're referring
11 to the expert report?

12 MR. LEVINE: Yes.

13 MS. WIEKER: Exhibit 2?

14 MR. LEVINE: Yes.

15 A. It's wound repair.

16 (BY MR. LEVINE)

17 Q. Yeah.

18 I had -- I didn't ask you this
19 before, but have you found any -- other than
20 that, have you found any other mistakes in
21 your -- either of your expert reports?

22 A. No.

23 Q. Okay.

24 A. And I'm sure spell check didn't
25 catch that.

1 Q. I read it as -- I read it as
2 wound. I didn't even realize it was would,
3 so I'm in the same boat.

4 The next -- if we can go back
5 to Kuo, the second step of Kuo, it says to
6 add cells; is that right?

7 A. Correct.

8 Q. And does Paragraph 58 of Kuo
9 describe the types of cells that can be used?

10 A. Yes.

11 Q. And under Paragraph 58, is one
12 of the cell types epithelial cells that Kuo
13 says can be used?

14 A. Where did you see that?
15 Epithelial, yeah. There's about 20, 30, 40
16 different cell types and epithelial is one of
17 them.

18 Q. Are epithelial cells in the
19 skin?

20 MS. WIEKER: Objection to form.
21 (BY MR. LEVINE)

22 Q. You can answer.

23 A. Epidermis consists of a type of
24 epithelial cells.

25 Q. And the line right under

1 epithelial cells, it talks about fibroblast.

2 And fibroblast would be in the
3 connective tissue layer of -- of the dermis;
4 is that correct?

5 MS. WIEKER: Objection to form.
6 (BY MR. LEVINE)

7 Q. You can answer.

8 A. Fibroblast is a cell type that
9 is present in dermis, the cell layer under
10 the epidermis.

11 Q. And that would be -- would that
12 be considered connective tissue?

13 A. The dermis, yes.

14 Q. Okay. And the next line refers
15 to keratinocytes.

16 Do you see that?

17 A. I don't see that.

18 Q. It's on the very next line
19 after -- under fibroblasts the end of -- the
20 end of the line. Keratinocytes. It says
21 fibroblast, myoblast --

22 A. It says: "Epithelial,
23 endothelial, fibroblast, and nerve cells may
24 be employed in the constructs intended to
25 function as replacements or enhancements for

1 any of the wide variety of tissue types that
2 contain these cells."

3 Q. And if you go a little higher
4 up --

5 A. Oh, higher up.

6 Q. Higher up, the second sentence:
7 "In one embodiment, the cells are eukaryotic
8 cells. Exemplary cell types include, but are
9 not limited to," and then it lists a bunch of
10 different cells.

11 A. Yes, keratinocytes.

12 Q. And are keratinocytes in the
13 skin as well?

14 MS. WIEKER: Objection to form.

15 A. Keratinocytes are part of the
16 epidermis in the skin.

17 (BY MR. LEVINE)

18 Q. And then towards the end of
19 that same paragraph, it says: "In general,
20 any cells may be employed that are" --

21 A. Sorry, I don't follow you.

22 Q. Sure. I'm sorry, it's --

23 A. Which paragraph?

24 Q. Same paragraph, Paragraph 58.

25 A. Yes. In general, yes.

1 Q. It says: "In general, any
2 cells may be employed that are found in the
3 natural tissue to which the construct is
4 intended to correspond."

5 So is Kuo teaching a POSA to
6 use the cell type that corresponds to the
7 tissue the POSA is trying to treat?

8 MS. WIEKER: Objection to form.
9 (BY MR. LEVINE)

10 Q. You can answer.

11 A. What Kuo teaches is that the
12 type of cells that one may use for the
13 treatment or the regeneration or the repair
14 of the tissue, the intended tissue.

15 However, as I indicated in my
16 report, the cells are a very important
17 component of the tissue-engineering strategy
18 but not the only important component.

19 And additional considerations,
20 including the material mechanical properties,
21 the material degradation kinetics are also
22 important considerations.

23 Q. Okay. In Paragraph 125 of
24 Exhibit 2, which is your declaration for the
25 IPR concerning the '227 patent --

1 A. Yes.

2 Q. -- you talk about the elastic
3 modulus?

4 A. Correct.

5 Q. Where is that principle
6 discussed in the '227 patent?

7 MS. WIEKER: Objection to form.

8 A. Which principle?

9 (BY MR. LEVINE)

10 Q. Elastic modulus.

11 A. I'm not sure if it is discussed
12 in the '227 patent. You want me to check the
13 entire application or the examples or can you
14 point me anywhere in the '227 patent.

15 Q. I don't think it is discussed.
16 That's why I was asking you if you knew some
17 place that it was that I had not found.

18 A. Again, I don't recall. If you
19 say that it's not discussed, I'll take your
20 word.

21 Q. Okay. Let me --

22 A. But, again, my opinion is not
23 limited to the '227 patent. And the opinion,
24 again, is about how a person of skill in the
25 art would have thought at the time of the

1 invention about the regeneration of the
2 different tissues and the important material
3 parameters that the person of skill in the
4 art would need to consider.

5 (Marked Mikos Exhibit No. 15.)

6 (BY MR. LEVINE)

7 Q. Let me mark as the next exhibit
8 as Mikos Exhibit 15 a document entitled
9 "Repair of tendon defect with dermal
10 fibroblast engineered tendon in a porcine
11 model."

12 MS. WIEKER: Thank you.

13 A. Give me one second to check my
14 report. Yes, I checked.

15 (BY MR. LEVINE)

16 Q. Dr. Mikos, this -- this article
17 is published in Tissue Engineering.

18 Is this the journal that you're
19 on the editorial board on?

20 A. I'm the founding editor and
21 editor-in-chief of the journal.

22 Q. And so would you have been
23 aware of this article as the founding editor
24 editor-in-chief of the journal?

25 A. There are 50 percent chances

1 that I would have handled the peer review of
2 this articles -- article. There are
3 two editor-in-chiefs that handle the peer
4 review of all articles that are submitted to
5 Tissue Engineering.

6 So as I said, the chances are
7 50 percent that I would have handled this
8 article.

9 Q. And I think you mentioned
10 before, though, that once the issue comes out
11 you would have read the title and the
12 abstracts?

13 A. Correct. Yes.

14 Q. And I would -- I would -- well,
15 I won't say that. Strike that.

16 Do you agree that this journal
17 is a highly reputable journal?

18 A. Absolutely.

19 Q. And it's peer reviewed,
20 correct?

21 A. Absolutely.

22 Q. And if you turn to Page 777 of
23 this article under "Experimental Design," it
24 says: "The experimental group N equals 15, a
25 tendon defect was repaired by a dermal

1 fibroblast engineered tendon."

2 Do you see that?

3 A. Yes. I see what you just read.

4 Q. And it looks like they had two
5 control groups, one in which a tendon defect
6 was prepared by a tenocyte-engineered tendon,
7 and the third was a control group where the
8 tendon defect was prepared by the PGA
9 scaffold alone.

10 Do you see that?

11 A. Yes.

12 Q. And at Page 783 of this
13 article, there's a section called
14 "Biomechanical Analysis of Engineered
15 Tendon."

16 A. Yes.

17 Q. And is it correct that the
18 authors are analyzing the mechanical
19 properties of the engineered tendons by
20 assessing tensile strength?

21 MS. WIEKER: Objection to form.

22 A. That's how it was -- I'm
23 reading as the first sentence of that
24 section: "To analyze the mechanical property
25 of the engineered tendons, tensile strength

1 was chosen as a parameter."

2 (BY MR. LEVINE)

3 Q. And it says it was analyzed by
4 an ANOVA test.

5 Do you know what that refers
6 to?

7 A. I know what ANOVA stands for.
8 It's analysis of variance. It's a
9 statistical test.

10 Q. Oh.

11 And do you see in the second
12 sentence it says: "As shown in Figure 9 in
13 Table 2, the tensile strength significantly
14 increased with time in the formed tissues of
15 the three groups when P less than 0.05 when
16 analyzed by an ANOVA test."

17 And if you look at Table 2 on
18 Page 787, it looks like they analyzed it at
19 6 weeks, 14 weeks, and 26 weeks; is that
20 correct?

21 MS. WIEKER: Objection to form.

22 A. Again, that's what the table
23 shows. I mean, this is an article that was
24 published many years ago. I may have read
25 the abstract but I will -- if you ask me any

1 questions about the experimental conditions
2 or the experimental tests or the results, I
3 will have to review the article.

4 (BY MR. LEVINE)

5 Q. And in the -- not the next
6 sentence but the one after that --

7 A. Which page are we?

8 Q. Same page on 783 under
9 biomechanical analysis of engineered tendon.

10 A. Yes.

11 Q. It says: "A two-sample T test
12 comparison with each other's strengths showed
13 that there was no significant difference in
14 tensile strength between fibroblast and
15 tenocyte engineered tendons in all three time
16 points"; is that correct?

17 A. That's what the sentence reads.

18 Q. And is it correct that dermal
19 fibroblasts were the cell types that were
20 experimented with in Huang2 that we were
21 discussing earlier?

22 MS. WIEKER: Objection to form.

23 A. Specific type of fibroblast was
24 used in Huang2. I read Section 2.3 on
25 Page 1792 of the Exhibit 9 that says normal

1 primary human skin fibroblast from newborn
2 forensic -- foreskin were a gift from the
3 Dr. James Rheinwald of the Harvard NIH Skin
4 Disease Research Center.

5 (BY MR. LEVINE)

6 Q. And are those -- those are
7 dermal fibroblast, a type of -- a specific
8 type of dermal fibroblast; is that right?

9 MS. WIEKER: Objection to form.

10 A. They're all referred here as
11 dermal fibroblast. It's a different type of
12 fibroblast. There are many different types
13 of fibroblast.

14 (BY MR. LEVINE)

15 Q. Dermal meaning from the skin,
16 correct, from the dermis layer of the skin?

17 A. The word "dermal" would refer
18 to that.

19 Q. And let me ask you a -- a
20 question. If we turn back to Exhibit 15, the
21 Liu article, on Page 786 on the right-hand
22 column, it says: "Compared to BMSCs, dermal
23 fibroblasts share more common characteristics
24 with tenocytes. Both cells are terminally --
25 are terminal differentiated cells and

1 originate -- originate from mesoderm."

2 Do you agree with that
3 statement?

4 MS. WIEKER: Objection to form.

5 A. I'm positive about the
6 tenocytes. I am not a hundred percent sure
7 about the dermal fibroblast, whether they
8 originate from the mesoderm.

9 (BY MR. LEVINE)

10 Q. Okay. The next sentence says:
11 "During in vitro culture, both exhibit
12 similar cell morphology."

13 Do you agree with that
14 statement?

15 A. Again, that's their statement
16 that characterizes the observations of the
17 authors from the cell culture experiments, so
18 it is what it is.

19 Q. Okay. "Biochemically both
20 cells produce major extracellular matrix
21 Type I collagen, although dermal fibroblast
22 also produced Type 3 collagen."

23 Sitting here today, do you
24 agree with that statement as a scientific
25 matter?

1 MS. WIEKER: Objection to form.

2 A. Again, the authors refer to the
3 specific cell culture conditions that they
4 employ in their studies. This is a result of
5 the study. The study was -- the manuscript
6 was subject to peer review and it passed the
7 peer review. I don't -- and the article was
8 not retracted afterwards so I don't have any
9 reason not to believe the results.

10 (BY MR. LEVINE)

11 Q. And then it says:
12 "Functionally both cells form connective
13 tissues to carry out tissue support --
14 supporting functions."

15 Do you agree with that
16 statement as well in a general context and
17 not necessarily limited to this particular
18 article?

19 MS. WIEKER: Objection to form.

20 A. Again, in a general case, not
21 related to this article or this particular
22 case and the particular patents and
23 declaration, this is -- in general I say this
24 is a correct statement.

25

1 (BY MR. LEVINE)

2 Q. Do you agree that dermal
3 fibroblasts are an easily accessible cell
4 source?

5 MS. WIEKER: Objection to form.

6 A. Again, in the context of this
7 article, one will have to consider how the
8 cells were accessible and whether the
9 statement is valid. I don't have any reason
10 not to believe that this is not a valid
11 statement.

12 (BY MR. LEVINE)

13 Q. And in the next -- very next
14 paragraph that starts with the words "the
15 result," is it correct that, at least in the
16 author's view, that dermal fibroblasts may --
17 may replace tenocytes for tendon engineering?

18 MS. WIEKER: Objection to form.

19 (BY MR. LEVINE)

20 Q. You can answer.

21 A. Where did you read that?

22 Q. It's in the very next
23 paragraph.

24 A. So the first sentence says:
25 "The result of the study demonstrated that

1 tendons engineered by two different cell
2 types exhibited similar features in their
3 gross view, histology, and biomechanical
4 property, indicating that dermal fibroblasts
5 may replace tenocytes for tendon
6 engineering."

7 Q. Right. So my question was: Is
8 it correct that the authors at least
9 concluded, based on this study, that dermal
10 fibroblasts may replace tenocytes for tendon
11 engineering?

12 MS. WIEKER: Objection to form.

13 Lack of foundation.

14 A. Again, one needs to consider
15 that this particular study was conducted in
16 the porcine model in pigs, so I would limit
17 the results and the conclusions to pigs.

18 (BY MR. LEVINE)

19 Q. And weren't they using the pig
20 as a acceptable model for what's likely to
21 happen in humans?

22 MS. WIEKER: Objection to form.

23 Lack of foundation.

24 A. There is no such thing as
25 acceptable model. There's no study that

1 works in animal model necessary translating
2 to humans.

3 (BY MR. LEVINE)

4 Q. But they weren't doing the
5 study necessarily to repair injuries to pigs,
6 the idea of the study was as a model to see
7 what would happen in humans, correct?

8 MS. WIEKER: Objection to form.
9 Lack of foundation.

10 (BY MR. LEVINE)

11 Q. You can answer.

12 A. Again, in the model, that
13 worked. However, the results from that model
14 do not translate into humans. And there are
15 many studies that work in many models that do
16 not translate into humans.

17 Q. If the porcine model was not a
18 representative model of humans, would the
19 paper have been published in Tissue
20 Engineering?

21 MS. WIEKER: Objection to form.

22 A. This is the reason that the
23 authors stated there was porcine model even
24 in the title so that the readers can realize
25 that this is done in the porcine model and

1 the community knows that whatever is done in
2 any model, although may appear encouraging,
3 does not translate into humans.

4 (BY MR. LEVINE)

5 Q. Necessarily, correct?

6 MS. WIEKER: Objection to form.

7 A. In most conditions.

8 (BY MR. LEVINE)

9 Q. Let me mark as the next
10 exhibit, which is exhibit -- this is
11 Exhibit 16, a patent application to Lee,
12 et al., with a number 0331980.

13 There you go.

14 A. Thank you.

15 (Marked Mikos Exhibit No. 16.)

16 MS. WIEKER: Thank you.

17 (BY MR. LEVINE)

18 Q. Is this one of the publications
19 you reviewed in connection with your expert
20 opinions in this case?

21 A. Yes.

22 Q. If you'd turn to Paragraph 63
23 of Lee, which --

24 A. Which page is that?

25 Q. It's on Page 5.

1 A. Yes.

2 Q. And it says -- the first word
3 is "electrospinning."

4 Do you see that?

5 A. Yes.

6 Q. And in this paragraph, is Lee
7 describing how he electrospun -- strike that.

8 In this paragraph, is Lee
9 explaining how she electrospun the nano --
10 the nano -- the nanofibers that are used in
11 this publication?

12 MS. WIEKER: Objection to form.

13 A. It's actually he.

14 (BY MR. LEVINE)

15 Q. Is it he? I stand corrected.
16 My original question was -- was correct.

17 It -- in this paragraph, does
18 Lee explain how Lee obtained the electrospun
19 fibers used in the experiments discussed in
20 this publication?

21 MS. WIEKER: Objection to form.

22 A. Give me one second --

23 (BY MR. LEVINE)

24 Q. Sure.

25 A. -- to refresh my memory.

1 Yes.

2 Q. And just as -- do you, by any
3 chance, know Sang Jin Lee?

4 A. I do know him.

5 Q. In what context?

6 A. We have collaborated in the
7 past and we are collaborating presently. And
8 we have coauthored papers together and we
9 were awarded research grants together.

10 Q. Would you consider him an
11 expert in the field of tissue engineering?

12 MS. WIEKER: Objection to form.

13 A. Dr. Sang Jin Lee, based on his
14 publication or his record in the community,
15 yes, I will characterize him as an expert in
16 the tissue engineering field.

17 (BY MR. LEVINE)

18 Q. And what about James Yoo, do
19 you know that individual who is another
20 inventor listed on this patent?

21 A. I do know him, Dr. James Yoo.

22 Q. And how do you know Dr. James
23 Yoo?

24 A. Same capacity as Dr. Sang Jin
25 Lee. We have collaborated together in the

1 past. We have published papers together in
2 the past. We have received research awards
3 together in the past.

4 Q. And Anthony Atala, do you know
5 him as well?

6 A. I know him as well. He's part
7 of the same group. He's actually the leader
8 of the group at WFIRM, the Wake Forest
9 Institute for Regenerative Medicine.

10 We have collaborated together,
11 received grants together, published papers
12 together.

13 I must say also that we have
14 participated together in many continuing
15 education courses.

16 I offer a continuing education
17 course on advances in tissue engineering
18 every summer in Houston at Rice University
19 that until recently was in person.

20 And recently it has -- after
21 the pandemic, it's virtual. But Dr. Yoo,
22 Dr. Atala have participated. And I also
23 participated over the years in the continuing
24 education course that Dr. Atala organizes at
25 Wake Forest called "Regenerative Medicine

1 Essentials."

2 Q. By any chance, have you talked
3 to any of the three inventors about any of
4 your opinions in this case?

5 A. No.

6 Q. Do they know that you are
7 working as an expert in this case?

8 MS. WIEKER: Objection to form.
9 Lack of foundation.

10 A. I have not discussed this case
11 or the details of this case or my involvement
12 in this case or my reports in this case with
13 them. And they are not aware of my
14 involvement in any way.

15 (BY MR. LEVINE)

16 Q. So if we can go back to
17 Paragraph 63.

18 A. Exhibit 16 again.

19 Q. Yes. The -- the Lee patent
20 publication.

21 A. Okay. Yes.

22 Q. Towards the bottom of the
23 paragraph, third-to-last sentence, it says:
24 "After the fabrication process, the
25 electrospun PCL/collagen nanofiber meshes

1 were crosslinked under vapor of 2.5 percent
2 glutaraldehyde solution for 6 hours to
3 increase stability and strength of collagen."

4 Is it correct that the authors
5 are reporting that they crosslinked the
6 PCL/collagen nanofiber measures to increase
7 their stability and strength?

8 MS. WIEKER: Objection to form.
9 (BY MR. LEVINE)

10 Q. You can answer.

11 A. Glutaraldehyde cannot crosslink
12 PCL, so glutaraldehyde can only crosslink
13 collagen.

14 So what they did is that they
15 used a glutaraldehyde to crosslink the
16 collagen and increase the stability and
17 strength of the collagen.

18 Q. So are -- are you saying
19 they -- they crosslinked the collagen before
20 they electrospun the fibers?

21 A. No.

22 MS. WIEKER: Objection to form.
23 (BY MR. LEVINE)

24 Q. Okay.

25 A. They crosslink the collagen

1 after they electrospun the fibers.

2 Q. So the fibers were -- were a
3 blend of PCL and collagen and then they used
4 crosslink -- crosslinking to increase the
5 strength and stability of the collagen
6 component of the blended PCL/collagen fibers.

7 Is that right?

8 MS. WIEKER: Objection to form.

9 A. That's how I read the statement
10 here.

11 (BY MR. LEVINE)

12 Q. Sitting here today, and -- and
13 knowing their reputation, do you -- do you
14 disagree with the authors of this publication
15 that their crosslinking of the collagen
16 increased its strength in the context of the
17 blended PCL/collagen fibers?

18 MS. WIEKER: Objection to form.

19 A. I'm sure that the authors had
20 reasons to crosslink the collagen. One of
21 the parameters here that is very important to
22 consider for crosslinking is the relative
23 amount of collagen to PCL that they used in
24 the study.

25 I offer extensive opinions in

1 my report about how blending of PCL with
2 collagen can increase the mechanical
3 properties in the stability of the fibers.

4 Obviously, the PCL-to-collagen
5 ratio is a very important parameter in
6 increasing the stability of the fibers.

7 Obviously, for the conditions
8 reported here in this patents, that the
9 authors felt it was necessary to include the
10 crosslinking of the collagen.

11 (BY MR. LEVINE)

12 Q. Okay. Can I ask you to turn --
13 same exhibit, Exhibit 16, the second page,
14 Figures 1E, 1F, 1G, and 1H.

15 A. Yes.

16 Q. Are those the type of analysis
17 that you're referring to when we were talking
18 about in the beginning of your deposition
19 your paper at 537 where you said you did
20 histograms of the angles of orientation?

21 MS. WIEKER: Objection to form.

22 A. You're referring to the paper
23 by Smoak --

24 (BY MR. LEVINE)

25 Q. Yes.

1 A. -- published in Science
2 Advances?

3 We did similar analysis. Now,
4 however, the histograms that we produced, to
5 the best of my recollection, were more
6 accurate than this one.

7 And that is they reported the
8 number of fibers in increments of 10 degrees
9 rather than 30 degrees as shown here in this
10 document.

11 Q. So your paper reported in
12 increments of 10 degrees and they're
13 reporting in increments of 30 degrees; is
14 that right?

15 A. That's in Figure 1E through H,
16 yes.

17 Q. Okay. Would this be considered
18 an FFT analysis, then?

19 MS. WIEKER: Objection to form.

20 A. This was the result of an FFT
21 analysis using the ImageJ software.

22 (BY MR. LEVINE)

23 Q. In Lee?

24 A. This kind of analysis --

25 Q. Yeah.

1 A. -- that was done in our lab,
2 that was done with as an FFT analysis using
3 ImageJ.

4 I think the same type of
5 analysis was done here. I would have to
6 double-check, but I don't think that they did
7 any different analysis.

8 Q. Okay.

9 MR. LEVINE: A good time for a
10 break?

11 MS. WIEKER: Yep.

12 MR. LEVINE: Okay.

13 THE VIDEOGRAPHER: Off the
14 record at 3:47 p.m.

15 (Break from 3:47 p.m. to 4:02 p.m.)

16 THE VIDEOGRAPHER: Back on the
17 record at 4:02 p.m. Beginning Tape 5.
18 (BY MR. LEVINE)

19 Q. Dr. Mikos, during -- during the
20 breaks, did you discuss the substance of your
21 testimony with your counsel?

22 A. No.

23 Q. And if I can ask you to turn to
24 Paragraph 158 of Exhibit 2, which is your
25 report on the '227, the first sentence --

1 second sentence states: "Lee does not
2 express any doubt regarding the alignment of
3 its fibers."

4 Do you see that?

5 A. Yes.

6 Q. Do you agree that Lee obtained
7 aligned blended collagen/PCL fibers?

8 MS. WIEKER: Objection to form.

9 A. The ECM results that are
10 presented in Lee's Exhibit 16 indicate
11 aligned fibers. For example, when I see
12 Figure 1D and 1H, that's my understanding
13 that these are aligned fibers and, again,
14 these fibers were formed with PCL/collagen
15 blends 1 to 1.

16 (BY MR. LEVINE)

17 Q. Okay. If I can turn you back
18 to Exhibit 4, which is the '227 patent.

19 A. Yes.

20 Q. In any example of the '227
21 patent, did the inventors actually treat a
22 tendon injury?

23 MS. WIEKER: Objection to form.

24 A. In any of the four examples?
25

1 (BY MR. LEVINE)

2 Q. Yes.

3 A. Let me review those examples.

4 I did not see in Examples 1
5 through 4 of the '227 patents any mention of
6 an animal model for the tissue repair, and
7 the tissue repair that you're referring to
8 was the tendon, right?

9 Q. Correct.

10 A. Yes.

11 Q. And since you've just reviewed
12 the -- the examples, in any of the examples
13 of the '227 patent did the inventors actually
14 treat a ligament injury?

15 MS. WIEKER: Objection to form.

16 A. Again, just reading Examples 1
17 through 4 of the '227 patent, I don't see in
18 the examples any study involving an animal
19 model for the repair of ligament.

20 (BY MR. LEVINE)

21 Q. And the same question regarding
22 nerve: In any example of the '227 patent,
23 did the inventors actually treat a nerve
24 injury?

25 MS. WIEKER: Objection to form.

1 A. There are studies involving the
2 dorsal root ganglia in the examples that
3 would translate to the repair of nerve
4 tissue.

5 (BY MR. LEVINE)

6 Q. But they don't actually treat a
7 nerve tissue, correct?

8 MS. WIEKER: Objection to form.

9 A. What would you call treat?

10 (BY MR. LEVINE)

11 Q. Actually implant a scaffold,
12 treat a nerve injury.

13 MS. WIEKER: Objection to form.

14 A. There are in vitro studies that
15 are support -- that are presented but I don't
16 have any individual studies in Examples 1
17 through 4 of the '227 patent.

18 (BY MR. LEVINE)

19 Q. Okay.

20 MR. LEVINE: I have no further
21 questions.

22 MS. WIEKER: Okay. If it's all
23 right with you, let's just stay on the
24 record. I'm going to confirm my notes
25 and we'll go from there.

1 Dr. Mikos, I do not have any
2 questions for you on redirect.

3 THE WITNESS: Thank you.

4 MS. WIEKER: Thank you for
5 your -- your time today.

6 MR. LEVINE: Thank you very
7 much for your time today.

8 THE WITNESS: Thank you.

9 THE VIDEOGRAPHER: Off the
10 record at 4:10 p.m.

11 (The deposition concluded at 4:10 p.m.)
12
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25

Please indicate changes on this sheet of paper, giving the change, page number, line number and reason for the change. Please sign each page of changes.

[illegible]

ANTONIOS G. MIKOS

S I G N A T U R E O F W I T N E S S

I, ANTONIOS G. MIKOS, solemnly swear or
affirm under the pains and penalties of
perjury that the foregoing pages contain a
true and correct transcript of the testimony
given by me at the time and place stated with
the corrections, if any, and the reasons
therefor noted on the foregoing correction
page(s), and that I am signing this before a
Notary Public.

ANTONIOS G. MIKOS

STATE OF _____ *

COUNTY OF _____ *

SUBSCRIBED AND SWORN TO BEFORE
ME BY ANTONIOS G. MIKOS on this, the _____
day of _____, 2026.

Notary Public, State of _____

My Commission Expires: _____

Job 7048658-001

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4 EMBODY, INC. AND ZIMMER BIOMET HOLDINGS,
5 INC.,
6 Petitioner

7 V.

8 LIFENET HEALTH,
9 Patent Owner.

10 Case IPR2025-00248
U.S. Patent No. 10,137,223

11 THE STATE OF _____:
12 COUNTY OF _____:

13 I, MENDY A. SCHNEIDER, a Certified
14 Shorthand Reporter in and for the State of
15 Texas, do hereby certify that the facts as
16 stated by me in the caption hereto are true;
17 that the above and foregoing answers of the
18 witness, ANTONIOS G. MIKOS, to the
19 interrogatories as indicated were made before
20 me by the said witness after being first duly
21 sworn to testify the truth, and same were
22 reduced to typewriting under my direction;
23 that the above and foregoing deposition as
24 set forth in typewriting is a full, true, and
25 correct transcript of the proceedings had at

1 the time of taking of said deposition.

2 I further certify that I am not, in any
3 capacity, a regular employee of the party in
4 whose behalf this deposition is taken, nor in
5 the regular employ of this attorney; and I
6 certify that I am not interested in the
7 cause, nor of kin or counsel to either of the
8 parties.

9 That the amount of time used by
10 each party at the deposition is as follows:

11 MR. LEVINE - 05:19:35
12
13

14 GIVEN UNDER MY HAND AND SEAL OF OFFICE,
on this, the 23rd of January 2026.

15 
16

17 MENDY A. SCHNEIDER, CSR, RPR
Certification No.: 7761
Expiration Date: 1-31-2027
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