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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
INTER PARTES REVIEW NO: IPR2025-00827

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MIM SOFTWARE INC.,	:	
Petitioner,	:	
	:	IPR2025-00827.
vs.	:	U.S. PATENT NO.
	:	11,941,817
EXINI DIAGNOSTICS AB,	:	
Patent Owner.	:	

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DEPOSITION OF BRUCE ROSEN, M.D., PH.D., a witness called by counsel for the Patent Owner Exini Diagnostics AB, before Jane M. Werner, Registered Merit Reporter and Notary Public in and for the Commonwealth of Massachusetts, at the Offices of Massachusetts General Hospital, Building 149, 13th Street, Room 2301E, Charlestown, Massachusetts, on Tuesday, January 6, 2026, commencing at 9:00 a.m.
PRESENT:

Thompson Hine
(By Jeffrey Metzcar, Esq.)
Discovery Place, 10050 Innovation Drive,
Suite 400, Dayton, Ohio 45342-4934.
for Petitioner, MIM Software Inc.
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PRESENT: (Continued)

Choate, Hall & Stewart LLP

(By John Calhoun, Esq.; Derek Farquhar,
Esq.; and Ronen Adato, Esq.)

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* * * * *

I N D E X

WITNESS: DIRECT CROSS REDIRECT RECROSS

BRUCE ROSEN, M.D., Ph.D.

(By Mr. Calhoun) -- 5

(By Mr. Metzcar) 151

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E X H I B I T S

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E X H I B I T S
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P R O C E E D I N G S

BRUCE ROSEN, M.D., PH.D.

a witness called for examination by counsel for the Patent Owner Exini Diagnostics AB, having been satisfactorily identified by the production of his driver's license and being first duly sworn by the Notary Public, was examined and testified as follows:

CROSS EXAMINATION

BY MR. CALHOUN:

Q. Good morning, Dr. Rosen.

A. Good morning.

Q. My name is John Calhoun. I'm from the law firm of Choate, Hall & Stewart, and I represent the patent owners, Exini Diagnostics, here today.

Dr. Rosen, have you been deposed before?

A. I have been.

Q. And when was that?

A. I've been deposed on a few occasions. Maybe three or four occasions over the last 25 years or so. The most recent was probably two or two and a half years ago.

Q. And was that the Steady State Imaging case?

A. Yes.

1 Q. So you may already be familiar with some of
2 these ground rules that I'll go over, since you've
3 been deposed a few times before. But we'll go over
4 them anyway, just to make sure we're on the same
5 page.

6 So please answer all questions verbally and
7 not with physical movements, like a nod or a shrug,
8 because we're not taking a video of your testimony
9 today.

10 A. Understood.

11 Q. And so that the court reporter can get it
12 on the record, please wait before I've completed my
13 questions before responding, and I'll do the same
14 with your answers. That makes it easier for the
15 court reporter and gives some clear testimony.

16 If you need to have a question repeated,
17 please just let me know, and I'm happy to repeat the
18 question. And if you don't understand a question,
19 please let me know, and I'll do my best to rephrase
20 it.

21 A. Okay.

22 Q. Does that all make sense?

23 A. It does.

24 Q. And is there any reason that you can't

1 testify truthfully and fully here today?

2 A. There is not.

3 Q. No medications or anything that would
4 prevent that?

5 A. No, sir.

6 Q. What did you do to prepare for your
7 deposition today?

8 A. Read a number of different documents, and I
9 spoke to Mr. Metzcar on several occasions over the
10 last several months.

11 Q. And without disclosing any of the contents
12 of your discussions with Mr. Metzcar, how many times
13 did you meet with Mr. Metzcar?

14 A. Many times. I would say maybe half a dozen
15 as a guess.

16 Q. And across those half dozen times, about
17 how long in total did you spend preparing with Mr.
18 Metzcar?

19 A. In specific conversations with him,
20 typically they would be hour-long meetings. Some
21 might be a little shorter. Some were significantly
22 longer; two or three hours.

23 Q. And you mentioned you reviewed documents in
24 preparation for your deposition today.

1 Which documents did you review?

2 A. I reviewed a number of the patents,
3 including the patent in question, the '817 patent,
4 and other documents that I made reference to in my
5 deposition report.

6 Q. And so you only reviewed documents that you
7 cited in your declaration?

8 A. Those are the ones that I used as the basis
9 of forming my opinions; plus my general, you know,
10 background and expertise in the field of medical
11 imaging over the last number of years.

12 Q. Were there any documents you reviewed while
13 preparing for today's deposition that weren't cited
14 in your declaration?

15 A. No specific documents, no.

16 Q. And did you speak with anyone else to
17 prepare for this deposition other than Mr. Metzcar
18 or one of his colleagues?

19 A. I did not.

20 Q. How did you become aware of this IPR?

21 A. I believe a partner or an associate of Mr.
22 Metzcar's introduced me to the possibility --
23 somebody I had worked with on a previous case; the
24 one you made reference to.

1 Q. And were you familiar with the company, MIM
2 Software, before being contacted about potentially
3 working as an expert for MIM Software?

4 A. I was not.

5 Q. And did you know anyone at MIM Software
6 before being contacted about potentially serving as
7 an expert for this IPR?

8 A. I did not.

9 Q. Were you familiar with G.E. or G.E.
10 Healthcare before being contacted about working as a
11 potential expert for this IPR?

12 A. I was.

13 Q. How so?

14 A. G.E. is a major vendor of medical imaging
15 equipment, some of which we have within our
16 department of radiology. And I've had a
17 relationship with them for many, many years now.

18 Q. Have you previously served as an expert
19 witness on behalf of G.E. Healthcare or one of the
20 G.E. companies?

21 A. Well, we did talk about the previous issue
22 with SSI. That's the only time I can remember.
23 There was a case many years ago where G.E. was
24 another plaintiff or defendant. I always get those

1 confused. I was working for a different medical
2 imaging company. And this was the FONAR case.

3 Q. So you were in that case adverse to the
4 G.E. entity?

5 A. No. We were alongside them, but I wasn't
6 working directly with G.E.

7 Q. Oh. So there was a G.E. entity that was a
8 co-plaintiff or co-defendant?

9 A. Correct.

10 Q. How many times have you served as an expert
11 witness on behalf of G.E. Healthcare or a different
12 G.E. entity?

13 A. I believe just that one time in the SSI
14 case.

15 MR. CALHOUN: I'd like to introduce, Dr.
16 Rosen, what's been previously marked in this
17 proceeding as Exhibit 1001.

18 (Document previously marked as
19 Exhibit 1001 for identification)

20 Q. Do you recognize this document?

21 A. I do.

22 Q. And what is it?

23 A. It is what we've been calling the '817
24 patent.

1 Q. Can you take a look on the first page at
2 the top left, where it says "Inventors."

3 A. Okay.

4 Q. And do you see those four names there?

5 A. I do.

6 Q. Prior to this IPR, had you heard of any of
7 the four inventors listed here?

8 A. Not that I can recall, no.

9 Q. And do you see one line up, there's a list
10 of "Applicant: Exini Diagnostics AB"?

11 A. I see that.

12 Q. Prior to this IPR, were you familiar with
13 Exini?

14 A. I was not.

15 MR. CALHOUN: I'd like to now introduce
16 what's been marked Exhibit 1003.

17 (Document previously marked as Rosen
18 Exhibit 1003 for identification)

19 Q. Do you recognize this document?

20 A. The first page is the first page of my CV.

21 Q. This is your CV. Is all of the information
22 in your CV accurate?

23 A. To the very best of my knowledge, it is.

24 Q. And is this a complete summary of your

1 relevant experiences for purposes of the opinions in
2 your declaration?

3 A. It is complete, with the possible exception
4 that perhaps one or two other articles may have
5 found their way into press since the time that this
6 was prepared, which I see it looks like January of
7 2025. So it's possible there may be some additional
8 papers subsequent to that.

9 Q. And can you think what those papers are?

10 A. I cannot off the top of my head, no.

11 Q. Do you know that there are affirmatively
12 such papers, or you're just unsure, given the time
13 delta?

14 A. I am unsure, given the time delta.

15 Q. Other than the potential of additional
16 publications, is there any other new information
17 concerning your education or experience that
18 supports your opinions in today's IPR that arose
19 since you prepared this version of your CV?

20 A. I think this CV does represent a
21 comprehensive view of my background in the format
22 that medical school likes it to be in.

23 Q. Understood.

24 You received your Ph.D. from MIT in medical

1 physics in 1984; right?

2 A. If that's what it says, yes, indeed, I did.
3 We can go to my office and look at the diploma, but
4 I believe this is correct, yes.

5 Q. We'll take your word for it.

6 And what did your studies in that Ph.D.
7 focus on?

8 A. It focused on a new technique for magnetic
9 resonance imaging, called "magnetic resonance
10 chemical shift imaging." And that was the topic of
11 my thesis.

12 Q. And was that focused on the brain?

13 A. No. It was focused on both body imaging
14 and brain imaging.

15 Q. What do you mean by "body imaging"?

16 A. The specific experiments I did were
17 quantifying liver content in fatty liver disease.

18 Q. And then after getting your Ph.D., you were
19 a radiology resident at MGH from about 1984 to 1987;
20 is that right?

21 A. That's correct.

22 Q. Please turn to the bottom of Page 1. And
23 under "Internship and Residencies," there's a
24 reference to -- the first line under "Internship and

1 Residencies" says, "1983 to 1984. Clinical and
2 Research Fellow in the Department of Radiology at
3 MGH."

4 And then under "Research Fellowships," the
5 second line, it says the same thing that I just read
6 under "Internship and Residencies."

7 Are those referring to the same experience,
8 or are those different experiences?

9 A. They are the same experience listed in two
10 places, because it had both a clinical and research
11 component to it.

12 Q. And then since your training in various
13 capacities, you've been a researcher and professor
14 at HMS and MGH; is that right?

15 A. That is correct.

16 Q. Could you please turn to Page 12 of your
17 CV, please.

18 If you go down a number of lines under the
19 subheading called "Current," you'll see an entry
20 that says "2022 to 2027. Nutrition Obesity Research
21 Center at Harvard (NORCH) Metabolic Imaging Core - 3
22 NIH."

23 A. I see that.

24 Q. Why is this highlighted?

1 A. Honestly, for no particular reason. Every
2 so often -- there's no particular reason why this is
3 different than others. It's just some artifact of
4 the process by which my assistant and I generate.

5 Q. Just essentially a highlighted typo?

6 A. Correct.

7 Q. If we turn to Page 27, this begins a list
8 of your publications; is that correct?

9 A. That is correct.

10 Q. And there are over 470 articles in
11 radiology and neuroimaging here, right?

12 A. Amongst other fields, yes.

13 Q. None of these publications involve
14 segmenting an anatomical image using a convolutional
15 neural network to address prostate cancer, right?

16 A. Constrained in that way, that is a correct
17 statement.

18 Q. And none of these publications use
19 segmentation to quantify tracer uptake in organs by
20 analyzing a 3D functional image, right?

21 A. I'm not sure that that's true. Do you want
22 to state one more time the constraints that you --

23 Q. Happy to.

24 None of these publications use segmentation

1 to quantify tracer uptake in organs by analyzing a
2 3D functional image; is that right?

3 A. I'm not sure that's correct, no.

4 Q. And what do you recall that contradicts
5 that?

6 A. I've done some significant work in
7 measuring a tumor functional uptake registered to
8 anatomical images using, you know, PET for the
9 functional imaging and MRI for the anatomical
10 imaging.

11 Q. Can you point me to the study that involves
12 the use of a PET image as the 3D functional image?

13 A. Uh-hum. Give me a moment here.

14 Q. Take your time, please.

15 A. (Witness reviews document) This would be
16 easier with a "search" function, I'm afraid.

17 (Witness reviews document)

18 Reference 185 would be one example.

19 Q. And that is the Aronen paper; "High
20 microvascular blood volume is associated with high
21 glucose uptake and tumor angiogenesis in human
22 gliomas"?

23 A. That's correct.

24 Q. What did that paper involve?

1 A. That paper involved imaging patients with
2 brain tumors -- that's the human gliomas -- using
3 magnetic resonance imaging and positron emission
4 tomography.

5 Q. And as you mentioned, glioma is a brain
6 tumor, right?

7 A. That is correct.

8 Q. And so none of your publications use
9 segmentations to quantify tracer uptake in organs by
10 analyzing a 3D functional image for the purposes of
11 prostate cancer; is that fair?

12 A. I believe that would be a fair statement,
13 yes.

14 Q. And none of them use a PSMA binding agent,
15 right?

16 A. I believe that's also true.

17 Q. In fact, none of these publications involve
18 the analysis of a 3D functional image obtained using
19 a PSMA binding agent, right?

20 A. Well, there, I would have to check to see
21 if my more recent articles may include PSMA, because
22 we do research with PSMA.

23 Q. Please go ahead.

24 A. No. They would be in the articles that

1 happened in 2025.

2 Q. They wouldn't be in your CV?

3 A. They would be in the more recent.

4 Q. Am I right that you haven't personally
5 authored any segmentation code bases?

6 A. Could you please describe what you mean by
7 "code bases."

8 Q. Have you designed any training procedures
9 for deep learning networks?

10 A. Do you mean, have I written the code to do
11 such trainings?

12 Q. Yes.

13 A. I have not.

14 Q. What's your understanding of the term
15 "segmentation code base"?

16 A. I would understand it to be a code,
17 computer algorithms, to perform the process of
18 segmentation.

19 Q. And you haven't -- I think this is
20 incorporated in your prior answer, but you haven't
21 personally authored any such segmentation code base?

22 A. I have certainly authored manuscripts that
23 describe some code bases. My role in the paper was
24 not to write the code itself.

1 Q. Dr. Rosen, you understand the priority date
2 of the '817 patent at issue in the IPR is January
3 7th, 2019, correct?

4 A. I do understand that.

5 Q. Let me ask you a big picture question.

6 Did the field of machine learning change a
7 lot between 2012 and January 2019?

8 A. I would say the field of machine learning
9 has been an active one during that period and before
10 it and after it.

11 Q. And so just focus for the moment on 2012 to
12 January 2019. Can you summarize for me the major
13 ways in which the field changed?

14 A. Well, neural nets had been around for some
15 time before 2012.

16 I believe it was in 2012 the AlexNet
17 performance in the ImageNet competition showed that
18 a particular flavor of neural nets, a convolutional
19 neural net, could outperform others. So that was a
20 significant advance in the 2012 time frame. Of
21 course, there have been -- there was a lot of
22 excitement generated and advances since then.

23 Q. And did the field of machine learning
24 change a lot between 2012 and 2019; specifically in

1 the subfield of medical imaging analysis?

2 A. It was an active area before 2012 and
3 remained active after 2012.

4 Q. And how did it change after 2012, but
5 before January 2019? Or -- go ahead.

6 A. Maybe you can help me understand exactly
7 what you're talking about when you ask for change.

8 Q. Sure. Sitting here today, can you identify
9 any major changes in the technical ability or
10 function of machine learning and machine learning
11 algorithms as applied to medical imaging analysis
12 between 2012 and 2019?

13 A. Certainly, the increasingly common use of
14 these convolutional neural nets that had been
15 developed prior to 2012, they came into greater use
16 in medical applications during the time frame that
17 you're discussing.

18 Q. In medical imaging analysis specifically?

19 A. In medical imaging analysis.

20 Q. And what do you mean by, "they came into
21 greater use"?

22 A. Investigators began to use that particular
23 architecture over other architectures because of the
24 perceived advantages that they may confer. It was

1 an active area of research.

2 Q. And can you think of any other major ways
3 in which the use of machine learning and medical
4 imaging analysis changed between 2012 and January
5 2019?

6 A. My recollection is that the widespread
7 commercialization of those tools probably occurred
8 towards the end of that period and extending into
9 the 2020s, when the field became much more active
10 commercially. That was, in my mind, probably the
11 biggest change.

12 Q. And has the field of machine learning
13 changed a lot since January 7th, 2019 until today?

14 A. It has continued to evolve rapidly and
15 dynamically, yes.

16 Q. And how so, as applied to medical imaging
17 analysis?

18 A. One element is, as I just mentioned, that
19 there's been significant commercial development in
20 that space. A number of companies, big and small,
21 began to build tools using some of the more facile
22 machine learning algorithms for various medical
23 imaging purposes.

24 Q. Prior to January 7th, 2019, in your

1 experience, was it relatively straightforward to use
2 machine learning to segment 3D medical images in the
3 clinical environment?

4 A. There certainly was quite a lot of work in
5 image segmentation prior to that date. It was
6 certainly an active area of research. And there
7 were some domains of clinical applications.

8 Q. I'll ask that one more time, with emphasis
9 on the angle that I'm most interested in in the
10 question.

11 So prior to January 7th, 2019, in your
12 experience, was it relatively straightforward to use
13 machine learning to segment 3D medical images in the
14 clinical environment?

15 A. Some of the tools were. And they were
16 used.

17 Q. What's an example of a tool that was
18 straightforward to use for medical imaging analysis
19 prior to January 7, 2019?

20 A. The Freesurfer tool would be one example
21 that I'm familiar with.

22 Q. What would be an example of a tool that was
23 not straightforward to use for medical imaging
24 analysis prior to January 7, 2019?

1 A. I'm not sure I can easily answer that
2 question.

3 Q. You can't think of one right now?

4 A. What do you mean by "wasn't straightforward
5 to use"? I want to make sure I understand the
6 question before I give up on it.

7 Q. I mean a tool whose application, for
8 purposes of medical imaging analysis, was broadly
9 known and one would apply it, reasonably expecting
10 to succeed.

11 A. And you're asking for tools that did not
12 meet that criteria?

13 Q. Correct.

14 A. Well, there are any number of tools that
15 were developed by investigators that were less
16 useful than others.

17 Q. So I'm not asking about their utility. I'm
18 asking about whether someone in your position, say,
19 prior to January 7th, 2019, would have reasonably
20 expected that they could use that machine learning
21 tool to perform 3D segmentation on a medical image
22 and expect to succeed in doing so fully accurately.

23 Can you think of any machine learning tools
24 prior to January 7th, 2019 that would not fit that

1 bill?

2 MR. METZCAR: Objection, form. You can
3 answer.

4 A. Um, nothing immediately comes to mind.

5 Q. Great. Thank you.

6 A. Perhaps tools that don't have utility just
7 don't become widely known.

8 Q. Understood. Thank you.

9 You submitted a declaration in this IPR,
10 correct?

11 A. I did.

12 Q. And in your declaration, did you give your
13 complete opinions on whether the '817 patent is
14 valid or invalid?

15 A. Within the page limits and word count
16 limits. As complete as I was allowed to, correct.

17 Q. And is anything missing from your
18 declaration that you rely on to support your
19 invalidity analysis and opinions?

20 A. The opinions expressed there were supported
21 by the citations that are listed, as well as, you
22 know, my own understanding of the field.

23 Q. How did you prepare your declaration?

24 A. Um, I started with conversations about the

1 case and the relevant patents with Mr. Metzcar.

2 We --

3 Q. I just caution you not to reveal the
4 contents. You can talk about the topics --

5 A. Yes.

6 Q. -- at a very high level of abstraction that
7 you discussed with Mr. Metzcar, but I'm not asking
8 you to disclose the content of your conversation
9 with him.

10 A. Understood and understood why. And I'll
11 try not to.

12 We discussed the case.

13 Q. Uh-hum.

14 A. Discussed the patent in question. Reviewed
15 some of the prior art. I have provided perspectives
16 on where I felt the prior art cited fit in relative
17 to the '817 patent and its claims. And a draft was
18 generated by Mr. Metzcar, which I reviewed, edited,
19 and then submitted the final version.

20 Q. Did you search for any relevant documents
21 supporting your opinions yourself, or did you rely
22 on documents that Mr. Metzcar and his team provided
23 to you?

24 A. I reviewed -- excuse me. I relied on the

1 documents for the opinion; but of course, during the
2 course of my work, I'm exposed to many, many papers.
3 And that forms the basis of my general understanding
4 of the field.

5 Q. And so just to make sure I understand, so
6 you relied, for purposes of the opinions in your
7 declaration, on the documents that Mr. Metzcar and
8 his team provided to you, colored by your broader,
9 long experience in the field?

10 A. I think that's a fair way to put it.

11 Q. Great.

12 And other than your long-term experience as
13 a researcher and professor, is there anything else
14 you relied on for your opinions in this declaration
15 that's not cited in the declaration?

16 A. Not that I can think of at this point.

17 Q. And then sitting here today, are there any
18 amendments to or corrections to your declaration
19 that you wish to make to any portion of the
20 declaration?

21 A. Not that I know of at this point.

22 Q. I'd like to turn back to Exhibit 1001,
23 which is the patent.

24 How would you describe the invention

1 claimed in the '817 patent?

2 A. Well, I think it's well put in the opening
3 of the abstract; presented as systems and methods
4 for automated analysis of three-dimensional medical
5 images to identify volumes and relate them to their
6 corresponding anatomical regions.

7 Q. And what problem in the field did the '817
8 patent seek to solve?

9 MR. METZCAR: Objection, foundation. Go
10 ahead.

11 A. I think the thrust of my understanding is
12 that they were hoping to find ways to relate
13 functional images to their anatomical counterparts
14 and use that as a way to better understand the
15 diagnostic significance of the functional image in
16 the context of the anatomy of the person that they
17 were looking at.

18 Q. If you would, let's turn to Column 17 of
19 the specification.

20 A. Okay.

21 Q. And then starting at Line 14 --

22 A. Okay.

23 Q. -- it says, "In certain embodiments, the 3D
24 anatomical image is a full body image and wherein,

1 at step (b), the instructions cause the processor to
2 automatically determine, using one or more
3 localization modules implementing machine learning
4 techniques (e.g., wherein each localization module
5 is a CNN module that implements a CNN), a plurality
6 of initial VOIs within the 3D anatomical image, each
7 initial VOI corresponding to a particular anatomical
8 region (e.g., a group of related tissue, such as a
9 pelvic region, a chest region, a head and/or neck
10 region, a spine region, an upper body region, a
11 lower body region, etc.) and in which an associated
12 subset of the target VOIs are located; and for each
13 initial VOI, automatically identify, using one or
14 more segmentation modules implementing machine
15 learning techniques (e.g., wherein each segmentation
16 module is a CNN module that implements a CNN) the
17 associated subset of target VOIs."

18 So in this paragraph, the specification
19 describes localization and segmentation modules that
20 implement machine learning techniques, right?

21 A. I would say that's a fair characterization.

22 Q. And it gives a CNN module as an example of
23 those machine learning modules, right?

24 A. "E.g., CNN." So it is an example.

1 Q. And the specification describes the modules
2 as being applied per anatomical region to identify
3 VOIs for that region, right?

4 A. That's what this paragraph is describing;
5 3D anatomical imaging and the operation thereof.

6 Q. Let's now turn to Example 2 in the
7 specification, which starts at Column 47.

8 A. Did you say "47"?

9 Q. 47.

10 And this reports "Example 2: "Automated
11 Segmentation of the Skeleton in Low-Dose CT and
12 Quantification of Metastatic Prostate Cancer in [18F]
13 DCFPyL PET."

14 A. I see that.

15 Q. And this reports that, "PSMA-PET/CT hybrid
16 imaging is a promising diagnostic platform for
17 prostate cancer patients. While manual delineation
18 of organs in three-dimensional CT images is often
19 needed for accurate diagnostics and treatment
20 planning, such manual delineation is a
21 time-consuming process. To address this challenge,
22 this example demonstrates automating the process of
23 accurate bone segmentation in whole body CT images
24 using deep learning approaches in accordance with

1 the whole body segmentation technology described
2 herein. As described in this example, the
3 anatomical information gained via such skeletal
4 segmentation can be used to create a fully automated
5 lesion detection algorithm in [18F] DCFPyL (PyL-PSMA)
6 PET images."

7 A. I see that.

8 Q. And then if you turn to Column 48, at the
9 very top it says, "A deep learning algorithm based
10 on cascaded deep learning convolutional neural
11 networks for semantic segmentation of 12 skeletal
12 regions was developed. In particular, the 12
13 skeletal regions were the thoracic and lumbar
14 vertebrae, sinister (left)/dexter (right) ribs,
15 sternum, sinister (left)/dexter (right) clavicle,
16 sinister (left)/dexter (right) scapula, sinister
17 (left)/dexter (right) ilium, and the sacrum. A
18 training set (N=90) and validation set (N=22) of
19 pairs of low-dose CT images and manually crafted
20 segmentation maps were used to develop the deep
21 learning algorithm. The algorithm's performance was
22 assessed on a test set (N=10) of low-dose CT images
23 obtained from a PyL-PSMA study."

24 And so the spec is reporting for this

1 example that training on manually crafted
2 segmentation maps is supervised learning, right?

3 A. As they describe it here, that's how I
4 would understand it.

5 Q. And the example here is reporting, if you
6 go down to Column 48, beginning Line 24, is
7 reporting held-out validation and Dice performance
8 consistent with supervised deep learning network
9 training; is that right?

10 A. I see it uses a Dice algorithm to assess
11 its accuracy.

12 Q. And that's consistent with supervised deep
13 learning network training, right?

14 A. That's a typical metric that's used to
15 evaluate the performance of training, supervised or
16 unsupervised.

17 Q. Let's turn now a little back in the patent
18 to Figure 5A, if you would, please.

19 A. Do you have a page?

20 Q. It is Page 11, as marked in the bottom left
21 of Exhibit 1001.

22 And so do you see here at the top of Figure
23 5A, it reports the first step in this demonstrative
24 says, "Receive a 3D anatomical image (e.g., full

1 body image) " ?

2 A. I see that.

3 Q. And then the next step is "Identify target
4 volume for each target tissue region."

5 A. Okay.

6 Q. And then it says as the next step, "Stitch
7 target volumes together."

8 A. I see that.

9 Q. And then if you turn the page to Figure 5B,
10 am I right that the first three steps in Figure 5B
11 are the same as the first three steps in Figure 5A?

12 A. It does seem to be that way.

13 Q. And they both say, "Receive a 3D anatomical
14 image," "Identify a target VOI for each target
15 tissue region," and "Stitch target volumes
16 together," right?

17 A. I see it says that.

18 Q. So both of these figures are describing
19 digitally stitching together segmentation masks into
20 a consolidated single representation, right?

21 A. I would want to read the figure caption
22 before I would really want to weigh in on exactly
23 what this figure is meant to represent. (Witness
24 reviews document)

1 Q. So if you turn to Column 34 --

2 A. 34, okay. I was just looking at the brief
3 description of the figures on Column 27, but...

4 Q. You're welcome to look at Column 27 first
5 also.

6 A. Yeah, just give me one second.

7 Q. Really what I'm asking is just to take your
8 time.

9 A. (Witness reviews document) Okay. So the
10 figure is an illustrative embodiment, a single
11 embodiment.

12 Q. Uh-hum.

13 A. Sorry, on 34, then?

14 Q. Correct. 34, starting on Line 27, that
15 paragraph.

16 A. Okay. (Witness reviews document)

17 Q. And so it says here, "Figure 5 is a block
18 flow diagram showing an example process 500 for
19 performing segmentation to identify a plurality of
20 target tissue regions. As shown in Figure 5, a
21 machine learning module receives a 3D anatomical
22 image (e.g., a full body image) as input 502, and
23 identifies, for each of a plurality of target tissue
24 region, a target volume comprising a graphical

1 representation of the target tissue region within
2 the 3D anatomical image 504. The target volumes are
3 stitched together 506 to form a segmentation map 510
4 that comprises a plurality of segmentation masks
5 512, with each segmentation mask representing an
6 identified target volume."

7 A. I read that along with you, yes.
8 Accurately read.

9 Q. Thank you. Which is harder than it looks.
10 So Figure 5 shows -- scratch that. I'll start
11 again.

12 So Figure 5A and B, are describing
13 digitally stitching together individual segmentation
14 masks into a single consolidated representation,
15 right?

16 A. In this embodiment as described, yes.

17 Q. Let's now turn to Figures 6A and 6B. So 6A
18 and 6B are both on Page 13 of Exhibit 1001.

19 And so this figure shows you you begin with
20 a raw CT image, perform coarse segmentation, then
21 segment predefined subregions, and then merge whole
22 body segmentation, correct?

23 A. I see that those are the words used at the
24 top of that diagram.

1 Q. And so just to make sure I understand it
2 correctly, so this is showing how segmentation
3 results associated with different anatomical regions
4 are merged to provide a whole body segmentation; is
5 that right?

6 A. Again, if you would give me a moment, I
7 would like to read the figure caption to make sure I
8 understand how they're using those terms.

9 Q. Uh-hum.

10 A. (Witness reviews document)

11 Q. And so if you go to Column 48 at Line 58 --
12 and so I'll read it in.

13 A. I was just reading 34, which I guess is
14 still referring to Figure 5. They talk about using
15 one or more machine learning modules to perform
16 intermediate analysis and processing. So maybe one;
17 maybe more.

18 Now, I'm sorry, you had directed me to?

19 Q. Column 48, starting at Line 58.

20 A. Figure 6A shows --

21 Q. Uh-hum. So it says, "Figure 6A shows a
22 block flow diagram illustrating an embodiment of the
23 segmentation processes described herein that is used
24 in the PyL-PET/CT image analysis described in this

1 example. As in process 500, shown in Figure 5, in
2 process 600 an anatomical image is received. In
3 particular, in process 600, a CT image is received
4 610a. In this example, process 600 is used to
5 identify and segment the CT image into target
6 volumes of interest corresponding to 49 specific
7 bones and 8 soft tissue regions (in this example,
8 example version 3 of the CNN-based segmentation
9 approach described in example 1 is used). In order
10 to identify the target volumes, a coarse
11 segmentation is performed 620a to localize a set of
12 initial volumes of interest, or subregions, e.g., as
13 described in Example 1. A fine segmentation is then
14 performed within each of the sub-regions to identify
15 the specific target volumes of interest that
16 correspond to the target 49 bone and 8 soft tissue
17 regions 630a. Segmentation masks representing the
18 identified target volumes can be created, and merged
19 640a, for example to create a 3D whole body
20 segmentation map."

21 And so you would agree with me for purposes
22 of level setting, that Figure 6A and 6B are showing
23 how segmentation results associated with different
24 anatomical regions are merged to provide a whole

1 body segmentation map, right?

2 A. They don't describe how the merging is
3 done, but those are the words they use, yes.

4 Q. But they are merged?

5 A. Yes.

6 Q. There's a reference here to Example 1, as
7 we just read. So let's go look at Example 1 that
8 begins -- the description of Example 1 begins on
9 Column 42 at Line 14.

10 A. I see that.

11 Q. So "Example 1-CNN Based Whole Body
12 Segmentation."

13 And the paragraph beginning at Line 17
14 reads, "Example 1 describes an example approach for
15 whole body segmentation. The implementation in this
16 example uses five neural networks to segment bones
17 within an entire torso. A first neural network is
18 used to roughly localize different regions of the
19 body. The results are used to divide the body into
20 four regions. In each of these regions, a
21 corresponding neural network is then used to perform
22 segmentation into distinct bones. The results from
23 all four regions are then combined into a finished
24 result (e.g., a final segmentation map)."

1 So this is describing dividing the body
2 into four regions; and then for each region, using a
3 corresponding neural network to segment the distinct
4 bones?

5 A. I see that. You properly reported the
6 reading of the paragraph.

7 Q. And then the results from all four regions
8 are combined into a final segmentation map?

9 A. Here, the word "combined" is used, yes.

10 Q. Like what's shown then in Figures 6A and
11 6B?

12 A. Well, 6A and 6B talk about "merging."
13 Again, not explicitly defined.

14 Q. Let's turn, if you would, to Column 5 and
15 the paragraph beginning at Line 37.

16 A. Uh-hum.

17 Q. And that paragraph says, "In certain
18 embodiments, step (c) comprises digitally stitching
19 together the plurality of 3D segmentation masks to
20 form the 3D segmentation map {e.g., by creating an
21 initially empty image volume (e.g., initializing all
22 voxel values to zero) and then inserting labels from
23 each segmentation mask into the image volume [e.g.,
24 by mapping labeled (e.g., as representing a

1 particular target tissue region as determined by a
2 machine learning module) voxels of input images to
3 one or machine learning modules to voxels of the
4 image volume (e.g., so as to match voxels of the
5 image volume to voxels of the input images that
6 represent a same physical location, thereby labeling
7 voxels of the image volume correctly)}}."

8 A. I read that. It seems like there might be
9 a typo.

10 Q. Yes. As it stands, the specification here
11 is describing the 3D segmentation map in terms of
12 voxels, right?

13 A. This paragraph starts with, "In certain
14 embodiments step (c)..." So it would be universal
15 for me to understand what "step (c)" was, which I
16 assume is described above.

17 Q. Yes. You can take a moment to look, if
18 you'd like.

19 A. Okay. (Witness reviews document)

20 Q. You see it's referring to --

21 A. I see step (c): "Determining, by the
22 processor, a 3D segmentation map representing a
23 plurality of 3D segmentation masks, each 3D
24 segmentation mask representing a particular

1 identified target VOI (e.g., automatically,
2 digitally stitching together the plurality of 3D
3 segmentation masks to form the 3D segmentation
4 map)."

5 Q. And so the paragraph beginning at Column 5,
6 Line 37, along with the language you just read, is
7 describing the 3D segmentation map in terms of
8 voxels, right?

9 A. Correct.

10 Q. And that is, the 3D segmentation map is
11 itself an image volume comprising a plurality of 3D
12 voxels, right?

13 A. The definition of a "segmentation map" is a
14 plurality of segmentation masks.

15 So I'm sorry, your question one more time?

16 Q. The paragraph beginning at Column 5, Line
17 37 describes, as we just agreed, is a 3D
18 segmentation map in terms of voxels. And I was
19 clarifying that the 3D segmentation map described
20 here is itself an image volume comprising a
21 plurality of 3D voxels.

22 MR. METZCAR: Objection, foundation. You
23 can go ahead and answer.

24 A. For a 3D segmentation map. I'm just

1 reading this section, so we're all on the same page.
2 "{For example, by creating an initially empty image
3 volume (e.g., initialling all voxel values to zero)
4 and then inserting labels from each segmentation
5 mask into the image volume [e.g., by mapping labeled
6 (for example, as representing a particular target
7 tissue region as determined by a machine learning
8 module) voxels of input images to one or machine
9 learning modules" -- that's maybe where the typo
10 is -- "to voxels of the image volume..."

11 MR. METZCAR: If you're reading out loud,
12 she has to take down every word that you say. So if
13 you're just reading to yourself, you can read it
14 quietly.

15 THE WITNESS: I see.

16 A. Okay. So I apologize, but could you frame
17 your question one more time?

18 Q. Sure. So as described here, the 3D
19 segmentation map is itself an image volume
20 comprising a plurality of 3D voxels, right?

21 MR. METZCAR: Objection, foundation. You
22 can answer.

23 A. As I'm reading this paragraph now, I think
24 that would be a fair characterization.

1 Q. And so it's describing the creation of a 3D
2 segmentation map in terms of creating a single
3 labeled 3D image, right?

4 A. A single labeled 3D mask with potentially
5 multiple areas identified within that mask; a
6 multi-parametric mask.

7 Q. Let's now turn to Column 48, if you would.
8 And starting at Line 43 -- so we're back on Example
9 3 for a moment -- and you see here -- let me know
10 when you're there.

11 A. I am.

12 Q. You see here, "Example 3: Automated Whole
13 Body Segmentation for PyL-PET Image Analysis and
14 Lesion Detection"?

15 A. Yes.

16 Q. And if you could go to Line 63 -- I'll
17 start at the beginning of that paragraph. "Figure
18 6A shows a block flow diagram illustrating an
19 embodiment of the segmentation processes described
20 herein that is used in the PyL-PET/CT image analysis
21 described in this example. As in process 500 shown
22 in Figure 5, in process 600 an anatomical image is
23 received. In particular, in process 600, a CT image
24 is received 610a. In this example, process 600 is

1 used to identify and segment the CT image into
2 target volumes of interest corresponding to 49
3 specific bones and 8 soft tissue regions."

4 Did I read that correctly?

5 A. You did.

6 Q. And then on the next page, if you look at
7 Column 49 and the top of Column 50, you see it lists
8 the 49 bones and the 8 soft tissue regions, right?

9 A. I see that long list, yes.

10 Q. And then right after the list of soft
11 tissue regions -- we're at Column 50, Line 10 -- and
12 it says, "Figure 6B shows a series of CT images
13 overlaid with annotations illustrating the steps in
14 the whole-body segmentation process 600 described in
15 this example. An example raw CT image that is
16 received at step 610a is shown in 610b. Image 620b
17 shows results of a coarse segmentation (different
18 regions identified are shown as colored regions)
19 used to identify the initial volumes of interest in
20 the CT image. Image 630b shows 'bounding boxes'
21 identifying initial volumes of interest in which
22 fine segmentation is performed to identify the
23 target volumes of interest corresponding to the 49
24 bones and 8 soft tissue regions. Image 640

1 illustrates the final, merged whole body
2 segmentation."

3 So this passage is describing segmentation
4 outputs of multiple masks which are merged into a 3D
5 whole body map, right?

6 A. I'm having some trouble just saying "yes"
7 to that.

8 Q. And why is that?

9 A. The reason is that as described, for
10 example, in 630b, it describes a bounding box, a
11 series of bounding boxes. They're visible on the
12 image, though barely. Those bounding boxes are not
13 directly merged with finer segmentations that would
14 come from 640b. They're used to define regions of
15 interest that ultimately then determine the
16 individual relevance of interest. But I wouldn't
17 say it's a merger of the output of, say, from 620a
18 to 630 -- 620b to 630b and those bounding boxes.
19 Those are not merged, as I would use the term
20 "merged" with the output of 630b to 640b. They're
21 used to help define the limits of the segmentation
22 for 640b, but we're not merging those outputs.
23 So...

24 Q. But no segmentation is performed by a CNN

1 in each of those bounding boxes, right?

2 A. Could you please repeat that?

3 Q. But no segmentation is performed by a CNN
4 in each of those bounding -- actually, strike that.
5 I'll start more basically first.

6 So you agree that the last sentence in the
7 paragraph beginning in Column 50, Line 10, says,
8 "Image 640 illustrates the final merged whole body
9 segmentation," right?

10 A. That is what it says, yes.

11 Q. And if you turn to Figure 6B -- sorry, 6A
12 and 6B on Page 13 of Exhibit 1001, what is reported
13 as Step 640 is "merge whole body segmentation,"
14 correct?

15 A. The sentence, um, Line 20 in Column 50 does
16 say, "image 640 illustrates the final merged whole
17 body segmentation."

18 Q. And so is it your opinion that the verb
19 "merged" as used in the specification is inaccurate?

20 A. No, I didn't mean to imply that.

21 Q. And so would you agree, then, that this is
22 describing how the segmentation outputs of multiple
23 masks are merged into a 3D whole body map?

24 A. It describes the fact -- it uses the term

1 "merged" to describe the whole body segmentation.

2 Q. And do you believe that's an inaccurate
3 description?

4 A. No.

5 Q. All right. You can put the patent down
6 now.

7 How would you construe the term "3D
8 segmentation map" as used in Claim 1 of the '817
9 patent?

10 A. Um, I take it from the intrinsic evidence
11 of the patent itself that it is a plurality of
12 segmentation masks.

13 Q. So your -- the construction of the term "3D
14 segmentation map" in Claim 1 of the '817 patent that
15 you think is accurate is a plurality of 3D
16 segmentation masks?

17 A. I believe that comes directly from the '817
18 patent itself, yes.

19 Q. And under your interpretation, would an
20 overlay of hot spots on an anatomical image qualify
21 as a 3D segmentation map?

22 A. The map of the hot spots themselves could
23 certainly be a segmentation map -- excuse me, a
24 segmentation mask. And if there were multiple, then

1 perhaps that term "map" could be used. It's an
2 uncommon term.

3 Q. So an overlay of hot spots on an anatomical
4 image would qualify as a 3D segmentation map, right?

5 A. If it was defined as a segmentation mask, a
6 3D segmentation mask, then that would qualify as a
7 3D segmentation mask.

8 Q. And that would mean that any image with
9 labeled regions would qualify as a 3D segmentation
10 map, then, right?

11 A. As I said, as defined in the patent --
12 because that's the only definition I have to go
13 by -- it's a plurality of masks.

14 So to my rudimentary understanding,
15 plurality would mean more than one. So if it
16 represented more than one mask, more than one
17 identifier, then that would be using the terminology
18 of the patent as "segmentation map."

19 Q. I just want to make sure I understand the
20 contours without over- or underselling it.

21 A. Okay.

22 Q. So would any image with labeled regions
23 would -- strike that.

24 So any image with more than one labeled

1 region would qualify as a 3D segmentation map under
2 your proposed construction, right?

3 A. No, not the way you said it.

4 Q. So what's missing in how I described it?

5 A. You said "any image." The image, itself,
6 the entirety of the image, is not the segmentation
7 mask or map. It is the -- the mask would be the
8 pixel-wise labeled areas. And if there were more
9 than one such labeled area, that could represent, by
10 the terminology of this patent, a segmentation map.
11 Not the image itself.

12 Q. Got it. And so is this right, then; that
13 under your construction, a 3D segmentation map would
14 be that relevant pixel-wise portion of the image,
15 provided it has one or more labeled regions?

16 A. Perhaps the question now is what we mean by
17 "plurality." To my mind, "plurality" would mean
18 more than one.

19 Q. Agreed.

20 A. Okay.

21 Q. Agreed on that.

22 A. We're agreed on that one. So when you
23 said, "one or more" --

24 Q. Sorry, let me rephrase. I misspoke.

1 So under your proposed construction of a 3D
2 segmentation map, the relevant pixel-wise portion of
3 a medical image would contain a 3D segmentation map
4 if it contains more than one labeled region?

5 MR. METZCAR: Objection, form. You can
6 answer.

7 A. If there is more than one segmentation mask
8 or a segmentation mask that had annotations of more
9 than a single region.

10 Q. And so does your construction require
11 combining the different masks to create the map?

12 A. It's not in the definition of the -- the
13 patent, itself, describes a map strictly as a
14 plurality of masks. It doesn't talk specifically
15 about how that gets created.

16 Q. Let's go to column -- so let's go to
17 Exhibit 1001, which is the '817 patent, and look at
18 Column 5.

19 A. You promised me I could put it down.
20 I'm sorry, what was that page, again?

21 Q. It's Column 5, Paragraph 37.

22 MR. METZCAR: Did you mean Line 37?

23 MR. CALHOUN: Yes. Column 5, Line 37.

24 A. "In certain embodiments..."

1 Q. Yes. And we read this before; but it says,
2 "In certain embodiments, step (c)," which as we saw
3 in the preceding paragraph is the step by which
4 you're taught to, "determining, by the processor, a
5 3D segmentation map representing a plurality of 3D
6 segmentation masks, each...segmentation mask
7 representing a particular identified target VOI
8 (e.g., automatically, digitally stitching together
9 the plurality of 3D segmentation masks to form the
10 3D segmentation map)."

11 I read that part correctly, correct?

12 A. Correct.

13 Q. And then beginning at Line 37, where it
14 elaborates on step (c), it says -- and I now
15 quote -- "In certain embodiments, step (c) comprises
16 digitally stitching together the plurality of 3D
17 segmentation masks to form the 3D segmentation map."

18 A. I see that.

19 Q. And so you would agree that here, the
20 specification is emphasizing that one must stitch
21 together the masks into a unified map, right?

22 A. In this paragraph, it describes, "in
23 certain embodiments."

24 So in this particular embodiment, it

1 describes -- it uses the word "stitching."

2 Q. And if you'd look with me, please, at image
3 5A, which is on Page 11, you would agree that 5A at
4 Step 506 refers to "stitch target volumes together,"
5 correct?

6 A. I see that word.

7 Q. And you see that word again on Figure 5B at
8 Step 526?

9 A. Yes.

10 Q. And then at the next page, Figure 6A, the
11 final step says, "merge whole body segmentation,"
12 correct?

13 A. That is the word it uses, different than
14 "stitch."

15 Q. And so you would agree with me that at
16 least there are multiple iterations throughout the
17 spec that reference stitching together or merging or
18 combining masks to form the 3D segmentation map,
19 right?

20 A. There are several embodiments. What I
21 don't see is any of that language in the claims,
22 however.

23 Q. How is a 3D segmentation map different than
24 the 3D segmentation masks themselves?

1 A. By the definition of this patent, it just
2 represents a plurality of such masks. Again, it's
3 not a common term of art, in my experience.

4 Q. And what do you mean by the patent defines
5 the term "3D segmentation map"?

6 A. It uses that phrase. And so that's how I
7 take it as the definition. It's how it describes
8 it.

9 Q. What do you mean, "it's how it describes
10 it"?

11 A. It uses the term "a segmentation map
12 represents a plurality of segmentation masks."

13 Q. You mean the language in 1C?

14 A. The language in 1 --

15 Q. In Claim 1C.

16 A. Correct.

17 Q. And so let's for a moment take that
18 language from Claim 1C. So it says, "Determining,
19 by the processor, a 3D segmentation map representing
20 a plurality of 3D segmentation masks, each 3D
21 segmentation mask representing a particular
22 identified target VOI."

23 Did I read that correctly?

24 A. Yes, you did.

1 Q. And you are interpreting the phrase "a 3D
2 segmentation map representing a plurality of 3D
3 segmentation masks" to support the construction that
4 you shared earlier, which is that a 3D segmentation
5 map means a plurality of 3D segmentation masks,
6 right?

7 A. I believe that's correct, yes.

8 Q. And so help me understand. On your
9 interpretation or your proposed construction of a 3D
10 segmentation map, if a 3D segmentation map is simply
11 a plurality of 3D segmentation masks, is a 3D
12 segmentation map no different than the 3D
13 segmentation masks themselves?

14 A. Described here, the map is a plurality,
15 more than one, segmentation mask.

16 Q. So yes?

17 A. What was the question again?

18 Q. On your construction of 3D segmentation map
19 as a plurality of 3D segmentation masks, am I right,
20 then, that a 3D segmentation map is no different
21 than the 3D segmentation masks themselves -- than
22 the combination -- let me rephrase it, actually.
23 Now I understand what the confusion was.

24 Based on your construction of 3D

1 segmentation map as a plurality of 3D segmentation
2 masks, am I right that the 3D segmentation map
3 itself is then no different than the plurality of 3D
4 segmentation masks themselves?

5 MR. METZCAR: Objection, form. You can
6 answer.

7 A. As I understand the claims, that's how I
8 would interpret it, yes.

9 Q. And so the import of that is that a 3D
10 segmentation map is essentially just the set of 3D
11 segmentation masks that you've used to somehow
12 distinguish the several regions within the image?

13 MR. METZCAR: Objection, form. You can
14 answer.

15 A. Could I ask you to rephrase that, just so I
16 make sure I'm hearing it clearly?

17 MR. CALHOUN: Sure. Actually, let's move
18 on.

19 So I'd like to introduce what's been
20 previously marked in this proceeding as Exhibit
21 1005.

22 (Document previously marked as Rosen
23 Exhibit 1005 for identification)

24 THE WITNESS: I'm not going to put this

1 away, though. I know your games.

2 MR. CALHOUN: You're getting wise.

3 BY MR. CALHOUN:

4 Q. Do you recognize this document, Dr. Rosen?

5 A. I do.

6 Q. And what is it?

7 A. It is what I've been calling the "Renisch
8 patent."

9 Q. And you contend that the Renisch reference
10 anticipates Claims 1 to 5, 7, 10 to 14, 16, 19, and
11 26 of the '817 patent, right?

12 A. I'll have to trust that you accurately
13 relayed what I wrote in the document.

14 Q. I represent I have accurately relayed it.

15 A. Okay. So then yes.

16 Q. Why doesn't Renisch anticipate Claim 6?
17 And you can take a look at the '817 patent if you'd
18 like.

19 A. The claims that it anticipates were the
20 ones I was asked to opine on. I wasn't asked to
21 opine on Claim 6.

22 Q. Why doesn't Renisch anticipate Claim 8?

23 A. I think that would be the same answer.

24 Q. And so like Claim 6, you don't have an

1 opinion about whether Renisch anticipates or renders
2 obvious Claim 8?

3 A. If it's not described in my document, then
4 I formed no opinion.

5 Q. Sitting here, you don't recall?

6 A. Right. Thank you. That's a better answer.

7 Q. You do contend that Renisch anticipates
8 Limitation B of Claim 1, right?

9 A. Yes.

10 Q. And feel free to pull up the '817 patent if
11 you'd like. But Limitation B of Claim 1 states,
12 "Automatically identifying by the processor using
13 one or more machine learning modules for each of a
14 plurality of target tissue regions a corresponding
15 target volume of interest (VOI) within the 3D
16 anatomical image," correct?

17 A. You're reading from 1B?

18 Q. That's correct.

19 A. (Witness reviews document) Okay. Yes.

20 Q. Now let's turn to Paragraph 27 of the
21 Renisch reference; so 27 of the specification. And
22 just tell me when you're there.

23 A. I think I'm there. The segmentation unit
24 76?

1 Q. That's right. And so it says, "The
2 segmentation unit 76 is capable of employing
3 different types of segmentation methods. For
4 example, the segmentation unit 76 can employ a
5 model-based segmentation in which the central
6 assumption is that the anatomical structures of
7 interest have, to some extent, relatively consistent
8 forms of geometry and position across patients. A
9 library of three-dimensional anatomical structure
10 modules explaining the shape, geometrical location,
11 size, and variations thereof are defined in an
12 anatomical database 84 prior to the segmentation."

13 You'd agree that the example that Renisch
14 is describing here does not explain how to use or
15 implement clustering, right?

16 A. The section that you read does not describe
17 clustering algorithms; though, of course, they are
18 described later in that same paragraph.

19 Q. And the excerpt we just read does not
20 describe how to implement or use the process called
21 "clustering," right? Specifically, it does not
22 describe how to implement it beyond simply
23 referencing it as "other segmentation method,"
24 correct?

1 A. As a known segmentation method with
2 extensive literature, it doesn't describe it in
3 greater detail in this paragraph, correct.

4 Q. So Paragraph 27 does not describe how
5 Renisch or a POSITA would implement the process of
6 clustering in conjunction with segmentation unit 76,
7 correct?

8 A. I think that would be a fair statement.

9 Q. And Paragraph 27 does not describe how you
10 or a POSITA would implement the process of using a
11 neural network in conjunction with segmentation unit
12 76, correct?

13 A. It says here "contemplated," but doesn't
14 describe in detail how to do so.

15 Q. Instead, is it fair to say that Paragraph
16 27 describes, quote, a model-based, end quote,
17 segmentation, which, quote, "in which the central
18 assumption is that the anatomical structures of
19 interest have, to some extent, relatively consistent
20 forms of geometry and position across patients,"
21 right?

22 A. That is what it says.

23 Q. And then it describes a library of
24 three-dimensional anatomical structure models that

1 explain the shape, geometry, size and variations
2 that are then used as templates to identify and
3 define the boundaries of the structure of interest,
4 right?

5 A. I think you've summarized that opening part
6 of the paragraph correctly.

7 Q. So Renisch's models here are templates that
8 give the geometry of a typical structure that he's
9 interested in, right?

10 A. Renisch is describing in this paragraph a
11 generic segmentation unit and describing a number of
12 different ways one can do that segmentation, one of
13 which is, as you mentioned, a template-based
14 approach. And it gives somewhat more detail on
15 that, but also goes on to mention a number of other
16 methods that can be used to generate segmentations,
17 including various machine learning algorithms.

18 Q. Understood.

19 And in this particular implementation that
20 he is describing in greater detail, other than just
21 referencing the name of it, he is describing models
22 that you use as templates that give the geometry of
23 the structure that you're addressing, right?

24 A. It does use -- I think that's a fair

1 summary of what this is saying.

2 Q. And then in Paragraph 28, Renisch continues
3 that, "The segmentation unit 76 can also employ an
4 atlas of normal anatomical structures which is
5 mapped to the actual anatomical image. In such an
6 embodiment, the atlas includes the anatomical
7 database 84," right?

8 A. I see that paragraph, yeah.

9 Q. And so Renisch is describing in Paragraph
10 28, quote, an atlas of normal anatomical structures,
11 end quote, as one uses in atlas image segmentation,
12 right?

13 A. Again, it is describing one method to do
14 segmentation; in this case, an atlas-based method.

15 Q. Right. Renisch's anatomical structure
16 models are defined prior to segmentation, right?

17 A. Give me one moment to reread the paragraph.

18 Q. Please take your time.

19 A. (Witness reviews document) "Yes" I think
20 is a fair answer to your question.

21 Q. And so --

22 A. In this embodiment, if you will.

23 Q. And so those anatomical structure models
24 are inputs, not outputs or results, of Renisch's

1 segmentation, right?

2 A. The output is the segmentation of those
3 anatomical areas.

4 Q. And so those anatomical structure models
5 are the inputs?

6 MR. METZCAR: Objection, form. You can
7 answer.

8 A. Here it describes that during the
9 segmentation, the models act as templates to
10 identify the boundaries of the structures of
11 interest.

12 Q. And so they're inputs; not the outputs of
13 the segmentation, right?

14 A. The atlas, itself, is not the output. That
15 would be of less value, because it's not
16 patient-specific; that is correct.

17 Q. And you'd agree that model-based and atlas
18 segmentation are not machine learning modules,
19 right?

20 A. There are machine learning approaches that
21 use atlases as a foundation as a starting point, but
22 they can also be implemented in a non-machine
23 learning way --

24 Q. Would you agree that -- apologies. I

1 accidentally cut you off. Please finish your
2 answer.

3 (Court reporter reads back last answer)

4 A. And we can just stop right there. Good.
5 You cut me off just in time before I said anything
6 else stupid.

7 Q. You would agree that the specific
8 implementation that Renisch is discussing in
9 Paragraphs 27 and 28 specifically is describing a
10 model-based or atlas segmentation approach that is
11 different than a machine learning module, right?

12 A. It does appear that they are describing a
13 non-machine learning-based approach in these two
14 paragraphs.

15 Q. And so --

16 A. Can I carry on and say --

17 Q. Yes, of course.

18 A. The description, itself, is still quite
19 brief, so it certainly could be a non-machine
20 learning-based approach. I'm not sure that the
21 language would necessarily exclude using those
22 anatomical prescribers as part of a machine learning
23 algorithm, which people do.

24 Q. But you'd agree that nothing in Paragraphs

1 27 or 28 affirmatively suggest the use of a machine
2 learning module in the implementation that Renisch
3 is discussing in these paragraphs, right?

4 MR. METZCAR: Objection, foundation. Go
5 ahead. You can answer.

6 A. I would say it isn't described, but nor is
7 it excluded.

8 Q. And so let's look at the last sentence of
9 Paragraph 27, which you referenced before, which
10 says, "It is to be appreciated, however, that other
11 segmentation methods such as clustering, edge
12 detection, region growing, principal components
13 analysis, neural network, and the like are also
14 contemplated."

15 Did I read that correctly?

16 A. You did.

17 Q. Could you walk me through the differences
18 between clustering, edge detection, region growing,
19 principals components analysis, neural network at a
20 high level?

21 A. Sure. Clustering analysis is a statistical
22 method, a machine learning method, where the
23 statistical properties of the input data are used to
24 identify similarities in the characteristics of the

1 image intensities or colors, etc., and areas with
2 common or similar properties are organized together.

3 Edge detection is focused on defining areas
4 of transition in signal intensity or color, whatever
5 the property of the image is.

6 Region growing is almost kind of in some
7 ways the opposite of edge detection. It starts
8 inside, with a value within a potential area of
9 interest, and then extends its investigated volume
10 by moving out from there and stopping when the
11 signal intensities are no longer similar to that in
12 the original area.

13 A principal component analysis is somewhat
14 similar in principle to clustering. It looks for,
15 again, properties of the signal intensities that can
16 kind of reduce the dimensionality of the information
17 to common elements and then labels those common
18 elements along a certain direction.

19 Of course, neural networks, a topic of some
20 interest here, is a technology that's been around
21 for quite some time -- since certainly the '40s in
22 principal -- and of course, is a very common method
23 for doing all sorts of image analysis tasks,
24 including segmentation.

1 Q. Are artificial neural networks and neural
2 networks the same thing or are they different?

3 A. Well, as a neuroscientist, I would say a
4 neural network could literally refer to neurons in
5 the brain. And we use that phrase all the time. I
6 think we might add the artificial neural network to
7 describe computational models that in some way
8 parallel that structure of biological neural
9 networks. That's how I would distinguish the two.

10 I think neural network in this setting, in
11 the setting of a medical image discussion, would not
12 be referring to the brain itself, but would be
13 referring to a man-made or computational
14 representation that has similarities and thus, one
15 could also label, I think synonymously, an
16 artificial neural network.

17 Q. So in the domain of medical image analysis,
18 as opposed to brain anatomy, your view is that
19 "artificial neural network" and "neural network" are
20 synonymous?

21 A. In many contexts, that would be true.

22 Q. What are the contexts --

23 A. I'm not sure I can say that in every
24 possible context that those would be used completely

1 synonymously.

2 Q. But you think that generally, they're
3 synonymous in the context of medical imaging
4 analysis; not brain anatomy?

5 A. I would say so.

6 Q. Does Renisch use the term "artificial
7 neural network" or "artificial neural networks"?

8 A. I'm not sure. I don't believe so, but --

9 Q. I'll represent that he doesn't.

10 A. Okay. Then I'll leave it to somebody else
11 to challenge that, if it's challengeable.

12 Q. I believe I'm right.

13 How would a --

14 A. But I don't believe he's referring to brain
15 anatomy in this section.

16 Q. Agreed.

17 How would a POSITA, or person of ordinary
18 skill in the art, have understood the term "neural
19 network" as of the priority date of the '817 patent
20 in January 2019?

21 A. I think they would understand it in the
22 context of this extended history of algorithms that
23 were designed -- learning algorithms that were
24 designed to mimic elements of the biological anatomy

1 that we talked about and would encompass the variety
2 of different structures for how one constructs such
3 networks that had evolved since those early days
4 into the, you know, common convolutional neural
5 network models that were prevalent in 2019.

6 Q. And --

7 A. I would say to encompass all of that.

8 Q. And would that understanding have changed
9 at all since the January 2019 priority date through
10 to today?

11 A. In general, no. The specifics of the
12 algorithms have continued to evolve, as they evolved
13 beforehand. But I think the general concept has
14 been stable.

15 Q. Is a neural network the same thing as
16 machine learning?

17 A. No. A neural network is a form -- an
18 algorithmic form which can be considered machine
19 learning because it learns from data and experience.
20 But it is not the only machine learning algorithm.

21 Q. Is it fair to say that a neural network is
22 a framework for computation?

23 A. I'm not sure how you're using the phrase
24 "framework."

1 Q. By itself, a neural network does nothing
2 until it's paired with some kind of learning
3 algorithm, right?

4 A. I think in the context of this paragraph,
5 it's talking about an algorithm that has a purpose.
6 In this case, the purpose is clearly segmentation.
7 So I think it's inclusive of its overall
8 structure -- perhaps what you meant by
9 "framework" -- as well as its implementation for the
10 particular purpose that it was described in this
11 paragraph; i.e., medical segmentation.

12 Q. Understood as to your interpretation of the
13 use of the phrase in Paragraph 27.

14 As a definitional matter, leaving Paragraph
15 27 aside for the moment -- your interpretation
16 acknowledged -- a neural network is a structure for
17 computation that until it's combined with some kind
18 of learning algorithm, is not inherently a machine
19 learning module, right?

20 A. I don't know that that would be a common
21 construct that people would readily understand. I
22 certainly don't readily understand that the way you
23 described it; that distinction you're trying to
24 make.

1 Q. And so your opinion is that in the field of
2 medical imaging analysis, the reference to a neural
3 network by itself affirmatively refers to a machine
4 learning module?

5 A. In this context of this paragraph,
6 absolutely.

7 Q. Outside of the context of Paragraph 27.

8 A. I would say that would be the most common
9 understanding and the most common use of that
10 phrase. Certainly how I would understand it.

11 Q. Does the term "clustering" necessarily
12 connote a type of machine learning module? Or could
13 that refer to non-machine learning analysis?

14 A. I typically think of "clustering" as a
15 machine learning approach, because it learns from
16 the data itself. So described in that way, I would
17 consider it a machine learning algorithm.

18 Q. But you would agree that the term
19 "clustering" encompasses unsupervised data analysis
20 techniques that can be used without machine
21 learning, right?

22 A. If they're learning, then I would say they
23 fall under the definition of "machine learning."
24 They're learning from data. They're learning from

1 properties of the data itself and are not explicitly
2 programmed. And that, to me, is the definition of
3 "machine learning algorithms."

4 Q. I understand your opinion that
5 "clustering," as a term, can encompass a machine
6 learning approach. But you would agree that it also
7 encompasses unsupervised data analysis techniques as
8 well, right?

9 A. I'm not sure I would choose to agree with
10 the statement as you made it. I think I'll stand
11 with my original statement.

12 Q. So let me just ask one thing to be clear
13 for the record.

14 And so it is your opinion that the term
15 "clustering" does not encompass, amongst potentially
16 more than one method, an unsupervised data analysis
17 technique that can be used without machine learning?

18 MR. METZCAR: Objection, form. You can
19 answer.

20 A. My understanding, how I've used the term
21 and understood it, because the data is informing the
22 output and the properties of the data, it would
23 constitute a machine learning algorithm, as I use
24 the term.

1 Q. And it's your opinion that the term "neural
2 network," even to the extent it encompasses more
3 than one potential technique, does not encompass a
4 simple reference to a framework or structure for
5 computation, correct?

6 A. (Pause)

7 Q. Would you like me to rephrase?

8 A. Yeah. Yes.

9 Q. It is your opinion that the term "neural
10 network" does not at least encompass in its
11 definition a mere framework or structure for
12 computation, correct?

13 A. In the context here, I would say it does
14 not. Maybe that's --

15 Q. What about outside the context of Paragraph
16 27?

17 A. As I think a POSITA -- how do you say it --
18 would understand it, it includes -- it would
19 encompass algorithms that have a purpose and not,
20 you know -- and so it would encompass the algorithm
21 itself.

22 Q. But not just the framework or structure for
23 computation without applying a learning algorithm?

24 A. As commonly used in this frame, I would say

1 that's true.

2 MR. CALHOUN: I'd like to now introduce
3 what's been previously marked in this proceeding as
4 Exhibit 1016.

5 THE WITNESS: I'm just stretching.

6 MR. CALHOUN: Would you like to take a
7 break?

8 THE WITNESS: I could.

9 MR. CALHOUN: Let's go off the record.

10 (Recess taken from 10:46 to 10:53)

11 MR. CALHOUN: Once more with feeling. I'd
12 like to now introduce what's been previously marked
13 in this proceeding as Exhibit 1016.

14 (Document previously marked as Rosen
15 Exhibit 1016 for identification)

16 BY MR. CALHOUN:

17 Q. Dr. Rosen, do you recognize this document?

18 A. I'm embarrassed to say I don't have a clear
19 recollection of it at this moment.

20 Q. Do you recall whether you read this
21 document before?

22 A. As we're sitting here, I honestly don't
23 recall.

24 Q. Let's go to Page 9 of the document, which

1 if you go by the bottom left-hand pagination, is
2 Page 11 of 12 -- that's incorrect. Page 9 of 12 on
3 the pagination on the bottom left-hand page.

4 A. Okay.

5 Q. And if you look at the first full paragraph
6 that begins on that page, it says, "In clustering,
7 the aim is to construct decision boundaries based on
8 unlabeled training data. Clustering is the process
9 of finding natural grouping clusters in
10 multidimensional feature space. It is difficult
11 because clusters of different shapes and sizes can
12 occur in multidimensional feature space. A number
13 of functional definitions of clusters have been
14 proposed. Patterns within a cluster are more
15 similar to each other than patterns belonging to
16 different clusters. Image segmentation may be
17 considered a clustering process in which the pixels
18 are classified into the attribute regions based on
19 the texture feature vector calculated around the
20 pixel local neighborhood. Fuzzy clustering is a
21 good method of classifying collection of data point
22 to reside in multiple clusters with different
23 degrees of membership (fuzzy c mean algorithm)."

24 Did I read that correctly?

1 A. You did.

2 Q. And so this is describing the process of
3 finding natural grouping clusters multidimensional
4 feature space, right?

5 A. Correct. More or less how I described it.

6 Q. And so then if you go to Page 8 of 12.

7 A. Go back?

8 Q. Go back to Page 8 of 12. Under the
9 subheading at the bottom right, "Unsupervised
10 methods," it says, "Most of the unsupervised
11 algorithms are cluster based and not dependent on
12 training and training data. The two commonly used
13 algorithms for clustering are K-mean or Hard C-mean
14 and Fuzzy C-means."

15 What's a "K-mean algorithm"?

16 A. I'm not familiar with the technical
17 definition that K means "clustered." It's a form of
18 clustering; but beyond that, I can't describe the
19 algorithm.

20 Q. Understood.

21 If you go up a bit on the same page, do you
22 see the subsection, "Supervised methods"?

23 A. I do.

24 Q. And in the first sentence, Sharma states,

1 "In the supervised category, we can place mostly
2 Artificial Neural Network (ANN) based algorithms."

3 Did I read that correctly?

4 A. Uh-hum.

5 Q. And the term "Artificial Neural Network" is
6 capitalized at the first letter of each word of
7 "Artificial Neural Network," right?

8 A. Uh-hum.

9 Q. Why does Sharma capitalize that term?

10 A. I couldn't tell you.

11 Q. And why do you think Sharma uses the phrase
12 "Artificial Neural Network" rather than "Neural
13 Network"?

14 A. Just choice. And certainly to distinguish
15 it from biological ones.

16 Q. But it's your opinion he could have sort of
17 interchangeably used the word "Neural Network,"
18 provided it was understood in the context of this
19 article; that this article is referring to "imaging
20 analysis," rather than brain anatomy?

21 A. I think so, yes.

22 Q. Let's go down, then, to the second
23 paragraph in this same section, which begins with,
24 "In case of ANN" -- and I'll skip two sentences

1 here, just in reading aloud, and begin with,
2 "Although a variety of different neural network
3 based algorithms have been developed for texture
4 based segmentation and classification with good
5 classification accuracy, most of these texture
6 classifier algorithms require extensive supervision,
7 training; their performance is sensitive to training
8 parameters and is adversely affected in the presence
9 of noise. At times supervised image segmentation
10 and classification methods become very expensive,
11 difficult and even impossible to correctly select
12 and label the training data with its true category.
13 Training is the main requirement of many ANN based
14 algorithms where the classifiers need to be trained
15 before it can be applied to segmentation and
16 classification problem. Further, for different data
17 sets, analysis of different images of different type
18 and format, the whole effort of selecting training
19 data set and training is required to be redone."

20 And so Sharma is teaching here that ANNs
21 may be, quote, very expensive, difficult, and even
22 impossible, end quote, to use for segmentation for a
23 variety of reasons he listed there, right?

24 A. Well, first, I'll note that he also

1 interchangeably uses this phrase "ANN" and "neural
2 networks"; "Although a variety of different neural
3 network based algorithms..." So that supports my
4 previous contention that they're pretty much used
5 interchangeably.

6 Now, could you pose your question one more
7 time?

8 Q. So Sharma is teaching here, in what I just
9 read, that ANNs may be, quote, very expensive,
10 difficult, and even impossible, end quote, to use
11 for segmentation for the variety of reasons that he
12 lists in this paragraph, right?

13 A. He does say at times, that could be true.
14 "At times supervised image segmentation and
15 classification methods become very expensive,
16 difficult," etc.

17 Q. For the variety of reasons that he then
18 lists, right?

19 A. And then he goes on to list some of the
20 challenges.

21 I'm sorry, when was this article? 2010?
22 Journal of Medical Physics, Volume 35, Numbers 1 to
23 3, 2010. Do we agree on that date? I.e., prior to
24 Renisch and '817?

1 Q. One other question for you -- and I'll read
2 out the sentence again. It says, "Although a
3 variety" -- I'll read out the sentence again and
4 emphasize the term that I want to ask you about.
5 "Although a variety of different neural network
6 based algorithms have been developed for texture
7 based segmentation and classification with good
8 classification accuracy, most of these texture
9 classifier algorithms require extensive supervision
10 and training..."

11 What does Sharma mean by a "texture
12 classifier algorithm"?

13 A. Again, in a paper from 2010, I would guess
14 that they're talking about algorithms that are
15 looking for features within a given area of volume
16 of interest that reflect the homogeneity or
17 heterogeneity of the intensities, for lack of a
18 better term; whatever those intensities may
19 represent, and the spatial scales of those intensity
20 variations across the image. That would generally
21 be the image texture.

22 Q. Got it.

23 If you go up on the same page or on the
24 same column, there is the section that begins,

1 "Artificial Intelligence Tools for Segmentation and
2 Classification."

3 A. Okay.

4 Q. And then that first paragraph says,
5 "Automatic segmentation methods have been based on
6 artificial intelligence based techniques. AI
7 techniques can be classified as supervised and
8 unsupervised. Supervised segmentation requires
9 operator interaction throughout the segmentation
10 process whereas unsupervised methods generally
11 require operator involvement only after segmentation
12 is complete. Unsupervised methods are preferred to
13 ensure a reproducible result; however, operator
14 interaction is still required for error correction
15 in the event of an inadequate result."

16 What does -- so here, Sharma is talking
17 about supervised techniques as, quote, requiring
18 operator interaction throughout the segmentation
19 process, end quote, correct?

20 A. In this 2010 article, back in that day, 15
21 years ago, that's how he's describing it, yes.

22 Q. What does he mean by that?

23 A. In the history of segmentation, there was a
24 whole series of steps that developed over time.

1 Segmentation, for example, was originally performed
2 manually. Then there were techniques that were
3 designed to help automate the process of manual
4 segmentation.

5 Q. Uh-hum.

6 A. Then there were techniques that would do
7 the segmentation, but required annotation from an
8 expert trainer to correct mistakes that might be
9 made in the algorithms.

10 Q. Uh-hum.

11 A. And in the modern era, in the best case,
12 the machines can do this without the supervision of
13 a human.

14 So as I would imagine from a 2010 paper
15 developed in the early phases of this evolution,
16 this supervised segmentation would involve that kind
17 of second and third step I was talking about, where
18 there is human intervention in the process of
19 generating the ultimate segmentation.

20 Q. So does this statement accurately represent
21 the state of the art of artificial intelligence
22 tools for segmentation as of the priority date of
23 the '817 patent in January 2019?

24 A. Well, first I would need to read the whole

1 paper to really understand exactly what it's
2 claiming and not claiming. I would, however, say
3 that in the 2010 date, it may not fully represent
4 what the state of the art looked like in 2019, since
5 that certainly was a moving target. It would be
6 hard to deny that.

7 Q. In what ways would this statement no longer
8 have represented the state of the art by January
9 2019?

10 MR. METZCAR: Objection, form.

11 A. Please point to the particular statement
12 you're referring to. Is it the "Supervised
13 segmentation requires operator interaction"? That
14 single sentence?

15 Q. Yes. So let's take the statement,
16 "Supervised segmentation requires operator
17 interaction throughout the segmentation process."

18 Does that statement accurately represent
19 the state of the art as of the priority date of the
20 '817 patent that is January of 2019?

21 A. Um, it's hard to say, just reading that one
22 sentence out of the context. But it is certainly
23 true that over time, the needs for operator
24 interaction have diminished, as algorithms have

1 improved. And so exactly what the state of the art
2 is when this person wrote this paper probably in
3 2009 or 2008, before it got published, there's no
4 doubt that the degree of operator interaction has
5 overall decreased for any given task.

6 MR. CALHOUN: Can we go off the record.

7 (Off the record from 11:10 to 11:12)

8 BY MR. CALHOUN:

9 Q. So before we went off the record, Dr.
10 Rosen, I asked you to look at the statement that
11 supervised segmentation requires operator
12 interaction throughout the segmentation process.

13 And I asked you, Does that statement
14 accurately represent the state of the art as of the
15 priority date of the '817 patent, which is January
16 2019.

17 And you said -- and I will paraphrase here
18 and give you an opportunity to fully answer, but:
19 Hard to say. The degree of operator interaction has
20 overall decreased for any given task from the
21 publication or writing of the Sharma paper up until
22 the January 2019 priority date.

23 Is that a fair paraphrase?

24 A. I think so.

1 Q. By the January 2019 priority date, had the
2 required operator involvement been reduced to zero?
3 That is, no operator involvement was necessary?

4 A. For some tasks.

5 Q. What would be an example of a task where
6 operator involvement had become unnecessary?

7 A. Um, certainly by 2019, it was possible to
8 generate segmentations without operator
9 intervention. The question was always whether there
10 were errors associated with it.

11 Q. By 2019, was operator involvement needed to
12 identify each of the plurality of target tissue
13 regions?

14 A. I would say that there were successful
15 examples of image segmentation that could identify
16 organs, bony structures; the kind of structures that
17 were discussed in the '817 patent.

18 Q. So by 2019, there were some examples where
19 operator involvement would not be required and some
20 where it might be required, to some degree?

21 A. I think that's a fair statement.

22 Q. So let's turn back to Renisch.

23 Renisch never explicitly uses the term
24 "segmentation map," right?

1 A. That is correct.

2 Q. And he never explicitly uses the term
3 "segmentation mask" when describing his claimed
4 method, right?

5 A. If you search for the word "mask," you
6 won't find it. The conceptual find.

7 Q. So let's look a bit closer at what Renisch
8 is teaching.

9 And I'd ask you to start at Paragraph 25.
10 And that says, "Continuing with reference to Figure
11 1 and further reference to Figures 2 and 3B, the
12 diagnostic system 10 includes a hot spot detection
13 system 70 for automatic detection of a region of
14 interest (ROI) pertaining to a lesion and automatic
15 quantification of metabolic activity in detected
16 lesions," and then we skip a little bit and we
17 resume, "A segmentation unit 76 segments the
18 anatomical first image representation 72 into
19 regions which correspond to anatomical structures,"
20 and then we skip and resume, "In the case of
21 FDG-PET, the brain 78, the heart 80, and the bladder
22 82 are organs of Figure 3B which, when functioning
23 normally, are examples of anatomical structures
24 which often show high uptake unrelated to cancer."

1 Did I read that correctly?

2 A. Well, with some skips.

3 Q. With some skips.

4 A. The parts you read, I think you got right.

5 Q. Thank you.

6 So the first step here is that the
7 anatomical image is segmented into regions
8 corresponding to anatomical structures, with the
9 examples here of the brain, heart, bladder, liver,
10 etc., right -- or brain, heart and bladder?

11 A. Yes, it does anatomical segmentation.

12 Q. And so that's what we see as the
13 segmentation step in Paragraph 25. And then there
14 is a description that we've already discussed
15 earlier in your deposition from Paragraphs 26 to 28
16 about the segmentation unit, right?

17 A. Yes.

18 Q. And then we get to the detection step at
19 Paragraph 29 --

20 A. Can I elaborate on my answer?

21 Q. Yes.

22 A. It looks as though Paragraph 26 was
23 referring to the functional images. But Paragraphs
24 27 and 28 were the ones we talked about before.

1 Q. You are correct; that's right.

2 And then when we get to Paragraph 29,
3 that's the beginning of the discussion of the
4 detection step, which says, "With continuing
5 reference to Figure 2 and further reference to
6 Figures 3A and 4, a hot spot detection unit 90
7 detects from the second functional image
8 representation 74 regions of high intensity 92,
9 depicted in Figure 3A. The regions of high
10 intensity 92, generally referred to as hot spots,
11 are regions in the functional second image
12 representation that indicate high metabolic
13 activity, which potentially can be caused by tumor
14 growth or by other malignant processes."

15 And so what Renisch is describing here is
16 detecting high intensity regions throughout the
17 entirety of his functional image representation,
18 right?

19 MR. METZCAR: Objection, foundation.

20 A. So they talk about all high-intensity
21 regions, both potential malignant ones and normal
22 functioning tissues. As that paragraph goes on,
23 these regions of high intensity also include normal
24 functioning structures.

1 Q. And so Renisch is explaining that you
2 detect high-intensity regions throughout the
3 entirety of that, quote, functional second image
4 representation?

5 A. That's how it's described in these
6 paragraphs.

7 Q. And then we get to the classification step,
8 starting at Paragraph 31, which says from the top,
9 "A classifying unit, processor, or algorithm 101
10 classifies the regions of high tracer uptake
11 according to their position relative to the
12 anatomical structures segmented from the anatomical
13 first image representation."

14 Did I read that correctly?

15 A. Please excuse me. I'm trying to make sure
16 I'm familiar with the steps between where we were
17 and where we're about to be.

18 Q. Take your time. Let me know when you're
19 ready, and I'll repose the question.

20 A. Thank you. (Witness reviews document) So
21 it defines hot spots based on the segmented regions
22 of the anatomical image. So it does anatomical
23 segmentation and determines hot spots within those
24 segmented anatomical areas. That's what I read in I

1 guess that's Paragraph -- it seems to go from 29 to
2 31.

3 Q. My question is at 31.

4 A. Right.

5 Q. So let me know when I can frame that
6 question.

7 A. Okay, please.

8 Q. And so at 31, when describing the
9 classification step, Renisch states there right at
10 the beginning of 31, "A classification unit,
11 processor, or algorithm 101 classifies the regions
12 of high tracer uptake according to their position
13 relative to the anatomical structures segmented from
14 the anatomical first image representation."

15 Did I read that correctly?

16 A. You did.

17 Q. So that's explaining that regions of high
18 tracer uptake detected in the functional image are
19 classified according to their position relative to
20 the segmented anatomical structures, correct?

21 A. That's what it says, yes.

22 Q. How would you calculate the position of one
23 object relative to another in this context?

24 A. I think a clarification of that can be

1 found in the preceding section. Unfortunately,
2 there aren't line labels, so we can try to count
3 down, but give me one moment.

4 Q. If you read the beginning of the sentence,
5 I can probably find it pretty quickly then.

6 A. It says -- give me one second. (Witness
7 reviews document) It says, "The uptake unit 100
8 correlates metabolic activity from the functional
9 image representation 74 corresponding to the
10 segmented regions of the anatomical image
11 representation 72 to determine an uptake value,
12 particularly a standardized uptake value (SUV), a
13 measure of the concentration of the
14 radiopharmaceutical tracer."

15 So with that is the context I would
16 understand the next section, this classification
17 unit, as defining tracer uptake within an
18 anatomically segmented volume.

19 Q. Could you calculate the position of one
20 object to another using a numerical representation
21 of the distance between the two? Like, the distance
22 between their boundaries or center of mass?

23 MR. METZCAR: Objection, form. You can
24 answer.

1 A. When Paragraph 31 talks about -- and again,
2 I'll call it the "classification, unit, processor or
3 algorithm 101 classifies the regions of high tracer
4 uptake according to their position relative to the
5 anatomical structure segmented."

6 So I do not believe they're referring to
7 some abstract spatial relations; but just, rather,
8 the overlap of the functional activation with the
9 anatomical regions defined.

10 So I can try to answer your question again,
11 but that's how I understand this notion of position
12 relative to the anatomical structure; not relative
13 to each other.

14 Q. And then if we go to the second sentence
15 now in 31. So we just discussed the classification
16 step.

17 Now, in the second sentence of 31, we get
18 to the suppression step. And that says, "A
19 suppression unit, processor, or algorithm 102 uses
20 the results of the classification unit to suppress
21 the regions of high intensity 92 in the functional
22 second image representation."

23 So as we've been discussing, am I right
24 that -- so I can make sure I can understand. So

1 Renisch is teaching that suppression happens in the
2 functional image, targeting high-intensity regions
3 based on both how they're classified according to
4 their position relative to the anatomical structures
5 in the first image; and second, on whether a given
6 anatomical structure is deemed normal?

7 A. I'm going to ask you to rephrase that. Let
8 me see if I could help identify it if you could
9 rephrase it, please.

10 Q. So we've been working our way through the
11 method that Renisch is describing. We just
12 discussed the suppression step.

13 Am I right that what Renisch is describing,
14 to make sure I understand it, is that suppression
15 happens in the functional image, targeting the
16 high-intensity regions based on both, first, how
17 they're classified -- I think he uses the phrase --
18 and I'll quote here in 31 -- "According to their
19 position relative to the anatomical structures
20 segmented from the anatomical first image
21 representation," end quote.

22 And so he uses that for suppression in the
23 functional image targeting high-intensity regions,
24 and he also uses on whether a given anatomical

1 structure is deemed normal.

2 MR. METZCAR: Objection, form. You can
3 answer.

4 A. I read what he's describing as defining
5 anatomical areas, spatially registering with
6 functional images, determining areas of high uptake
7 in the functional image according to where they are
8 within the anatomy. And then if they are from
9 regions that normally are high, suppressing that
10 anatomical area; the functional data from that
11 anatomical area. And I think that's consistent with
12 Figure 3.

13 Q. And so the anatomical segmentation is used
14 as a reference for deciding which high-intensity
15 regions to suppress?

16 A. The anatomical region defines organs which
17 have high normal uptake and thus, as they describe,
18 could potentially obscure areas of high intensity
19 that are abnormal. And so suppressing them, you
20 know, would improve your ability to detect those
21 areas.

22 Q. Got it. So in that case, to tweak it
23 slightly, it would be fair to say, as a summary
24 point, that anatomical segmentation is used as a

1 reference for deciding which high-intensity regions
2 to suppress, correct?

3 A. In this description, that's correct. Based
4 on knowledge of their function.

5 MR. CALHOUN: I'd like to show you what's
6 been marked previously in this proceeding as Exhibit
7 1007.

8 (Document previously marked as
9 Exhibit 1007 for identification)

10 Q. Do you recognize this document, Dr. Rosen?

11 A. I do.

12 Q. And what is it?

13 A. It is what I refer to in my report as the
14 "Zhao patent."

15 Q. And have you read this entire patent?

16 A. I have.

17 Q. You agree that Zhao never expressly refers
18 to 3D segmentation maps, right?

19 A. Zhao does refer to segmentation masks of 3D
20 objects, and so I would say it is a characteristic
21 of 3D segmentation. A CT image is a 3D image.

22 Q. Let me clarify. I asked or meant to ask,
23 Zhao never expressly refers to 3D segmentation maps?

24 A. It does not use the word "map." It does,

1 however, talk about a plurality of masks.

2 Q. And so you testified a moment ago as to 3D
3 segmentation masks, anticipating my next question
4 that, in your opinion, Zhao does refer to
5 segmentation masks of 3D objects.

6 What do you mean by that?

7 A. Zhao specifically talks about segmentation
8 of 3D medical images. For example, CT images. CT
9 images are images of 3D objects. And even a single
10 plane of a CT image represents a 3D object, because
11 it has both X, Y and Z information inherent in it,
12 as opposed to a conventional radiograph, which of
13 course, does not have that third axis of
14 information.

15 Q. And so a CT scanner requires multiple axial
16 two-dimensional imaging slices, correct?

17 A. Those slices have a thickness, as well as X
18 and Y positions.

19 So again, it represents a thin slab of the
20 3D object that's the body or organ investigated.

21 Q. And so when a radiologist --

22 A. It's intrinsically 3D, is what I would say.
23 Sorry.

24 Q. No apologies.

1 So when a radiologist views a displayed
2 frame on a screen, isn't it true that the
3 radiologist is reviewing that slice as a 2D slice?
4 No?

5 A. A radiologist would always look at the data
6 for multiple slices to put the framework of their
7 inspection of any given slice in the context of the
8 3D object. That's part of the functional review
9 process of imaging -- of reviewing CT images. The
10 same would be true for MRI.

11 Q. Understood.

12 And whether a radiologist, though, reviews
13 an individual frame, that's -- in that moment, he's
14 reviewing a 2D slice. It's not your testimony that
15 they're reviewing the third dimension of that slice
16 when interpreting the image?

17 A. Actually, that's not true.

18 Q. And why is that?

19 A. And the reason is that the slice thickness
20 information is visible, physically visible, to the
21 radiologist, based on the fact that the slice
22 thickness has a partial volume. And so that the
23 thickness of that slice and its position relative to
24 the rest of the anatomy actually is visible and

1 something that the radiologist definitely will look
2 at.

3 For example, if they're looking at tubular
4 structures that may lie along the plane, they may
5 have an incomplete visualization of, say, the
6 diameter of that object. And knowing the partial
7 volume turns out to be important as they interpret
8 that image, as just one example.

9 So I believe thinking of it in 3D -- the
10 screen, itself, is a two-dimensional screen. But
11 the interpretive process that a radiologist learns
12 is a 3D process. They learn to think and look in
13 3D.

14 Q. In your clinical experience, how often is
15 that third dimension relevant to your clinical
16 assessment of a CT image?

17 A. Very frequently.

18 Q. How often?

19 A. You know, it does depend on the specifics
20 of what you're looking at. But a determination, for
21 example, of the slice thickness is an important part
22 of how one protocols CT or MRI images based on the
23 anatomy and the clinical question.

24 So that understanding of that third

1 dimension is inherent before the patient even ever
2 gets on the table. And again, the radiologist will
3 always look at that slice in the context of other
4 slices. They scroll through the multiple slices to
5 build a 3D representation of that organ, the section
6 of the body, whatever. That's part of the
7 interpretive process.

8 Q. Let's look at Zhao here. If we go to
9 Column 7; Column 7, Line 65. So that's the last
10 full paragraph on Column 7. And it says here, "The
11 feature maps 204, 212, 220 may be max-pooled
12 spatially to generate the input to a next layer
13 below, as shown by hallow arrows 206, 214, and 222.
14 The max-pooling may be performed using any suitable
15 basis, e.g., 2 by 2, resulting in down-sampling of
16 an input by a factor of 2 in each of the two spatial
17 dimensions."

18 And so Zhao is describing here operations
19 in two spatial dimensions, right?

20 A. That's what this section that you just read
21 out is describing; operating, as it says, in the two
22 spatial dimensions.

23 Q. And then if we go to Column 8, Line 47, it
24 says, "The stack of feature maps 260 of the

1 expansion CNN 203 may be further converted to a
2 predicted mass 264, as shown by the solid arrow 262.
3 For example, the arrow 262 may form a fully
4 connected layer. For a binary mask, each pixel of
5 the mask 264 comprises a two-dimensional vector
6 representing the probability that the particular
7 pixel is part of the ROI and the probability that
8 the particular pixel is not part of the ROI. For a
9 mask for different types of ROI, each pixel of the
10 mask 265 would likewise comprise a multidimensional
11 vector representing the probabilities..."

12 Did I read that correctly?

13 A. You did.

14 Q. And this is defining the mask here in Zhao
15 as per pixel, right?

16 A. I'm sorry, please rephrase your question?

17 Q. So what we're reading here is defining the
18 mask that Zhao is disclosing on a per-pixel basis,
19 right?

20 A. Those are the phrases that it uses. But of
21 course, in the context of the patent and what it
22 describes when looking at CT images, it's talking
23 about organs and the volume of those, but doing so
24 on a slice-by-slice basis.

1 Q. Doing so on a two-dimensional vector and
2 looking at each pixel.

3 Zhao never uses the term "voxel" in any way
4 to describe his claimed invention, right?

5 A. I take it that you've searched for the
6 phrase "voxel" and haven't found it. So I'll accept
7 that if that's your claim.

8 But they do talk about regions of interest
9 and representing things like organs, which are
10 three-dimensional objects.

11 Q. Let's go to Column 5, Line 30.

12 A. Okay.

13 Q. And that says here, "Each pixel of the mask
14 may contain a value used to denote whether a
15 particular corresponding pixel of the digital image
16 is among any ROI..." And then we skip a little bit
17 and resume the quote, "For a mask capable of
18 representing multiple types of ROI, each pixel may
19 be at one of a number of values each corresponding
20 to one type of ROIs. A multi-value mask, however,
21 may be decomposed into a combination the more
22 fundamental binary masks each for one type of ROI."

23 Did I read that correctly?

24 A. You did; with the parts skipped over, yes.

1 Q. And so again, this passage is also talking
2 about pixels as in 2D images, right?

3 A. It's talking about -- it uses the phrase
4 "pixel," but it also talks about ROIs, which in the
5 broader context -- in the very next column, when
6 they're talking about CT images of lungs, those ROIs
7 represent volumes. So I would interpret this as
8 slices from a volumetric image.

9 Q. Does Zhao teach the stitching together of a
10 plurality of masks?

11 A. Zhao talks about a multi-value mask, which
12 may be decomposed into its combination. And so I
13 would say his teaching what is in '817, called a,
14 you know, a map, a segmentation map, because it
15 represents a plurality of individual areas; each
16 binary mask for each single type of ROI.

17 Q. But would you agree that -- let me start
18 again.

19 I understand your proposed construction of
20 a 3D segmentation map is a plurality of 3D
21 segmentation masks.

22 If the Judge were to conclude that the term
23 "3D segmentation map" further required that you have
24 to undergo a process of stitching the masks together

1 in order to form the map, in that hypothetical, you
2 would agree with me that Zhao doesn't teach the
3 stitching together of the multiple masks, right?

4 A. Because the '817 patent didn't describe the
5 stitching in its claims, I may not have reviewed
6 this document in detail enough to evaluate that,
7 because I didn't feel that the stitching was kind of
8 a required element in terms of the anticipation of
9 the patent. So I would need to read this in greater
10 detail to affirm or deny that particular point.

11 Q. Fair.

12 A. But it certainly seems to anticipate --
13 sorry, it does seem to anticipate segmentation maps
14 as a plurality of masks in the sentence that I just
15 read. The "stitching together" part, I would say I
16 would have to go through to answer your question --
17 to be confident to answer your question.

18 Q. So a fairer way to phrase that question is,
19 you don't have an opinion on whether Zhao teaches
20 "stitching together" a plurality of masks?

21 A. That's correct.

22 Q. Zhao's detailed embodiments discussed in
23 the specification, those focus on lung segmentation,
24 right?

1 A. Certainly, that lung is discussed, you
2 know, explicitly. I'd have to again read through to
3 see whether other organs were also discussed, but
4 certainly the lung was.

5 Q. Can you point to any examples or
6 embodiments in Zhao involving multi-organ map
7 construction?

8 A. Now I am going to have to take my time.

9 Q. Please take your time.

10 A. (Witness reviews document) The examples I
11 see, as I'm looking at it now, seem focused on the
12 lung.

13 Q. And I'll represent that's consistent with
14 our understanding, too.

15 So you would agree that there are no
16 examples or embodiments discussed in Zhao involving
17 multi-organ map construction?

18 MR. METZCAR: Objection, foundation.

19 A. I think my understanding is that the lung
20 was illustrated as an example. So it was in no way
21 exclusive to the lung.

22 Q. And you agree that there are -- would you
23 agree that there are no examples or embodiments in
24 Zhao involving the transfer of such a multi-organ

1 map to functional images?

2 MR. METZCAR: I'll object on foundation.
3 Again, you can answer.

4 A. That was -- I believe that's true, yes.

5 Q. It's your opinion that Renisch and Zhao
6 combine to render certain claims of the '817 patent
7 obvious, right?

8 A. Correct.

9 Q. What specific problems or limitations in
10 Renisch is it your opinion are solved by adding
11 Zhao?

12 A. So two points. It is my opinion that
13 Renisch on its own does fully anticipate '817.
14 However, I understand that there may be other
15 opinions on the issue of this notion of segmentation
16 masks. And in a belt-and-suspenders approach, if
17 you will, taking your language, Zhao specifically
18 teaches the use of segmentation masks and a
19 plurality of segmentation masks. And so if the
20 Board were to feel that Renisch was not fully
21 anticipatory because it didn't mention the notion of
22 segmentation masks using those words, Zhao does so.

23 Q. As of the January 2019 priority date of the
24 '817 patent, how would a POSITA have integrated

1 Zhao's loss function regime into Renisch's atlas
2 segmentation pipeline?

3 MR. METZCAR: Objection, form. You can
4 answer.

5 A. Again, it's my opinion that a POSITA would
6 understand that Renisch fully anticipates the notion
7 of segmentation. However, Zhao, by teaching the use
8 of the term "masks," provides context for
9 understanding what Renisch was referring to. And it
10 would be obvious to somebody of ordinary skill in
11 the art to use a segmentation mask as described in
12 Renisch to perform the segmentation functions --
13 excuse me, segmentation masks described in Zhao to
14 apply that concept, the creation of a mask and
15 masks -- mask and map, to use the language of '817
16 to what was described in Renisch.

17 Q. Would you agree, though, that neither
18 Renisch, nor Zhao describe the specific data
19 structures or APIs you would need to combine
20 Renisch's atlas segmentation with Zhao's loss
21 function teaching?

22 A. I think the key teaching of Zhao is the
23 concept of the segmentation mask and its plurality.
24 And it would be clear to be able to use that

1 principle as described in Zhao as an a viable means
2 to do the segmentation, as described in Renisch. I
3 don't believe a specific API was articulated.

4 Q. And it's your opinion that the choice of
5 API or the specific configuration of the data
6 structures don't need to be articulated in Renisch
7 or Zhao, because a POSITA would know -- a POSITA
8 would be motivated to combine them with a reasonable
9 expectation of success, because the POSITA would
10 understand, more or less, exactly which ones --
11 which data structures and APIs they could use --

12 A. Yes.

13 Q. -- to combine the two?

14 A. Yes.

15 Q. And so it would be your opinion that that
16 specific -- actually, let me rephrase.

17 So it would be your opinion that a slight
18 change in the configuration of the data
19 structures -- let's say in preprocessing, for
20 example -- wouldn't make a material difference to
21 the accuracy of this combined Renisch/Zhao method
22 that you're referring to?

23 A. I'm not sure I would agree with the
24 statement as you just made it.

1 Q. How would you qualify it?

2 A. Any change in the algorithm certainly runs
3 the risk of changing the output. And so the way you
4 phrased it, I couldn't say that a change in
5 algorithm would, by necessity, have no change in the
6 output -- the accuracy of the output, its propensity
7 for errors, etc. This is the subject of, you know,
8 detailed engineering.

9 However, the fundamental concepts laid out
10 I think are clear and were well known to the field
11 at the time of the '817 patent.

12 Q. You would at least agree that in combining
13 Renisch's atlas segmentation and Zhao's loss
14 function regime, in order to achieve the claimed
15 invention of the '817 patent, the POSITA would need
16 to configure the data structures, choose the API,
17 and so forth, right?

18 MR. METZCAR: Objection, foundation. You
19 can answer.

20 A. There's a lot that goes into writing,
21 working computer code. But based on the claims of
22 the patent, to implement those claims, Renisch and
23 Renisch with Zhao provide the fundamental teachings
24 that then engineers would use to choose the

1 specifics of the algorithms they choose to utilize,
2 including whether to do the segmentation slice by
3 slice and from that create a volume, or to do the
4 segmentation of the 3D data intrinsically, which of
5 course in the case of CT, since it's acquired as 2D
6 data, involves the merging of the data into the
7 slices of the 3D.

8 So whether you do the segmentation kind of
9 before you do that merger or after, these are
10 operational choices, both of which were well known
11 to the literature at that time.

12 MR. CALHOUN: I'd like to show you what I'm
13 going to mark as Exhibit 2039.

14 THE WITNESS: I'm going to give a warning
15 that I would like a break soon.

16 MR. CALHOUN: Let's do it now.

17 (Luncheon recess taken
18 from 11:57 to 12:31 p.m.)

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AFTERNOON SESSION

BY MR. CALHOUN:

Q. Dr. Rosen, during the break, did you discuss the subject of your testimony with Mr. Metzcar?

A. I did not.

MR. CALHOUN: I'd like to now show you what we're going to mark as Exhibit 2039.

(Document marked as Exhibit 2039 for identification)

Q. Dr. Rosen, do you recognize this document?

A. I do.

Q. And what is this document?

A. This is a paper published in 2019 in the journal, Neuro-Oncology, talking about assessment of glioma using a deep learning algorithm.

Q. And you are listed as an author on this publication, correct?

A. I am, along with several of my good friends and colleagues.

Q. And you see here at the top, this was published in 2019, with an Advance Access date of June 13, 2019?

A. I see that.

1 Q. Please turn to the third page, in the first
2 paragraph.

3 MR. METZCAR: I'm sorry, for the record,
4 what's the page number at the top? You said the
5 third page.

6 MR. CALHOUN: To Page No. 1414 on the top
7 left of the paper, with the paragraph that begins
8 with, "With the advent..."

9 A. Okay.

10 Q. And if you go to the third sentence in that
11 paragraph it says, "Existing deep learning methods
12 have not been developed for the post-operative
13 setting, where the surgical cavity and brain
14 distortion make it difficult to reliably outline the
15 boundaries of the tumor."

16 Did I read that correctly?

17 A. I see where it says that.

18 Q. So is the idea here in this sentence that
19 specific clinical settings can require developing
20 specific deep learning methods to account for the
21 realities of the specific clinical setting?

22 A. I think that's a fair statement.

23 Q. And then if we go down to the next
24 paragraph, which is the paragraph that begins,

1 "There are 2 key challenges to automatic tumor
2 segmentation," if we go halfway down that paragraph,
3 let me know when you've found the sentence that
4 begins, "The second challenge is generalizability."
5 Just let me know when you're there.

6 A. I see it.

7 Q. So that reads, "The second challenge is
8 generalizability: MR intensity values vary
9 substantially depending on the MR scanner properties
10 (including manufacturer, scanner type, and field
11 strength) and acquisition parameters (including echo
12 time, repetition time, and contrast injection
13 dose/timing) and can result in substantial
14 differences in tumor appearance. Consequently,
15 algorithms trained on limited datasets may not apply
16 well to data acquired from different institutions,
17 acquisition protocols, and patient populations."

18 Did I read that correctly?

19 A. You did.

20 Q. And so here, you and your coauthors are
21 cautioning that deep learning segmentation could
22 fail to generalize across sites and machines, right?

23 A. That is a concise summary of what that
24 sentence -- pair of sentences said.

1 Q. Would these concerns apply to the
2 combination of Renisch and Zhao or Renisch and any
3 of the other asserted references in your
4 declaration?

5 A. I see these as statements of the particular
6 engineering challenges of creating algorithms that
7 work broadly in realistic clinical settings.

8 The concepts of Renisch and the concepts in
9 Zhao I think are fully applicable, acknowledging the
10 reality that when one wants to build an actual
11 working algorithm, challenges can be encountered
12 specific to the particular purpose that the
13 algorithm is being put to.

14 MR. CALHOUN: I'd like to show you what I'm
15 going to mark as Exhibit 2040. You can put that
16 aside.

17 (Document marked as
18 Exhibit 2040 for identification)

19 BY MR. CALHOUN:

20 Q. Dr. Rosen, do you recognize this document?

21 A. I'm afraid I do. I do.

22 Q. And what is it?

23 A. This is another research investigation from
24 my graduate student, Ken Chang, and various

1 colleagues here, published in "Clinical Cancer
2 Research" in -- let's get the date right -- March of
3 2018.

4 Q. Yes.

5 And to be clear, you're listed as an author
6 on this paper, right?

7 A. I am.

8 Q. If you turn to the second page, which is
9 Page 1074, do you see the box at the top left
10 entitled "Translational Relevance"?

11 A. I do.

12 Q. And it says here, "Deep learning algorithms
13 can be trained to recognize patterns directly from
14 imaging. In our study, we used a residual
15 convolutional neural network to noninvasively
16 predict IDH status from MR imaging."

17 So this study is dealing with magnetic
18 resonance or MR images, correct?

19 A. That's right.

20 Q. If we turn to the third page, which is
21 1075, please turn and let me know when you're at the
22 heading, "Tumor Segmentation."

23 A. I'm there.

24 Q. "For the HUP and TCIA cohorts, MR imaging

1 for each patient was loaded into Matrix User Version
2 2.2 (University of Wisconsin, Madison, Wisconsin),
3 and 3D regions-of-interest were manually drawn
4 slice-by-slice in the axial plane for the FLAIR
5 image by a user (H. Zhou) followed by manual editing
6 by a neuroradiologist (Q. Shen). For the BWH
7 cohort, tumor outlines were drawn with a
8 user-driven, manual active contour segmentation
9 method with 3D Slicer software (version 4.6) on the
10 FLAIR image (K. Chang) and edited by an expert
11 neuroradiologist (R.Y. Huang; references 36, 37.
12 (The segmented contour was then overlaid with source
13 FLAIR, T2, T1 precontrast, and T1 postcontrast
14 images."

15 So here, you're talking about identifying
16 tumors in an MR image, right?

17 A. Correct.

18 Q. And in this paper, for some of the images,
19 a user named H. Zhou manually segmented a tumor
20 slice-by-slice, right?

21 A. For the FLAIR images, yes.

22 Q. And then a neuroradiologist named Q. Shen
23 manually edited them?

24 A. That's what it says, yes.

1 Q. And for some of the other images, like the
2 BWH cohort -- is "BWH cohort" just Brigham & Women's
3 Hospital?

4 A. Correct.

5 Q. So for the BWH cohort, tumor outlines were
6 drawn manually by K. Chang?

7 A. Ken Chang, yes.

8 Q. And then edited by neuroradiologist R.Y.
9 Huang?

10 A. Right.

11 Q. Why this two-step process? Why did you use
12 this two-step process in this study, where you had
13 one user draw the tumor outlines and then a
14 neuroradiologist manually edit them?

15 A. For the reason that the original users,
16 Zhou and Chang, were young investigators; a student
17 in the case of Ken Chang; post-doc I believe in the
18 case of Zhou. And the feeling was that doing the
19 best possible segmentation would be advantageous.

20 And so to check their work, an experienced
21 neuroradiologist would essentially confirm and edit,
22 if need be, the boundaries defined by these younger
23 investigators.

24 Q. Okay. So if we move down now for the

1 moment to the first paragraph under the heading
2 "Image preprocessing."

3 A. Uh-hum.

4 Q. So if you go down about halfway through,
5 I'll read from, "To utilize information..." Do you
6 see that sentence and I'll read from there?

7 A. I do.

8 Q. It says, "To utilize information from all
9 three spatial dimensions, we extracted coronal,
10 sagittal, and axial tumor slices from each patient.
11 Only slices with tumor were extracted. To extract a
12 slice, a bounding rectangle derived from the tumor
13 segmentation was drawn around the tumor. This
14 ensures that the entire tumor area is captured as
15 well as a portion of the tumor margin. Because
16 every tumor is different in size, all slices were
17 resized to 142 by 142 voxels for input into our
18 neural network."

19 So to analyze a tumor in an MR image, you
20 took slices -- coronal, sagittal, axial -- tumor
21 slices from each patient, right?

22 A. Correct.

23 Q. And then each slice cut through the tumor
24 that your two users then manually segmented, right?

1 A. I believe the segmentation came first --

2 Q. Sorry. Your two users manually segmented,
3 and then each slice cut through the tumor.

4 And so to extract a slice, you drew a
5 rectangle around the tumor, capturing the entire
6 tumor area, plus some additional margin, right?

7 A. (Witness nods head)

8 Q. And each slice is a 2D image, right?

9 A. Well, it is true that the word "slice"
10 would imply -- again, with the caveats in describing
11 what a slice means in the context of a 3D
12 image modality. Thickness is, of course, also --

13 THE COURT REPORTER: Could you repeat that?

14 A. Sorry. With the caveat, as we described
15 earlier, that a slice represents a 3D object and has
16 thickness, as well as its two dimensions. But, yes,
17 these were -- they were utilizing it -- as it says,
18 utilizing information from all three spatial
19 dimensions, they then extracted planes from -- data
20 from coronal, sagittal, axial planes for their
21 subsequent analysis.

22 Q. The last sentence says, "Because every
23 tumor is different in size, all slices were resized
24 to 142 by 142 voxels for input into our neural

1 network."

2 That's referring to two spatial dimensions,
3 right?

4 A. That's correct. Times all the slices that
5 were then generated.

6 Q. And so those 2D slices are then analyzed.
7 They're what are the input to your residual
8 convolutional neural network, right?

9 A. Correct.

10 Q. And so to analyze MR images -- scratch
11 that.

12 A. Of course, the tumor was -- sorry for
13 interrupting.

14 Q. So in this paper here, no image is
15 segmented using a convolutional neural network
16 right? Tumor segmentation is done manually, using
17 two operators, right?

18 A. That is correct in this paper.

19 MR. CALHOUN: I would like to show you, Dr.
20 Rosen, what's been previously marked in this
21 proceeding as Exhibit 1009 --

22 A. Can I just add before we move on to the
23 next topic to say that the point of the paper was
24 not tumor segmentation.

1 Q. Yes.

2 A. The network was designed to perform a
3 different function.

4 MR. CALHOUN: So this has been previously
5 marked as Exhibit 1009 in this proceeding.

6 (Document previously marked as Rosen
7 Exhibit 1009 for identification)

8 Q. Do you recognize this document, Dr. Rosen?

9 A. The PROMISE, yes.

10 Q. And what is this publication? What does
11 this publication describe?

12 A. It's a proposed classification for staging
13 of prostate cancers with a PSMA-targeted PET ligand.

14 Q. And have you read this entire paper?

15 A. I have.

16 Q. So as indicated here in the title, the
17 title is "Prostate Cancer Molecular Imaging
18 Standardized Evaluation (PROMISE) Proposed miTNM
19 Classification for the Interpretation of PSMA-Ligand
20 PET/CT."

21 So this is presenting a standardized
22 reporting framework for PSMA PET/CT that they call
23 "PROMISE," right?

24 A. Correct.

1 Q. This paper doesn't present a software
2 algorithm for automatic segmentation of a medical
3 image, right?

4 A. No. It proposes a means for clarification,
5 but doesn't describe the software tool to do so.

6 Q. Please turn to what is marked at the bottom
7 left as "Page 3 of 10." And let me know when you've
8 found the section on the right-hand side of Page 3
9 that begins with "miPSMA Score."

10 A. Okay, I've found that.

11 Q. And I'm going to read the first paragraph.
12 "We propose a miPSMA score that enables standardized
13 reporting of PSMA expression as detected with
14 PSMA-ligand PET. Expression categories are defined
15 in relation to mean uptake in the blood pool, liver,
16 and parotid gland (Table 1; Figure 1). Results are
17 reported as 0, 1, 2 or 3 for no, low, intermediate,
18 or high PSMA expression, respectively. Scores 2 and
19 3 are empirically considered typical for prostate
20 cancer lesions and favorable for PSMA-directed
21 radioligand therapy. Expression level is determined
22 visually, and we do not recommend uptake
23 measurements on a regular basis. Occasionally,
24 quantitative analyses might be necessary to

1 correctly assign a specific miPSMA score."

2 A. Thank you.

3 Q. So Eiber is indicating here that -- let me
4 rephrase.

5 The authors of this paper are indicating
6 that the reporting framework that they're proposing
7 doesn't generally recommend the use of automated
8 index computations, right?

9 A. I believe the way they describe this and
10 how I understand this paper is that they believe
11 that this determination -- this quantization of the
12 uptake -- the 0, 1, 2 and 3 that you described --
13 can be successfully done visually, often without
14 ambiguity. However, in situations where there might
15 be ambiguity -- and that's there occasionally --
16 then they suggest the quantitative analysis would be
17 necessary to correctly make the assignment.

18 So I believe they're saying that in
19 general, this could be done by visual inspection.
20 But quantitative tools may be helpful in situations
21 where there's ambiguity in that determination.

22 Q. And to tie to the text just a tad bit more,
23 they would say that on a regular basis, they would
24 not recommend uptake measurements; but that

1 occasionally, it might be necessary, right?

2 A. Those are the words. I interpret them to
3 mean they're not required on a regular basis.

4 Q. Let's go down to the end of the next
5 paragraph, where it says in the last sentence of
6 that paragraph, "Notably, SUV measurements in
7 PSMA-ligand PET require further validation and
8 investigation to clarify whether SUVmean, SUVmax, or
9 SUVpeak is the most appropriate parameter."

10 Did I read that correctly?

11 A. You did.

12 Q. So Eiber is noting here uncertainty over
13 whether SUVmean, SUVmax or SUVpeak are most appropriate
14 and is calling for prospective validation as to
15 which measure is the most appropriate, right?

16 A. It does say, "requires further validation."
17 It didn't necessarily -- it doesn't say "prospective
18 validation," which is I think the phrase that you
19 used. But it does suggest that further validation,
20 which could be retrospective or prospective.

21 Q. Let rephrase, then. Eiber is noting here
22 that there is uncertainty as to whether SUVmean, max,
23 or peak is the most appropriate parameter and
24 concludes that further validation and investigation

1 would be necessary to clarify which measurement is
2 most appropriate, right?

3 A. That's fair.

4 Q. And this paper also warns that
5 biodistribution differs across PSMA agents, right?

6 A. The first sentence of the next paragraph --
7 I'll read it -- "Detailed comparative data are
8 lacking on the biodistribution of various PSMA
9 ligands."

10 And so it would suggest that there remains
11 uncertainty as of the time of this paper on how the
12 different PSMA ligands may distribute across the
13 body. And that, of course, may also impact the
14 values that are derived from that.

15 Q. And actually, if you go back to Page 2 of
16 10, at the very top left, there's Table 1, where it
17 reports the miPSMA expression score.

18 A. Yes.

19 Q. And so this reports the miPSMA expression
20 score based on reported PSMA expression and uptake,
21 right?

22 A. Those are the labels on the columns.

23 Q. And this is presented as a -- the miPSMA
24 score is presented in the paper as a reader score to

1 aid reporting?

2 A. Correct.

3 Q. And do you see the footnote at the bottom
4 of Table 1 says, "For PSMA ligands with
5 liver-dominant excretion (e.g., [18F]-PSMA1007)
6 spleen is recommended as reference organ instead of
7 liver."

8 That's a reflection of this biodistribution
9 difference. Do you understand that footnote as
10 reflecting this biodistribution difference across
11 organs that we're discussing?

12 A. Yes.

13 Q. And so the paper is recommending here that
14 you change the reference organ based on that
15 different ligand biodistribution for at least the
16 two examples here?

17 A. The paper says "is recommended," so yes.

18 Q. And so as a result, this paper suggests
19 that there wouldn't be a reliable uniform index
20 value across different agents, right?

21 A. I read the paper as articulating the need
22 and benefit of having a scoring system, but that
23 that scoring system needs to be devised in light of
24 the specific properties of the tracer involved,

1 which might involve differences in biodistribution,
2 for example.

3 Q. I think we're on the same page. Let me try
4 to ask almost like an inverse question, then, to
5 confirm that we have nothing else to discuss on this
6 one.

7 So that would mean that -- would changing
8 the reference organ require a different
9 agent-specific logic and new thresholds?

10 A. If you change the agent, the specifics of
11 the agent, you would revisit exactly which criteria
12 you would use in coming up with a grading system.

13 Q. Let's turn to the first page here, Page 1
14 of 10. And if we look at the abstract, it's the
15 third sentence. Let me know when you've found it.
16 It starts with, "We propose a molecular..."

17 A. I see it.

18 Q. It says, "We propose a molecular imaging
19 TNM system (miTNM, Version 1.0) as a standardized
20 reporting framework for PSMA-ligand PET/CT or
21 PET/MRI."

22 And then we're going to skip two sentences
23 from the readout. And the final sentence -- sorry,
24 the second-to-the-last sentence says, "Specific

1 applications, such as assessment of prognosis or
2 impact on management, should be evaluated in future
3 trials. miTNM is a living framework that evolves
4 with clinical experience and scientific data."

5 So this paper is describing its proposed
6 scoring system as a, quote, living framework and, as
7 we saw earlier, for the use of computational
8 statistics, notes that further validation and
9 investigation would be necessary, right?

10 A. For any given tracer in any given setting.

11 Q. And so this paper would indicate that there
12 could be some difficulties to expecting success in
13 using this scoring system for actual clinical
14 prognosis or management, right?

15 A. This paper describes the issues one would
16 need to be sensitive to in trying to understand when
17 you could rely on results from this approach and
18 when you would want to exercise caution. Again, it
19 uses the phrase "the framework." And I think that's
20 a fair way to characterize what it is.

21 Q. And as a living framework that requires
22 further validation and investigation, you would
23 agree that Eiber and coauthors are making clear that
24 this paper isn't ready for immediate computational

1 application across 3D medical means?

2 MR. METZCAR: Objection, foundation. You
3 can answer.

4 A. I wouldn't have phrased it that way. I
5 would say that they've proposed a framework, which
6 they believe in settings is usable, but is a 1.0
7 version; that it has opportunities to be improved
8 upon.

9 The fact that it bears improvement doesn't
10 necessarily say it doesn't have utility at the stage
11 when it was written. And I think the authors
12 believe that it does have utility, albeit they
13 acknowledge that that utility is not perfect and it
14 is open for improvements along the lines that we
15 have been discussing.

16 Q. And let's go back to just Page 3 for one
17 moment, the second paragraph under "miPSMA Score,"
18 the final sentence beginning "Notably..." We read
19 that before, right?

20 A. "Notably," yeah.

21 Q. As applied to reporting SUV measurements,
22 Eiber and coauthors are being clear that they have
23 not yet determined -- they have not yet validated or
24 sufficiently investigated which SUV parameter would

1 be the most appropriate, right?

2 MR. METZCAR: Objection, foundation. You
3 can answer that.

4 A. I start with the beginning sentence of that
5 paragraph. "On the basis of personal experience, we
6 advise comparison of the mean SUVs of the respective
7 lesions and the reference organ."

8 So I interpret this to mean that first,
9 they have personal experience. They're using it in
10 a clinical setting. And their medical judgment as
11 of the time of the writing was that the mean SUV was
12 the one that they found most valuable: Based on
13 their personal experience, "we advise," so they're
14 making a specific recommendation.

15 However, they then go on to say that it's
16 possible that perhaps in future versions, other
17 metrics may prove to be even better. And that's how
18 I would interpret this question of clarifying SUVmean,
19 SUVmax, SUVpeak as the most appropriate measure. That,
20 of course, doesn't mean that the measure of mean
21 SUV, the one that they use here, is not appropriate.
22 It means there may be something that's more
23 appropriate or may not be.

24 Q. Let's turn back for a moment to Exhibit

1 2039. That's the 2019 Chang paper.

2 MR. METZCAR: I'm sorry, could you say that
3 again?

4 MR. CALHOUN: 2039. It's the 2019 Chang
5 paper.

6 A. For clarity, this is the Neuro-Oncology
7 paper?

8 Q. This is the Neuro-Oncology paper titled,
9 "Automatic assessment of glioma burden."

10 A. Okay.

11 Q. And if you look at the associated page,
12 which is numbered at the top right 1413, on the
13 first paragraph of the main text, it says in the
14 beginning -- I'll just read from the first
15 sentence -- "Gliomas are primary central nervous
16 system tumors with variable natural histories and
17 prognoses depending on their histologic and
18 molecular characteristics. The current gold
19 standard to determine treatment response and assess
20 tumor progression in clinical trials is the Response
21 Assessment in Neuro-Oncology (RANO) criteria."

22 A. Often pronounced "RANO."

23 Q. RANO. That was going to be my next
24 question.

1 A. Sorry.

2 Q. "For high-grade gliomas, including
3 glioblastomas or GBMs, radiographic response
4 assessment is based on (i) measurement of the 2D
5 product of maximum bidimensional diameters of
6 contrast-enhancing tumor and (ii) qualitative
7 evaluation of T2/fluid-attenuated inversion recovery
8 (FLAIR) abnormal hyperintense regions."

9 Did I read that correctly?

10 A. You did.

11 Q. And so as of June 2019 for the purposes of
12 this study, the gold standard was manual
13 delineation?

14 A. That is true.

15 Q. And the paper then continues, "However,
16 manual delineation of tumor boundaries can be
17 difficult due to the infiltrative nature of gliomas
18 and presence of heterogeneous contrast enhancement,
19 which is particularly common during anti-angiogenic
20 treatment. As a result, there can be substantial
21 interrater variability in 2D measurements for both
22 contrast-enhancing and FLAIR hyperintense tumors.
23 Furthermore, variability in segmentation can
24 introduce substantial variability in calculated mean

1 values of multi-parametric magnetic resonance (MR)
2 parameters, such as the volume transfer constant.
3 Consequently, there is great interest in developing
4 reproducible automated methods for segmentation and
5 calculation of the product of maximum bidimensional
6 diameters."

7 Did I read that correctly?

8 A. You did.

9 Q. Just to make sure I have this right,
10 "interrater variability" means variability from
11 human radiologist to human radiologist?

12 A. Correct.

13 Q. So as of June 2019, physicians felt there
14 was an unmet need for this kind of 3D solution to
15 reduce that interrater variability, right?

16 A. The researchers of this paper felt that
17 there was that unmet need. Interestingly enough,
18 the clinical community has been rather stuck on RANO
19 for quite some time.

20 Q. And then the next paragraph says -- this
21 starts the second paragraph of the main text --
22 "Although 2D linear measurements currently represent
23 the gold standard for response assessment,
24 volumetric measurements may capture tumor burden

1 more accurately, particularly because gliomas are
2 often irregularly shaped. However, volumetric
3 response assessment has not been adopted for routine
4 use due to the laborious efforts needed to perform
5 tumor segmentation using existing tools and a lack
6 of large-scale studies validating its benefit over
7 simpler 2D approaches."

8 Again, just to make sure I understand the
9 terminology precisely, "volumetric measurements"
10 means 3D measurements involving voxels, right?

11 A. A 3D measurement of the volume of the
12 tumor.

13 Q. Great, thank you.

14 And so as of the time of this paper, those
15 3D assessments had, quote, not been adopted for
16 routine use due to the laborious efforts needed, end
17 quote, to use them, as well as a lack of validation?

18 MR. METZCAR: Objection, foundation. Go
19 ahead.

20 A. Well, I would say we were half-right in
21 writing that statement.

22 Q. What do you mean by that?

23 A. I'll go on and describe, we were correct as
24 a statement of I believe demonstrable fact that

1 volumetric assessment was not routinely used in
2 clinical practice. So that part I think is correct.

3 However, we go on to say that the reason
4 for that is due to the laborious efforts needed to
5 perform tumor segmentation -- I'll just read from
6 this paragraph. "However, volumetric response
7 assessment has not been adopted for routine use" --
8 true, I say -- "due to the laborious efforts needed
9 to perform tumor segmentation using existing tools
10 and a lack of large-scale studies validating its
11 benefit over simpler 2D approaches."

12 And I'll have to say that it was our
13 hypothesis at the time of writing this paper that
14 provided such tools, there would be more wide-spread
15 clinical adoption. That has yet to happen, thus
16 raising to my mind whether our hypothesis was
17 correct or not.

18 Q. And then the paragraph continues, "A recent
19 consensus..." That's in the middle of the paragraph
20 where we left off.

21 A. I see it.

22 Q. "A recent consensus paper on brain tumor
23 imaging in clinical trials noted volumetric analysis
24 as an improvement to current protocols. An

1 automated segmentation tool could help facilitate
2 the use of tumor volume as a response endpoint in
3 clinical trials and allow integration into the
4 clinical workflow. Rapid and reproducible tumor
5 segmentation is also an essential step toward
6 voxel-based quantitative assessment of single as
7 well as multi-parametric imaging biomarkers of tumor
8 response to treatment."

9 Did I read that correctly?

10 A. You did.

11 Q. Harkening back to Eiber for a moment, the
12 PROMISE criteria that Eiber reports are a manual 2D
13 assessment, right?

14 A. It's a manual assessment acting on 3D
15 imaging data, PET data. So I may not understand why
16 you characterize it as a 2D assessment.

17 Q. I understand your point.

18 MR. CALHOUN: I'd like to introduce what's
19 been previously marked in this proceeding as Exhibit
20 1006.

21 (Document previously marked as
22 Exhibit 1006 for identification)

23 Q. Do you recognize this document, Dr. Rosen?

24 A. I do.

1 Q. And what is it?

2 A. This is what I label in my report the
3 "Suehling patent," if I'm pronouncing that
4 correctly. I'm not sure.

5 Q. I can't tell you any better than that.

6 A. Okay.

7 Q. Please turn to the second page, which is
8 Figure 1.

9 So you see here, this reports six steps.
10 First, "Receive 3D Medical Image." Next, "Detect
11 Body Parts. Next, "Detect Anatomical Landmarks,
12 Organs and Bone Structures," and then "Define Search
13 Regions Based on Detected Landmarks, Organs and Bone
14 Structures," and then "Detect Lesions in Each Search
15 Region Using Region-Specific Lesion Detector." And
16 then you "Output the Lesion Detection Results."

17 I read that correctly?

18 A. Yes.

19 Q. And then if we turn to Paragraph 25, we'll
20 find the description of Figure 1.

21 And you see here at Paragraph 25, it says
22 "referring to Figure 1, at step 102, a 3D medical
23 image is received. The medical image can be a 3D
24 medical image (volume)" --

1 A. I apologize, where are you reading from
2 now?

3 Q. From Paragraph 25.

4 MR. METZCAR: It begins at the bottom of
5 Page 2, first column.

6 A. Okay.

7 Q. I'll start from the top.

8 A. Okay.

9 Q. "Referring to Figure 1, at step 102, a 3D
10 medical image is received. The medical image can be
11 a 3D medical image (volume) generated using an
12 imaging modality, such as CT and MR. The medical
13 image can also be a 3D medical image generated using
14 a hybrid imaging modality, such as PET/CT and
15 PET/MR. The medical image can be received directly
16 from an image acquisition device (e.g., MR scanner,
17 CT scanner, etc.)."

18 There's nothing here in Suehling's
19 description of Figure 1 that describes receiving a
20 3D functional image and detecting hot spots by voxel
21 intensity in a PET SPECT image, right?

22 MR. METZCAR: Objection, foundation. You
23 can answer.

24 A. If you read what you just read to me and

1 elsewhere, it does specifically talk about hybrid
2 imaging modalities, PET/CT and PET/MR, and talk
3 about, if I recall correctly -- I could perhaps go
4 back and check this -- the notion of -- it was
5 either composite image I think that may have been
6 the phrase used.

7 And so I understand this as talking
8 about -- when they talk about "PET/CT" and "PET/MR,"
9 they're talking about the integration of functional
10 and structural imaging modalities.

11 Q. And do you see a description here in
12 Paragraph 25 that describes receiving a 3D
13 functional image and detecting hot spots by voxel
14 intensity?

15 A. Those words aren't used in that paragraph.

16 Q. Do you see the explanation of that type of
17 step in this paragraph?

18 A. I think if you're talking about medical
19 images coming from hybrid imaging modalities, it
20 would be inclusive of both the anatomical and
21 functional data. So I believe it does describe that
22 in its description of PET/CT and PET/MR, as hybrid
23 imaging methods which contain both data sets.

24 Q. You think it's implied, in other words?

1 MR. METZCAR: Objection to form. You can
2 answer.

3 A. Yeah, I think that's what was meant.

4 Q. Suehling never uses the term "segmentation
5 mask," right?

6 A. Again, without reading it through, I have
7 to trust that you've done the search and it's not
8 there. You're representing that to me here, and
9 I'll accept that.

10 Q. And Suehling never uses the term
11 "segmentation map," right?

12 A. That's almost certainly true.

13 Q. And Suehling never stitches together
14 multiple organ masks into a single labeled 3D
15 volume, right?

16 MR. METZCAR: Objection, foundation. You
17 can answer.

18 A. I would have to read the patent in detail,
19 but I would not be -- I don't recall reading about a
20 stitching process.

21 Q. To go back one step --

22 A. It does, of course, talk about multiple
23 anatomical landmarks.

24 Q. Let's go back for a second to Paragraph 25.

1 And I had asked whether that describes receiving a
2 3D functional image and detecting hot spots by voxel
3 intensity.

4 And you made the point that the reference
5 to hybrid imaging modality, such as PET/CT and
6 PET/MR, would, in your view, encompass the image.
7 You would agree, though, that there's no discussion
8 of tracers or uptake in Paragraph 25, right?

9 A. That is true. Though, of course, in a PET
10 image, you wouldn't take a PET image without a
11 tracer and its uptake. So again, it's implicit in
12 the description of a hybrid imaging modality.

13 Q. Please turn for a moment to Figure 8, which
14 is on Page 9 of 17, as marked on the bottom left.

15 A. Okay.

16 Q. I'd like you to take a look at Figure 8,
17 and then we're going to move to a description in the
18 specification.

19 A. Okay.

20 Q. So now let's turn to Paragraph 45.

21 A. Now that I have the image in my brain --

22 Q. And feel free to flip.

23 A. Paragraph 45, you said?

24 Q. Uh-hum. So it says, "In addition to the

1 display of detected lesion candidates, a 'fuzzy'
2 method of result visualization may be used. As
3 described above, the probabilistic detection
4 framework also outputs a probability map of each
5 image voxel belonging to a given lesion entity.
6 This probability map can be displayed similar to the
7 display of PET/CT data. Augmenting morphological CT
8 information, PET data displays metabolic activity of
9 body regions where tumors usually stand out as areas
10 with high image intensity. According to an
11 embodiment of the present invention, the probability
12 map can be displayed in a similar fashion to PET
13 data. Figure 8 illustrates displaying lesion
14 detection results using a probability map."

15 And so as described here, the probability
16 map in Figure 8 --

17 A. I'm sorry, I just want to carry on my
18 reading of the paragraph, so I can fully understand
19 what they mean in this.

20 Q. Please do.

21 A. (Witness reviews document) Okay.

22 Q. So the probability map shown in Figure 8
23 and described in Paragraph 45 is a visualization of
24 detector probabilities for CT, right?

1 A. No. If I can read from later in that same
2 paragraph -- it looks like it's labeled at the
3 bottom "Page 15 of 17" -- in the middle of that
4 first paragraph -- it's a long paragraph.

5 So at the top of that paragraph, this --
6 give me one second, please. "This 'fuzzy' form of
7 displaying lesion detection results allow clinicians
8 who are used to viewing similar images to interpret
9 the probability map similar to PET functional
10 measurements."

11 So I understand that they're generating
12 probability maps. In this case, probability going
13 back to where you read before, back on Page 14 of
14 17, Paragraph 1445, "This probability map" -- sorry.
15 "Augmenting morphologic CT information, PET data
16 displays metabolic activity of body regions where
17 tumors usually stand out. According to this
18 embodiment, the probability map can be displayed in
19 a similar fashion to the PET data."

20 So to me, it's somewhat ambiguous whether
21 they're displaying this using that hybrid
22 information or not. They sometimes refer to them
23 using it, and sometimes maybe it's less clear.

24 Q. So you see at the sentence -- let's take

1 the last full sentence on Page 14 of 17.

2 A. Okay.

3 Q. It says, "Figure 8 illustrates"?

4 A. I see it.

5 Q. So "Figure 8 illustrates displaying lesion
6 detection results using a probability map. Image
7 802 of Figure 8 shows a display of CT image data."

8 And so if we look at Figure 8, that's the
9 leftmost of the three images, right?

10 A. I see it.

11 Q. So that's a display of CT image data.

12 "As illustrated in Figure 8, image 804
13 shows a probability map displayed alone." And
14 that's the middle image on Figure 8.

15 And image 806 shows a probability map in a
16 fused mode overlaid on morphological image data,
17 right?

18 A. Yes.

19 Q. And so effectively, what we're seeing here
20 is this is offering a visualization approach, right?

21 A. That's essentially what it's focusing on.

22 Q. This isn't disclosing an intensity-based
23 hot spot detection system in PET imaging, right?

24 A. It really depends on how it's defining that

1 probability map and what it's acting on.

2 If it's acting on PET data, then that would
3 be a hot spot detection method. If it's acting on
4 CT data, then that wouldn't represent a functional
5 hot spot. That would be a hot spot based on other
6 criteria.

7 The description seems to envision both.

8 Q. But this is instead of PET data, right?
9 You read the sentence -- well, read the next two
10 sentences: "It is to be understood that the same
11 display options may also be presented in 3D
12 renderings. This 'fuzzy' form of displaying the
13 lesion detection results allows clinicians who are
14 used to viewing similar image to interpret the
15 probability map similar to PET functional
16 measurements."

17 So this is CT image data, as we read a few
18 sentences earlier, that Suehling is teaching you --
19 let me rephrase.

20 Suehling is teaching a visualization
21 approach for CT data. And the sentence that you
22 noted is not stating that they're creating this
23 visualization using PET data. Isn't it simply
24 saying that this form of display is similar to PET

1 functional measurements?

2 MR. METZCAR: Objection, form. You can
3 answer.

4 A. I believe there's some ambiguity in this
5 writing. And I interpret it differently than the
6 way you just did.

7 When it talks about image that allows
8 clinicians who are used to viewing similar image to
9 interpret the probability map similar to PET
10 functional measurements, that could be read to refer
11 to a probability map derived from the CT data only,
12 or it could refer to a probability map derived from
13 the PET data or the hybrid of the two.

14 And in that regard, I don't believe that
15 this particular set of sentences is extremely clear
16 on that point. The fact that they talk about hybrid
17 methods explicitly tells me that they are
18 envisioning acting on the functional PET data in
19 addition to the anatomical CT or MRI data.
20 Otherwise, why would they talk about hybrid
21 modalities.

22 MR. CALHOUN: I would like to introduce
23 what we will mark as Exhibit 2041. This is our last
24 document of the cross.

1 THE WITNESS: You promised that to me once
2 before, and then you went back. It could be the
3 last one, but we could start over.

4 MR. CALHOUN: Let's mark this 2041.

5 (Document marked as Rosen
6 Exhibit 2041 for identification)

7 THE WITNESS: Oh, my God.

8 BY MR. CALHOUN:

9 Q. Dr. Rosen, do you recognize this document?

10 A. I do.

11 Q. What is it?

12 A. It is a manuscript published in
13 Neuroinformatics on the topic of an open-source deep
14 learning toolbox which we labeled "DeepNeuro,"
15 developed by Andrew Beers, Jayashree
16 Kalpathy-Cramer, and their colleagues; myself
17 included.

18 Q. And this paper was published in January of
19 2021, right?

20 A. That's correct.

21 Q. Please turn to what's marked in the top
22 right-hand corner as "Page 2," and let's look at the
23 very last paragraph that begins at the bottom of
24 Page 2, which says, "Provided that these software

1 challenges are overcome, the unique nature of
2 medical imaging data produces additional barriers to
3 neuroscience researchers. Medical images require
4 numerous highly specialized preprocessing techniques
5 to account for differences between scanners and
6 imaging sequences, each of which can unpredictably
7 affect the performance of deep learning algorithms."

8 Did I read that correctly?

9 A. You did.

10 Q. So you noted here that medical images are
11 particularly difficult for 3D segmentation because
12 you have to account for differences between things
13 like scanners and imaging sequences, right?

14 MR. METZCAR: Objection, foundation. You
15 can answer.

16 A. That is correct. That is correct.

17 Q. And then if you turn to Page 4, you'll see
18 the subsection "2.21 Preprocessing." Could you let
19 me know when you're there.

20 A. Okay. It says, "Standardized preprocessing
21 methods are essential to deep learning pipelines
22 that operate on medical images, as slight
23 differences in preprocessing methods can lead to
24 catastrophic prediction failures."

1 So you're noting here that even slight
2 preprocessing changes can, quote -- quote, can lead
3 to catastrophic prediction failures, right?

4 A. That was the language that somebody chose
5 to use in writing this paper, correct.

6 Q. Neither Renisch or Zhao, for example,
7 identify a single uniform preprocessing pipeline
8 that a POSITA could have used in January 2019 for
9 multi-organ 3D segmentation, right?

10 A. They do not describe in detail
11 preprocessing pipelines, no.

12 Q. And let's go back to -- so if you go to
13 Page 3, one page back, I'm going to pick up on the
14 paragraph that we started earlier. And if you look
15 at the first new sentence on Page 3, it starts with
16 "Medical imaging data..." Do you see that?

17 A. I do.

18 Q. It says, "Medical imaging data is often
19 higher resolution (as with digital pathology) or in
20 higher dimensions (as with magnetic resonance (MR)
21 imaging data) than traditional datasets in computer
22 vision. As a result, images may need to be divided
23 into patches, slices, or other representations to be
24 computationally tractable in deep learning

1 algorithms, and the specific implementation of these
2 methods can have a significant impact on those
3 algorithms' performance. Postprocessing techniques,
4 particularly for segmentation algorithms, can have a
5 significant effect on a neural network's accuracy."

6 Did I read that right?

7 A. You did.

8 Q. And so this paper is reporting that medical
9 imaging data may need to be divided into patches or
10 slices to be computationally tractable, right?

11 A. They talk about specific classes of medical
12 images. Digital pathology, of course, is
13 characterized as having very large arrays of data,
14 much larger than CT images, for example. Or when
15 they talk about higher dimensions and their
16 reference is specifically to magnetic resonance,
17 they're talking about data that's not characterized
18 by a single intensity value, like a CT Hounsfield
19 number; but rather, might have a large number of
20 different intensities along several different
21 dimensions; the T1 dimension, T2, other diffusion,
22 etc.

23 So she's describing -- I see "she." It's
24 really Andrew is describing in this case and his

1 coauthors the challenges involved in some classes of
2 medical imaging data that make them more difficult
3 than, say, CT images or PET images, which are lower
4 resolution and have lower dimension. And thus, in
5 those specific cases, the needs, depending on -- I'm
6 going to check the date here, 2021 -- the ability
7 for modern GPUs and traditional storage values to
8 deal with those image and datasets may be more
9 limited and more challenging than they would be for,
10 say, a PET/CT image.

11 MR. CALHOUN: Just give me a moment.

12 THE WITNESS: You've been patient for me to
13 read, so I'll return the favor.

14 MR. CALHOUN: Thank you.

15 THE WITNESS: You don't need to stop. I'm
16 just standing. I'm not bolting for the door.

17 BY MR. CALHOUN:

18 Q. You would agree, Dr. Rosen, if we look at
19 the bottom of Page 2, that the first two sentences
20 of your paper say, "Provided that the software
21 challenges are overcome, the unique nature of
22 medical imaging data produces additional barriers to
23 the neuroscience researcher. Medical images often
24 require numerous, highly-specialized preprocessing

1 techniques to account for differences between
2 scanners and imaging sequences, each of which can
3 unpredictably affect the performance of deep
4 learning algorithms."

5 You would agree, based on those two
6 sentences and the third sentence that we just
7 discussed, that you and your coauthors were writing
8 about medical imaging data beyond the specific
9 examples -- the specific subset of examples you were
10 just discussing, right?

11 MR. METZCAR: Objection, form.

12 A. We were discussing that challenges
13 associated with certain types of medical images,
14 some data is frankly just denser, involving either
15 more dimensions or more voxels and thus, presents
16 computational challenges.

17 In addition, tools like MRI, also true of
18 digital pathology, have variations in contrast
19 intensity that tend to be worse, frankly, than in
20 other modalities and that add to the degree of
21 challenge and thus, the challenges involved there.

22 So I see this paragraph and the sentences
23 that we've been reading as referring to not every
24 medical image, but certain classes of medical images

1 that present particular challenges. And two
2 examples were given here.

3 Q. So let me try to -- I think I now know what
4 at least the common ground is.

5 So would it be fair to say that at the time
6 of the publication of this January 2021 paper that
7 you coauthored, you and your coauthors are noting
8 that certain medical images may need to be divided
9 into slices or patches to make them tractable for
10 deep learning algorithms?

11 A. At the time of this article, absolutely
12 true.

13 Q. And so the addition of more voxels or more
14 data can make medical images challenging to analyze?

15 A. That is also true.

16 MR. CALHOUN: Could we go off the record
17 for just a minute so I can confer with my
18 colleagues. I think we may be done or very close to
19 done.

20 MR. METZCAR: Absolutely.

21 (Recess taken from 1:39 to 1:56)

22 MR. CALHOUN: I have no further questions.

23 MR. METZCAR: And I would like to redirect
24 briefly. You might turn, so she can hear you. As

1 best you can.

2 THE WITNESS: Okay.

3 REDIRECT EXAMINATION

4 BY MR. METZCAR:

5 Q. Dr. Rosen, we just returned from a short
6 break. During that break, did we discuss your
7 testimony in any way?

8 A. We did not.

9 Q. Did we discuss the testimony you're about
10 to give?

11 A. No.

12 Q. We started out this morning, I believe,
13 with Mr. Calhoun asking you some questions about
14 your qualifications in your CV. Do you recall that?

15 A. I do.

16 Q. And I believe he asked you to locate if you
17 had any publications relating to -- I think it had
18 to do with quantification of uptake, maybe in PET
19 images, quantification of uptake in segmented
20 organs. Do you recall any of that discussion?

21 A. I do.

22 Q. Let me ask you, regardless of whether or
23 not you have any publications that are specific to
24 that topic, do you have any personal experience

1 with, first, segmenting organs in medical images?

2 A. I do.

3 Q. Do you have any personal experience --
4 regardless of whether or not you have any
5 publications, do you have any personal experience
6 with quantifications of uptake in functional images?

7 A. I do.

8 Q. Do you have any experience in
9 quantification of uptake from segmented organs in
10 functional images?

11 A. I do.

12 Q. And as you understand it, is the '817
13 patent that's at issue here, is it in any way
14 limited to PET images?

15 A. No.

16 Q. Can you just briefly explain to me your
17 personal experience with segmentation of organs in
18 medical images, regardless of whether or not you
19 have a publication that describes it.

20 A. Segmentation, of course, is a fundamental
21 part of what we do when we analyze medical images,
22 at least in many, many circumstances. I was one of
23 the earliest investigators to register and analyze
24 PET images and MRI images together. I think I made

1 reference to one of those papers. And so for many
2 years, the notion of co-registered PET and MR
3 pictures and the analysis of that data, both on a
4 voxel-wise level and on a segmented regional level,
5 has been a part of my experiences.

6 I've also for many years been involved in
7 the evolution of brain segmentation tools, starting
8 in the very earliest days of manual labeling of
9 those tools and all the way through to the
10 development of convolutional deep learning tools for
11 the segmentation of brain images, including
12 segmentation of gray matter and white matter and
13 other subregions of the brain, and also including
14 the segmentation of lesions within the brain.

15 And then, of course, as part of the broader
16 laboratory here at the Martinos Center, I see lots
17 and lots of image data and talks on imaging all
18 sorts of organs outside the brain, including the
19 prostate, with PSMA tracers, which is a topic of an
20 NIH investigation led by one of my colleagues here
21 at the Martinos Center and who I review his data and
22 results on a regular basis. The analysis of lung
23 lesions with PET tracers, both conventional PET
24 tracers and novel PET tracers, which also involve

1 segmentation of the lungs for the analysis. The
2 same is true for the heart. So because the Martinos
3 Center is a large, multidisciplinary group, there's
4 almost no part of the body that we don't analyze
5 medical images for that I'm not exposed to their
6 work, either directly or through the presentations
7 and review of data with my colleagues, students, and
8 fellows in the laboratory.

9 Q. My instruction was "briefly"; but
10 otherwise, you answered my question.

11 A. I'm so sorry.

12 Q. I'm teasing you. I'm kidding.

13 A. Yeah, we do that.

14 Q. If you can't have fun during a
15 deposition --

16 A. I'll try to listen to your question more
17 carefully.

18 Q. I'm kidding you.

19 Okay. Dr. Rosen, also earlier this
20 morning, Mr. Calhoun showed you some examples in the
21 '817 patent in which multiple segmentation modules
22 produced multiple segmentation masks. And those
23 masks were then -- I think the terminology was
24 either "stitched together" or "merged together." Do

1 you recall that?

2 A. I do.

3 Q. And you recall he quoted to you extensively
4 from some of these examples and showed you some
5 figures relating to those? Do you recall that?

6 A. I do.

7 Q. And do you recall in some of those
8 examples, you pointed out that the description
9 started with "In some embodiments..." Do you recall
10 any of that?

11 A. I do.

12 Q. As you understand it, do the claims of the
13 '817 patent require a step of stitching together
14 multiple masks or merging multiple masks?

15 A. I do not see any mention of that step in
16 the patent claims.

17 Q. In your experience, is it possible for a
18 single neural network to perform segmentation of
19 multiple organs at the same time, if it's trained to
20 do that?

21 A. It is possible.

22 Q. Have you seen such a thing in your
23 experience?

24 A. Yes. Typically, for example, in our brain

1 segmentation tool, the Freesurfer, we segment
2 multiple structures within the brain from a single
3 software algorithm.

4 Q. Okay. Can you turn to Exhibit 1001, which
5 is the '817 patent. I'd like to show you a passage
6 in that patent.

7 A. Okay.

8 Q. Column 35, starting at Line 20. Are you
9 there?

10 A. I am.

11 Q. Okay. So we just talked about Mr. Calhoun
12 showing you multiple examples in which different
13 segmentation masks were stitched together. And I'm
14 going to read this to you, starting at Line 20: "In
15 certain embodiments, multiple localization modules,
16 (for example, each tasked with identifying one or
17 more VOIs) may be used. For each individual VOI,
18 one or more segmentation modules may then be used to
19 perform fine segmentation and identify the one or
20 more desired target volumes of interest within the
21 initial volume of interest."

22 Do you see that?

23 A. I do.

24 Q. Do you understand that that description of

1 those embodiments corresponds to the examples that
2 Mr. Calhoun was describing to you --

3 MR. CALHOUN: Objection.

4 Q. -- in which multiple modules produce
5 multiple masks and then stitch them together?

6 MR. CALHOUN: Objection, leading.

7 A. In this section that you just read, it does
8 talk about distinct modules tasked with one or
9 potentially more volumes, suggesting that you would
10 have different modules for different volumes of
11 interest.

12 Q. Moving on to the next paragraph, it goes on
13 to say, "Various localization and segmentation
14 modules may be combined and implemented as a single
15 module and/or a single software application."

16 Do you see that?

17 A. I do.

18 Q. And is that consistent with your
19 understanding that a single neural network can also
20 perform segmentation of multiple organs?

21 MR. CALHOUN: Objection, leading.

22 A. I think the paragraph that you just read is
23 very clear that you could use a single software tool
24 they call an "application" or a "single module" that

1 may segment multiple areas, various locations. And
2 modules could be combined and implemented as a
3 single module or may be implemented separately.
4 It's a choice.

5 Q. Okay. Thank you. I want to move on to the
6 next topic, which is Renisch. If you could pull
7 that out. It's Exhibit 1005.

8 A. Okay.

9 Q. Do you recall that Mr. Calhoun asked you a
10 number of questions regarding Paragraphs 27 and 28
11 of Renisch that describe segmentation and various
12 segmentation techniques?

13 A. I do.

14 Q. I want to follow up on that questioning.
15 I believe that Mr. Calhoun asked you -- or
16 he made a statement to you with reference to the
17 referenced techniques of clustering and neural
18 network. I believe he said to you that Renisch does
19 not describe how to implement those. Do you recall
20 that?

21 A. I do recall that general discussion, yes.

22 Q. Regardless of whether or not Renisch
23 specifically describes how to implement clustering,
24 in your experience, would a person of ordinary skill

1 in the art know how to implement clustering for
2 segmentation as of the date of Renisch in 2012?

3 A. These were well-established techniques in
4 the machine learning literature. And so, yes, I
5 think somebody of ordinary skill in the art would
6 understand what that meant and the nature of such
7 algorithms.

8 Q. Okay. And just for example, I'll represent
9 to you that Renisch within the document at some
10 point mentions the use of a processor.

11 Having reviewed Renisch, do you recall
12 whether Renisch ever describes explicitly how to
13 implement the use of a processor?

14 A. I don't recall that, but -- yeah, I don't
15 recall that.

16 Q. But do you understand that a person of
17 skill in the art who reads Renisch in 2012 would
18 understand how to implement a processor?

19 A. Yes.

20 MR. CALHOUN: Objection, leading.

21 A. I believe somebody with skill in the art in
22 that time frame would understand what that meant and
23 how to implement it.

24 Q. I'll rephrase the question.

1 Would someone in 2012 at the time of
2 publication of Renisch understand how to implement a
3 processor?

4 A. Yes.

5 Q. And would they understand that, regardless
6 of whether or not Renisch explicitly described it?

7 A. They would.

8 MR. CALHOUN: Objection, leading.

9 Q. Okay. There was also some discussion about
10 atlas segmentation and specifically a discussion
11 about I believe both Paragraphs 27 and 28 of
12 Renisch.

13 Do you recall discussing the atlas
14 segmentation?

15 A. I do.

16 Q. I believe there might have been some
17 confusion during the testimony, so I want to be
18 clear.

19 At some point, Mr. Calhoun asked you,
20 regarding Paragraphs 27 and 28 of Renisch, asked you
21 if those paragraphs described machine learning.

22 And I believe you answered "No." And I
23 just want to get clarification from you.

24 Does Paragraph 27 of Renisch refer to

1 clustering and neural networks?

2 MR. CALHOUN: Objection, leading.

3 A. It does.

4 Q. In your opinion, are those machine learning
5 techniques?

6 A. They are.

7 Q. So I just want to be clear. Do Paragraphs
8 27 and 28 contain within them any reference -- any
9 discussion of machine learning techniques?

10 A. They explicitly do in their description of
11 clustering and neural networks, at least.

12 Q. Okay. There was also a lot of discussion
13 back and forth earlier about whether or not "neural
14 network" and "artificial neural network" are
15 synonymous. Do you recall that?

16 A. I do.

17 Q. I want to be perfectly clear.

18 In Paragraph 27 of Renisch, when Renisch
19 recites the term "neural network," do you understand
20 that to be the neural network of the anatomical
21 brain?

22 A. No, I do not. It is not a biological
23 network.

24 Q. Is it referring to an artificial neural

1 network, in your opinion?

2 MR. CALHOUN: Objection, leading.

3 A. I believe it is very much referring to a
4 man-made or an artificial neural network.

5 Q. There was also some discussion earlier this
6 morning about whether a neural network is a machine
7 learning module. Do you recall that?

8 A. I do.

9 Q. In your experience, is a neural network a
10 machine learning module?

11 A. I believe that it is; that neural network
12 algorithms are considered machine learning
13 algorithms for the purposes that they're put to.

14 Q. Okay. And I want you to look again at the
15 '817 patent, which is Exhibit 1001. Specifically
16 I'll direct your attention to Column 42, Line 43.

17 A. I see it.

18 Q. Actually, the sentence begins on 42. So
19 I'll say Column 42, Lines 42 and 43. I'll read to
20 you: "The machine learning modules (for example,
21 neural networks)." Do you see that?

22 A. I do.

23 Q. Do you have any reason to believe that
24 Renisch uses the term "neural network" in a way

1 different than the '817 patent uses the term "neural
2 network"?

3 A. I do not.

4 Q. I'd like to talk briefly about Exhibit
5 1007, which is Zhao. If you could pull that out.

6 A. Okay.

7 Q. Mr. Calhoun asked you some questions. I
8 believe he directed your attention to Column 8,
9 Line -- initially Line 47. And there was some
10 discussion about whether or not Zhao was segmenting
11 2 or 3D images. Do you recall that?

12 A. I'm sorry, I'm not sure my attention is
13 being directed to the right place. Where exactly --

14 Q. I believe he directed your attention to
15 Column 8, Line 47. And then he read to you --

16 A. Is this the stack of features map?

17 Q. Yes.

18 A. Maps.

19 Q. He read to you through the rest of that
20 column, to the point where it referred to "100 by
21 100 pixels."

22 A. We're talking about Zhao?

23 Q. Exhibit 1007, Column 8.

24 A. And on 47, starting, "The stack of feature

1 maps 260"? Is that what you want me --

2 Q. Let me try to simplify it for you. I
3 apologize. I'm probably being confusing.

4 Do you recall that he pointed you to some
5 portions of the specification of Zhao and asked you
6 about whether or not what he was reading from was
7 segmenting 2D images, as opposed to 3D images?

8 A. I remember that discussion, yes.

9 Q. I would like to direct your attention to a
10 different section of Zhao.

11 So if you look at towards the top of Column
12 5.

13 A. Okay.

14 Q. You see there's a heading, "Introduction"?

15 A. Yes.

16 Q. And the introduction continues through the
17 end of Column 5 and the start of Column 6, until do
18 you see that there's another section heading that
19 begins at Line 30 of Column 6? It says, "Data
20 Flows"?

21 A. I do.

22 Q. So I'm just directing your attention to the
23 introduction of Zhao.

24 Does Zhao describe in the introduction the

1 segmentation of CT images?

2 A. It does.

3 Q. And do you understand Zhao to be explaining
4 that he invented segmentation of CT images?

5 A. I do not believe that is what he is
6 representing. He's talking about CT segmentation in
7 the context of prior work.

8 Q. Okay. Do you see in Column 5 a description
9 of the creation of segmentation masks?

10 MR. CALHOUN: Objection, leading.

11 A. I see he talks about masks in several
12 sections in that introduction.

13 Q. As you understand -- having read the
14 introduction of Zhao, do you understand that Zhao is
15 claiming to have invented the use of segmentation
16 masks?

17 A. No. I believe that his description of
18 segmentation masks or multi-value masks are a
19 background to the invention of the patent and thus,
20 are in the "Introduction" section.

21 Q. Okay. So in that introduction, is he
22 describing his invention or background material?

23 A. Sorry, background material. Other people's
24 inventions.

1 Q. I see. I want to follow up on that.

2 Mr. Calhoun asked you a question -- he
3 asked you to point to a spot in Zhao that describes
4 multi-organ segmentation. Do you remember that?

5 A. I do.

6 Q. So I want to direct your attention to the
7 top of -- we're still in the introduction -- the top
8 of Column 6, Line 4. It says, "For example, an
9 entire ROI may be an entire organ." Do you see
10 that?

11 A. An ROI --

12 MR. CALHOUN: Objection. Mischaracterizes
13 the document.

14 A. I believe the sentence is, "For example, an
15 ROI may be an entire organ."

16 Q. What did I say?

17 A. You said, "an entire ROI may be an entire
18 organ," if I remember correctly.

19 Q. Apologies. But you've corrected me.

20 Okay. Then I want to -- so it says that an
21 ROI can be an entire organ.

22 A. Yes.

23 MR. CALHOUN: Objection. Mischaracterizes
24 the document.

1 Q. And then I'll direct your attention to
2 Column 5, Line 30, down through 41. You can read
3 that to yourself.

4 A. I'm sorry --

5 Q. Column 5, Line 30 through Line 42.

6 A. Okay. (Witness reviews document)

7 Q. Let me know when you're done.

8 A. Okay, I am.

9 Q. Where does that describe the creation of a
10 multi-value mask?

11 MR. CALHOUN: Objection, leading.

12 A. In that paragraph, towards the end, it
13 talks explicitly -- and I'll quote -- "a multi-value
14 mask, however, may be decomposed into a combination
15 the more" -- "into a combination the more functional
16 binary masks each for one type of ROI."

17 So, yes, I believe it does explicitly talk
18 about its description of a multi-value mask.

19 Q. And we already said that Zhao states that
20 an ROI can be an entire organ, correct?

21 A. Correct.

22 Q. So I'll ask you, then, again, does Zhao
23 describe or teach in any way the segmentation or --
24 I'm sorry, multi-organ segmentation?

1 A. It does. It does.

2 Q. Let's talk about Exhibit 1009, which is
3 Eiber.

4 Earlier Mr. Calhoun pointed out some
5 self-effacing statements in Eiber about it not
6 being -- it needed to be -- I can't remember the
7 terminology -- essentially double-checked or --

8 A. Validated.

9 Q. -- validated. Thank you for giving me the
10 correct word. Do you recall that?

11 A. I recall the conversation, yes.

12 Q. Do you know what the date of Eiber is?

13 A. I must. It was received in June of 2017
14 and ultimately published in 2018.

15 Q. Okay. Has the standard that's described in
16 Eiber ever been adopted by physicians?

17 A. I believe it has, yes.

18 Q. So it has been used?

19 A. Yes.

20 Q. Was it abandoned because it could not be
21 used?

22 MR. CALHOUN: Objection, leading.

23 A. No. It is a tool used in nuclear medicine
24 practice today.

1 Q. I would like to get some clarification
2 about Exhibit 2039, which is this Neuro-Oncology.

3 Again, Mr. Calhoun was asking you some
4 questions about potential difficulties with
5 implementing the techniques described in this
6 publication. Do you recall that?

7 A. I do.

8 Q. I just want to be clear. Is this study
9 that's described in this paper directed to MRIs?

10 A. It is.

11 Q. To the extent it involves identification of
12 tumors, is it using any nuclear medicine imaging?

13 A. This paper is not.

14 Q. So if this paper describes trying to
15 segment tumors from an MRI image, is that
16 segmentation based on an anatomical image?

17 MR. CALHOUN: Objection, leading.

18 A. It is based on two forms of anatomical
19 images: The postcontrast image and the FLAIR image;
20 both anatomical images, as you say.

21 Q. The '817 patent -- well, does the '817
22 patent describe convolutional neural networks for
23 automatically segmenting organs and bones?

24 MR. CALHOUN: Objection, leading.

1 A. I believe it does, yes.

2 Q. Are the organs and bones within the bodies
3 of most individuals a similar shape?

4 A. In general, yes.

5 Q. Would there be any additional difficulties
6 designing or training a neural network to segment a
7 tumor, as opposed to an organ?

8 MR. CALHOUN: Objection, form and leading.

9 A. Segmentation of tumors, especially on MRI,
10 because of the complex image intensity values that
11 are demonstrated in tumors with MRI, do present some
12 unique challenges for radiologists or automated
13 radiologists, computational tools, to do the
14 segmentation because of the heterogeneity of the
15 tumors themselves and the complexity of the image
16 contrast on MR pictures.

17 Q. How about just the shape of a tumor? Do
18 tumors come in different shapes and sizes?

19 A. They do, indeed. And gliomas, in
20 particular, are also challenging because of their
21 highly infiltrative nature. They grow into the
22 surrounding tissue. And the boundaries are often
23 quite difficult to demarcate because of this
24 sometimes avert, but sometimes quite subtle

1 infiltration of the tumor. And combined with the
2 heterogeneous contrast on those pictures,
3 differences in signal intensity, based on different
4 properties of the tumor, makes tumor segmentation in
5 the brain, especially with high-grade gliomas, which
6 are the most infiltrating of such tumors, quite
7 problematic.

8 Q. In your experience, is the training of a
9 machine learning algorithm to segment an organ
10 different than training a machine learning algorithm
11 to segment a tumor?

12 A. A tumor like a brain tumor is more
13 challenging and, frankly, a tumor anywhere in the
14 body, because the shape of the segmented area is
15 less --

16 THE COURT REPORTER: Can you repeat that?

17 A. I'm sorry. It is generally more
18 challenging to segment a tumor whose shapes tend to
19 be irregular, with ill-defined boundaries, than an
20 organ, which tends to have smooth boundaries and of
21 more regular shapes.

22 Q. We're almost done here.

23 There was some -- let me just call your
24 attention to Exhibit 2041. It's this HHS Public

1 Access, DeepNeuro document.

2 A. Okay. I'll try to find that.

3 Q. If you want, you can use mine.

4 A. Okay. Sorry.

5 Q. No, you're fine.

6 A. It must be here someplace. Okay, I'll use
7 yours.

8 Q. Do you recall there was some discussion
9 earlier associated with the -- I'm sorry, strike
10 that.

11 Do you recall that there was some
12 questioning earlier regarding the difficulties
13 associated with preprocessing of images?

14 A. I remember that discussion.

15 Q. Okay. What are some preprocessing
16 techniques that can be applied to images to improve
17 their use for segmentation?

18 A. There are a variety of different ones.
19 First would be intensity normalization. That's
20 especially challenging in the setting of magnetic
21 resonance imaging, as described in this paper;
22 because not only is there the intrinsic biological
23 difference in signal intensity, but the scanner
24 itself has heterogeneous signal intensity owing to

1 the techniques involved in the acquisition of the
2 data.

3 So intensity normalization is certainly an
4 important and preprocessing step. Registering
5 images may be a component of a preprocessing step,
6 depending on what one is trying to accomplish.

7 Normalization of size may be another
8 important preprocessing step, especially for neural
9 net algorithms.

10 Q. I'm going to pause you.

11 Can you explain what you mean by
12 "normalization of size"? Are you talking about the
13 size of the image? The number of pixels?

14 A. The size of the object within the field of
15 view --

16 Q. Understood.

17 A. -- normalizing the size of, say, the brain.

18 Q. I cut you off. Did you have anything else
19 to add, or is that good?

20 A. That's a good place to stop for now.

21 Q. Okay.

22 A. Unless you have other specifics.

23 Q. No.

24 And were these normalization techniques

1 that you just referenced, were these known in your
2 experience by a person of ordinary skill in the art
3 by 2019?

4 A. Yes, they were. And in fact, in the paper
5 itself, they describe several that have adopted
6 preprocessing tools, such as those from 3D Slicer,
7 which is a software tool developed here at Mass
8 General Brigham. And these were known tools and
9 freely available. They're open-source tools.

10 Q. So let me create the scene for you.

11 If I'm going to take an image from one CT
12 scanner or one PET scanner and I want to run it
13 through a convolutional neural network to analyze
14 it, but I want that convolutional neural network to
15 be able to analyze images from other scanners as
16 well; a different CT scanner and a different MR
17 scanner. So they're not hooked up together. I may
18 take a digital image from different scanners and use
19 the same convolutional neural network.

20 Is preprocessing a step that would
21 typically be applied to those images before
22 analyzing them?

23 MR. CALHOUN: Objection, leading --

24 A. Yes.

1 MR. CALHOUN: -- and form.

2 A. Yes.

3 Q. Do you remember offhand whether or not
4 Renisch explicitly describes any preprocessing?

5 A. I don't recall. I don't believe it
6 discusses it in detail.

7 Q. In detail. Understood.

8 Assuming that Renisch or someone practicing
9 Renisch in 2019 would apply preprocessing of the
10 images before analyzed, as described in Renisch, do
11 you see any impediment to combining Renisch and
12 Zhao, as you have suggested in your report?

13 MR. CALHOUN: Objection, leading and form.

14 A. I do not.

15 Q. Can you explain?

16 MR. CALHOUN: Objection, leading and form.

17 A. As I said, preprocessing steps were a
18 standard part of medical imaging analysis. The
19 open-source tools referred to in the previous
20 article we were discussing, the DeepNeuro, I believe
21 date back to 2012; the time frame of Renisch. So it
22 would be considered part of the overall environment
23 that somebody of ordinary skill in the art would
24 understand as an important enhancing step in

1 developing algorithms to be successful and more
2 robust. And thus, combining what Renisch teaches
3 with what Zhao teaches would be a natural
4 combination; an obvious one to do and with a high
5 likelihood of success, given both what they teach
6 and the background of the field in general,
7 including those processes.

8 MR. METZCAR: Thank you, Dr. Rosen. I
9 don't have any more questions.

10 MR. CALHOUN: Can we go off the record and
11 just discuss briefly if we have any recross.

12 (Recess taken from 2:35 to 2:39)

13 MR. CALHOUN: I have no further questions.
14 Thank you, Dr. Rosen.

15 MR. METZCAR: Thank you.

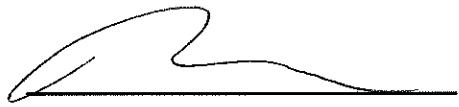
16 (Whereupon, the deposition was
17 concluded at 2:39 p.m.)
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C E R T I F I C A T E

I, BRUCE ROSEN, M.D., PH.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify under the pains and penalties of perjury that said transcript (with/without) suggested corrections is a true and accurate record of said testimony.

Dated at 2:42 pm, this 21st day of January, 2026.

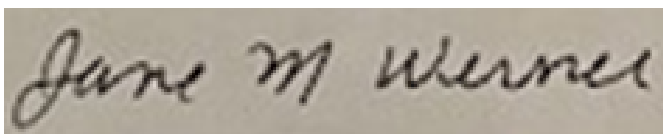


1 COMMONWEALTH OF MASSACHUSETTS)
2 SUFFOLK, SS.)

3 I, Jane M. Werner, RMR and Notary Public in and
4 for the Commonwealth of Massachusetts, do hereby
5 certify that there came before me on the 6th day of
6 January, 2026, at 9:00 a.m., the person hereinbefore
7 named, who was by me duly sworn to testify to the
8 truth and nothing but the truth of his knowledge
9 touching and concerning the matters in controversy
10 in this cause; that he was thereupon examined upon
11 his oath, and his examination reduced to typewriting
12 under my direction; and that the deposition is a
13 true record of the testimony given by the witness.

14 I further certify that I am neither attorney or
15 counsel for, nor related to or employed by, any
16 attorney or counsel employed by the parties hereto
17 or financially interested in the action.

18 In witness whereof, I have hereunto set my hand
19 and affixed my notarial seal this 9th day of
20 January, 2026.

21
22 

23 Notary Public
24 Commission expires 1/27/2028

AFFIDAVIT OF JANE M. WERNER

I, Jane M. Werner, hereby certify that:

1. I am authorized to take testimony under 35 U.S.C.23

2. The witness, Bruce Rosen, M.D., Ph.D., was duly sworn by me before commencement of testimony by the witness.

3. The transcript is a true record of the testimony given by the witness.

4. I recorded the testimony.

5. Counsel for the Patent Owner was present.

6. The deposition was taken in Charlestown, MA, on January 6, 2026. It began at 9:00 a.m. ended at 2:39 p.m.

7. I have no disqualifying interest, personal or financial, in a party.

8. To the best of my knowledge, the witness has not refused to read or sign the transcript.

I certify under penalty of perjury that the foregoing is true and correct. Executed on 1/11/26.

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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