1 IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
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3 PROGENICS PHARMACEUTICALS, INC.,)
et al,)
4)
Plaintiffs)
5) CA No. 24-10437-PBS
-VS-) Pages 1 - 66
6)
MIM SOFTWARE INC.,)
7)
Defendant)
8

9 **MOTION HEARING BY VIDEO**
10 BEFORE THE HONORABLE PATTI B. SARIS
11 UNITED STATES DISTRICT JUDGE

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15 United States District Court
16 1 Courthouse Way
Boston, Massachusetts 02210
17 October 8, 2024, 10:06 a.m.

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MIM Ex1035
MIM Software Inc. v. Progenics Pharmaceuticals, Inc.
Trial IPR2025-00630

A P P E A R A N C E S:

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P R O C E E D I N G

THE CLERK: Good morning, Judge.

THE COURT: Good morning.

THE CLERK: So I have both sides on, so I'll call the case.

THE COURT: Thank you.

THE CLERK: The Court calls Civil Action 24-10437, Progenics Pharmaceuticals Inc. et al v. MIM Software, Inc. Could counsel please identify themselves.

MR. BUNIS: Your Honor, Michael Bunis for the plaintiff, Progenics, and with me is my partner, Anita Spieth, also on behalf of Progenics.

MS. PIROZOLLO: This is Lisa Pirozollo on behalf of Defendant MIM Software, Inc., and with me are Alexis Cohen, Marla Butler, Jesse Jenike-Godshalk, and Jeff Metzcar, who have been admitted pro hac vice. Ms. Butler and Ms. Godshalk and Mr. Metzcar are from the firm of Thompson Hine.

THE COURT: Thank you. So are you dividing up the argument among different lawyers, or is just one person going to argue for each side?

MR. BUNIS: Your Honor, again, Michael Bunis here. I'll be handling the 101 eligibility subject matter for the motion today, and Ms. Spieth will be handling the 12(b)(6) issues that are also on the docket today.

THE COURT: Thank you.

MS. PIROZOLLO: And we are similarly dividing with the Court's permission. This is Lisa Pirozollo. I will do the 101 issues, and Ms. Butler will do the motion to dismiss based on plausibility of the infringement claim.

THE COURT: Fine. So I shouldn't admit this to you all, but I have the morning for you, and I am finding this case extremely difficult because there are so many patents. Is this what's known as a "patent thicket"?

MR. BUNIS: We would say "no," your Honor.

THE COURT: Well, I don't understand. I mean, I haven't spent the time, obviously, you have spent with it, but I don't understand really the difference between all of them, and I am -- let me just start with basics -- I am not going to look at each of the seven patents because it would take me the rest of the year to do that. So I am looking for a shortcut, if that's the pejorative way of referring to it, like one patent or two patents that would settle this case, or would at least move it to Step B. And I think we sent that message out to you earlier this week that I -- *Alice* is a very difficult case, very difficult, and I have written about it, and I've struggled with it. It takes a lot of analysis to get through seven patents, never mind just one, and, similarly, on a motion to dismiss at an early stage before I don't even understand the technology. So

1 you're asking a lot of one session to deal with seven patents.
2 Let's just start there.
3 So I would like to ask perhaps on the motion to
4 dismiss, is there one from each side, maybe take one patent
5 that might settle this or might resolve it so I could decide
6 whether I can do discovery on this case?
7 MS. BUTLER: So, your Honor, Marla Butler for MIM,
8 who obviously we brought the motion. And I think the issue
9 with the plausibility on the 12(b)(6) for failure to state a
10 claim is that, you know, while we could have made arguments
11 as to all seven of these patents, we did choose the three
12 very purposefully where we think the failure to sufficiently
13 allege infringement is the most egregious. And we didn't
14 try to identify multiple elements within the three patents
15 where we think that failure exists, but we identified one
16 element in each of those three patents. And I think, as
17 we've talked through this, I'd be in a position to explain
18 this to the Court as to why, even without a deep understanding
19 of the technology --
20 THE COURT: Well, maybe, maybe not. I am just
21 frustrated. I am one session, and I don't want to deal with
22 seven patents. So I think who -- I forget -- Ms. Pirozollo,
23 who's from Hale and Dorr, Bill Lee used to be great at this,
24 which is, like, what's the one thing that would settle this
25 case, or at least get it to Step B where I think there's

enough there for discovery? And it would be useful for you all to flag that for me because otherwise you'll be here for a year while this is pending analysis. And unlike most cases, no one has given me a tutorial on even the technology or pictures or slides, nothing. I mean, you're expecting me to sit and read through seven patents in a timely way. So as you can sense the frustration, I have not had someone do this to me in a really long time.

So I'm going to start off on the motion to dismiss, and I'm going to ask you, Mr. Bunis, to start off with what do you think -- explain to me these patents and this patent thicket, as far as I'm concerned. Which is the one that's going to be the crumbs that will bring me through the forest?

MR. BUNIS: Well, let me start by saying, obviously it's not our motion.

THE COURT: I understand, but --

MR. BUNIS: But we are perfectly comfortable using one of the patents. We think that the '817 patent, which is a later-filed patent, is helpful, but I'm more than happy to use one of the patents from the earlier family of patents. And Ms. Pirozollo selected the '346. I'm happy to use the '346. But the Court has to keep in mind, Judge, and I know you will, that it's not just Claim 1 when evaluating eligibility under *Alice;* you have to look at all of the

claims, and that's very --

THE COURT: Which one is it, from your point of view? You think if I get my way through '346 --

MR. BUNIS: We would prefer that you use '141 which is from the same family, Judge.

THE COURT: So you prefer '141.

Ms. Pirozollo, you're '346?

MS. PIROZOLLO: I suggested '346, and that is because of all the references to the specification. They have a common specification, and so our brief refers to the specification of the '346. So that's why we wanted to focus on that particular patent, because we do understand this is complicated, and we were trying to simplify things a little bit by focusing on that patent. I think the issues --

THE COURT: All right, so I will focus on '346.

Mr. Bunis, you want me to focus -- I want to give each side a chance -- you think '141 will do it?

MR. BUNIS: They share a common specification, Judge. I just want to make the conceptual point, and I know the Court is aware of this, that you can't just focus on one of the claims, in fact, just Claim 1 in '346; you need to look at all of the claims. And if we do that and the Court is open to all of that, then that's fine.

THE COURT: Well, all the claims within that patent?

MR. BUNIS: That's right.

THE COURT: Yes, yes. All right, so let's start on the 101, and then at some point, what do you think timewise? It's 10:10. Maybe 15 minutes a side? Is that enough, half an hour a side, and then we move to the motion to dismiss? What are you thinking?

MS. PIROZOLLO: I think a half an hour would be helpful, and I'll try to move through as quickly as possible and be shorter, if I can.

THE COURT: Shorter is not as key to me as understanding this.

MS. PIROZOLLO: I'll try to be clear, and, you know, I think half an hour would allow for you to interrupt me if I am not explaining clearly.

THE COURT: Okay. And would you call this a "patent thicket"?

MS. PIROZOLLO: I would agree that I don't see the difference between some of these claims in the invention, and we think that all these four patents that we've moved on are basically directed to the same thing.

THE COURT: Okay. All right, so you're the moving party, so go for it.

MS. PIROZOLLO: Okay, thank you, your Honor. So as you know, *Alice* Step One asks whether the claims are directed to an abstract idea. Here, the claims of the '346

1 patent clearly are. I'm going to discuss, first, the claims
2 and the governing case law, and then I wanted to address
3 under Step 1 Progenics' reliance on the fact that the claims
4 require a 3D image to be created, and also Progenics'
5 discussion of the *CardioNet* and *McRO* cases.
6 So the claims of the '346 patent are directed to
7 analyzing --
8 THE COURT: Hold on a second. I want to just pull
9 that out so I can mark up that patent.
10 Okay, I've got it here.
11 MS. PIROZOLLO: Okay. So the claims of the '346
12 patent are directed, and we focused on representative
13 Claim 1, of analyzing medical images to assess cancer risk
14 and presenting the results of that analysis. And so, for
15 example, if you look at Claim 1, there are the steps of
16 accessing medical images. That's romanette i. Performing
17 an analysis on the medical images using a machine-learning
18 algorithm. That's romanette ii. And displaying or
19 generating a report with the results of the analysis. That's
20 romanette iii. So the claims are directed to obtaining
21 medical images, analyzing them, and displaying the results
22 of the analysis.
23 THE COURT: But can I just stop you. On Roman ii,
24 I guess it is, it says "To generate the risk map --" so go
25 through the whole thing, it's a risk map -- "wherein the

1 risk map comprises a visual representation of tissue
2 overlaid with graphical denotations, marking one or more
3 regions of risk of cancer or risk of recurrence of cancer."
4 Okay, all right, so I just wanted to -- it's not
5 just an analysis. It's a specific kind of analysis?
6 MS. PIROZOLLO: Right. And the risk map under the
7 patents is, it says "A risk map comprises a visual
8 representation of tissue." And so what the risk map is,
9 according to the patent, is a visual representation of bones
10 and organs within a medical image.
11 THE COURT: But ones that are high-risk, right?
12 MS. PIROZOLLO: Well, what they do is they -- I'll
13 back up because this is admitted by Progenics.
14 So doctors analyze two types of medical images to
15 determine cancer risk: They analyze anatomical images,
16 which are images like CAT scans which will show a patient's
17 bones and organs, so they get the information of where the
18 bones and organs are from the anatomical images.
19 They also have what are called "functional images,"
20 and these are images like PET scans. And what the functional
21 images show is, if the patient has taken a radio-
22 pharmaceutical, that radiopharmaceutical will bind at places
23 where cancer might be occurring, and the functional image
24 will show where those locations are in the patient's body.
25 And so physicians use both the anatomical image, so that

they know where the bones and tissue are, and the functional image, so they see where the radiopharmaceutical is bound to determine the cancer risk.

So this claim is talking about -- although it doesn't specify the medical images in the claim, it's talking about using a machine-learning algorithm to create a visual representation of bones and tissue. So that's, you know, the anatomical image, and then using that to identify geographic locations of where radiopharmaceuticals are bound.

THE COURT: It's the overlay, right?

MS. PIROZOLLO: Yes, yes. And that's why in Progenics' brief they emphasize the 3D visualization or the risk -- the 3D image that's in the "wherein" clause at the top of Column 36 as the innovation of their -- one of the innovations of this claim.

THE COURT: So 3D is the inventive step under step two? Is that what it would be?

MS. PIROZOLLO: Well, what they say, although we disagree with it, is that the 3D image in the "wherein" clause, which is a "wherein" clause describing step two, is an innovation. But if the Court has its bearings on the claim, I can walk through why we still think this is an abstract idea.

THE COURT: It would be useful for me to actually -- because this is the real problem with 101 analyses: Usually

I get taught during the *Markman* hearing, and no one has taught me yet. So it's very helpful to have you both walk through the claims. Don't assume too much knowledge about anything.

MS. PIROZOLLO: Okay. I must say, you know, in the 101 case law, you know, the Federal Circuit has noted that even though claims are very long and complicated, that doesn't mean they still can't be directed to an abstract idea, so --

THE COURT: I get that, but I have to understand it in my gut first, okay?

MS. PIROZOLLO: Yes. With that in mind, what this claim is directed to is using machine learning to analyze medical images, which can include these anatomical and functional images, to identify cancer risk, and then displaying the results on a graphical user interface to patients.

But, of course, numerous cases, as you know, say just using automating activity that doctors performed historically is not patentable and is an abstract idea. And, of course, that was the issue in *Alice* where the claim was directed to intermediated settlements, and the court said adding the words "apply it with a computer" is not enough. And we've cited other cases in our brief that stand for that proposition that automating activity that had been

1 performed by humans is not enough. We cited *Credit*
2 *Acceptance* and the *Voter Verified* case. And we think the
3 logic of those cases, you can't just add "do it on a
4 computer" or "do it with machine learning" to activity
5 humans did and have that be a patentable idea. That's an
6 abstract idea, and I want to explain why we think that logic
7 applies here.
8 As Progenics concedes -- and this is where I'd
9 like to explain why we think you can find, on the basis of
10 this record, that what Progenics is doing is trying to
11 patent the use of machine-learning analysis to do what
12 doctors already have done for a long time, because doctors
13 have already analyzed medical images and located bones and
14 tissue and used that analysis to identify cancer risk. And
15 where this is clear in the record is, for example, in the
16 specification of the '346 patent. So you look at Column 2
17 of the specification where Progenics --
18 THE COURT: I'm getting there. I'm getting there.
19 MS. PIROZOLLO: Okay. And it's, you know, it's
20 most of Column 2, so I'll summarize. But what Column 2 is
21 describing in the background of the invention is how doctors
22 previously identified cancer risk and communicated those
23 results to patients. And what that column makes clear is
24 that it has a lengthy discussion about how physicians
25 analyzed medical images, created reports of that analysis,

1 and presented the results of that analysis to patients,
2 including assessment of cancer risk.
3 We also think the Second Amended Complaint makes
4 clear --
5 THE COURT: Excuse me. Is there anywhere in
6 Column 2, or elsewhere in the specification, that talks
7 about this overlay? In other words, was there a capability
8 of doing that before where --
9 MS. PIROZOLLO: Like -- yes, so what --
10 THE COURT: -- I don't know, collate or combine
11 the results of the anatomical and the functional?
12 MS. PIROZOLLO: Yes. The specification refers to
13 machines -- and I'll try to find the cite -- that would take
14 in proximity a CAT scan and a PET scan. So that technology
15 was known.
16 In addition, I would direct you to Progenics'
17 Second Amended Complaint at Paragraphs 19 to 21 in which
18 Progenics describes how doctors used anatomical and
19 functional images. And in Paragraph 21 of the Second
20 Amended Complaint, Progenics specifically says that a
21 physician would use a combination of a CAT scan and a PET
22 scan. So the idea of using both --
23 THE COURT: I'm looking through the complaint, and
24 I just want to make sure. 19 to 21, is that what you're
25 relying on?

MS. PIROZOLLO: Yes. And in particular, in Paragraph 21, Progenics refers to a combination of a CAT scan and a PET scan.

THE COURT: So 21 to 22 explain, though, that it was different beforehand. Am I looking at the right paragraphs?

MS. PIROZOLLO: Well, Paragraphs 20 to 21 are describing the traditional process for analyzing medical imaging. So this was before --

THE COURT: So you had two scans, one in each hand kind of thing, and the doctor would interpret, like, "Oh, here is where the risk of cancer is, here's where the tumors are, here's the organ," right? And then they would in their mind integrate the two?

MS. PIROZOLLO: Yes. They would use a combination. But, you know, doctors -- and I found the cite in the '346 specification -- I don't mean to make you jump around but --

THE COURT: No, that's okay. I'm here to learn. I'm here to learn. Go ahead.

MS. PIROZOLLO: At Column 27, there's a reference to "PET-CT scanner instruments common in many hospitals." So not only did doctors use both types of images, but the idea of, you know, combining those images to do the analysis was known.

THE COURT: Now, where are you looking at? What

column?

MS. PIROZOLLO: It's Column 27.

THE COURT: Line?

MS. PIROZOLLO: Lines 1 through 10.

THE COURT: Good, okay.

MS. PIROZOLLO: So it says, "In certain embodiments, composite images comprising CAT scans overlaid with PET scans are obtained using dedicated PET-CT scanner instruments common in many hospitals."

THE COURT: But that's embodiments of the patent, right, not prior?

MS. PIROZOLLO: Yes, it is, but I'm referring you to the PET-CT scanner instruments that were common in hospitals.

THE COURT: It doesn't say that here, right?

MS. PIROZOLLO: Yes. It says --

THE COURT: The fusion to create the composite image --

MS. PIROZOLLO: It doesn't use the words "fusion" and "composite," that is true.

THE COURT: Okay, all right.

MS. PIROZOLLO: But I'm going to actually get to that under the case law. You know, creating different types of visualization of data is an abstract idea under the case law, so manipulation of data --

THE COURT: All right, go ahead. I keep interrupting you because I'm learning, but go ahead.

MS. PIROZOLLO: Okay. So I wanted to direct you to the Second Amended Complaint which talks about how doctors use both types of medical images to identify cancer risk. And I'd also direct you to Progenics' opposition brief at Page 10 which talks about how doctors use both of these types of medical images to identify cancer risk.

So it's also undisputed with these claims that the claims only rely on generic computer equipment. So, you know, we were looking at Claim 1 of the '346 patent, and the reference there is only to a generic computer processor and memory. So there are no specifics in these claims about computer technology.

And so under *Alice* and the other cases we've cited, such as *Credit Acceptance* and *Voter Verified* and many others, just using generic computer equipment to automate activity historically performed by humans doesn't make an abstract idea patentable. So here all the claims are doing is automating this analysis of different types of medical images using generic computer equipment.

The claims do have a reference to machine learning, but they do not specify anything about that machine learning.

THE COURT: Is machine learning essentially AI?

MS. PIROZOLLO: Yes. In the spec, yes, that's my

understanding. In the spec, the only description of machine learning is convolutional neural networks and ANN, which is another type of neural network. So there's a generic description of kind of AI in the spec, but no specific improvement, or certainly not claimed, and also not described in the specification.

So that's our basic argument as to why these claims are taking the analysis of medical images and automating it, which is not patentable under *Alice*.

And I wanted to address two specific arguments Progenics is making to rebut that argument: one, Progenics' reliance on the 3D image that's referenced in the "wherein" clause, and Progenics' reliance on the *CardioNet* and *McRO* cases.

So Progenics in its opposition to our motion repeatedly characterizes 3D visualization as a specific, concrete solution that is patentable under 101, but the Federal Circuit has rejected similar arguments and held that claims requiring certain types of visualization or manipulation of data are abstract, and there are two cases I wanted to highlight on that point.

First, in the *Trading Technologies* case, which was about providing information to traders, the Federal Circuit held that providing a trader with additional financial information to facilitate market trades was abstract. And

in that case, the patentee made similar arguments to the ones Progenics is making here, arguing that the invention provided a particular graphical user interface that improves usability, visualization and efficiency; and that was the innovation in the claims. But the Federal Circuit rejected those arguments and held the claims were still just directed to a process of gathering, analyzing information and displaying results, and not any inventive technology for performing those functions. And that is also the case with Progenics' claims, which don't have any inventive technology for performing the claimed functions.

The Federal Circuit reached a similar result in the *AI Visualize* case which we've cited in our brief, which involved, appropriately, patents relating to the visualization of medical scans. And in *AI Visualize*, much like Progenics argues here, the patentee argued that the claims weren't directed to an abstract idea because they required, quote, "creation" of virtual views of medical images on the client's computer. And the Federal Circuit rejected that argument and invalidated the patent under 101, holding that the creation of a virtual view from existing data was simply abstract data manipulation, and that's at Page 1,379 of the *Trading Technologies* case.

So the logic of *Trading Technologies* -- Progenics has highlighted this 3D visualization as the key innovation

of its patents, but *Trading Technologies* and *AI Visualize* both teach that creation of a 3D visualization of data contained in medical images is simply data manipulation, which is abstract under the case law.

THE COURT: Excuse me. Did either of them involve 3D?

MS. PIROZOLLO: The virtual view may have. I --

THE COURT: Okay, don't worry about it. Don't worry. I'm just starting to roll up my sleeves.

MS. PIROZOLLO: I --

THE COURT: What does 3D mean? I have this image of, you know, the thing at the airport where you see a human being, you know what I mean, when you walk in?

MS. PIROZOLLO: A holograph.

THE COURT: A holograph, right. Does something pop up, and you know exactly where the cancer is, a big red spot? Or is this just something turning on screen?

MS. PIROZOLLO: It's just 3D, three-dimensional. And it's worth noting that CAT scans and PET scans are three-dimensional. So the medical images that you start with here are three-dimensional, so there's no magic to a 3D image. And even if there were, creating a 3D visualization isn't patentable under the 101 case law from the Federal Circuit.

THE COURT: So 3D means if you're, like -- well,

maybe I'll ask, something I can see here. I mean, it's not a flat picture but it's -- I'm just trying to figure out how you see that on screen. Maybe -- what does it even look like? It's not 3D --

MS. PIROZOLLO: If you look at Figure 4 of the patent, obviously it is 2D, but I think it gives you an idea of what they say their invention would show. So you can imagine looking at Figure 4 on a computer screen and seeing the bones of the patient and --

THE COURT: Okay, well, this doesn't really show it, but, in any event -- okay, thank you.

MS. PIROZOLLO: So I would like to move on, if it's okay with the Court, to talking about the *CardioNet* and *McRO* cases because --

THE COURT: You can if you want, but I really -- this is why I love having lawyers -- I should have had you come in person, you're both local -- because I love having people explain the technology and walk me through the parts of the patent that you find important. I'll give you a few minutes on it, but then I was wondering how we should handle the -- you also wanted and Mr. Bunis wanted me to focus on the '141 as well, so I want to take time to do that. But you're welcome to spend a few minutes on it, and then I'll -- I think probably we should -- are you prepared to address '141?

MS. PIROZOLLO: So I can make very quickly a couple of additional points.

THE COURT: Okay.

MS. PIROZOLLO: So I want to just make the point, because it's important if you review the *CardioNet* cases and *McRO* cases because Progenics argues that its patents have the rule-based way of analyzing medical images that takes them out of 101. And I actually can be brief and point you to -- well, I will say, if you look at the claims -- and we've looked at Claim 1 of the '346 patent, and this will be the same in Claim 1 of the '141 patent -- there are no rules in those claims for how you analyze medical images. There are no descriptions of specific things to look at in the medical image to determine cancer risk. So this is not a case where the claims themselves set forth rules, which could be patentable under cases like *CardioNet* and *McRO*.

And in fact at Page 10 of Progenics' brief, Progenics actually says what they mean when they say the claims are "rules-based." They say "Rules based," and then they have the parenthetical that says "e.g., machine learning based.)" So what Progenics is saying is, these claims have a rules-based analysis of medical images because we have the instruction to use machine learning. But the Federal Circuit has -- that's just like "apply it with a computer." That is not -- just saying "use machine

1 learning" is not setting forth specific rules or technological
2 improvements. That's just invoking the use of generic
3 computer technology to perform the analysis. And that is
4 very different from cases like *CardioNet* and *McRO,* which
5 have had, you know, very specific ways of, in *McRO,*
6 lip-syncing, and in *CardioNet*, diagnosing heart arrhythmias,
7 atrial fibrillation, and atrial flutter.
8 So I would just add --
9 THE COURT: We need to -- we're getting close to
10 the half an hour, so --
11 MS. PIROZOLLO: Okay, all right.
12 THE COURT: So maybe I'll move to Mr. Bunis, who
13 can both respond to you and then perhaps flag the one you
14 want me to focus on. Does that make some sense? And then
15 I'll give you rebuttal time?
16 MS. PIROZOLLO: That sounds fine. Thank you, your
17 Honor.
18 THE COURT: Thank you.
19 MR. BUNIS: Your Honor, forgive me. I think I got
20 a cold last night, and if you can't hear me very well,
21 please let me know, but hopefully I'm coming through loud
22 and clear.
23 THE COURT: I hope you're feeling better.
24 MR. BUNIS: Thank you.
25 THE COURT: I hope it isn't the big C.

1 MR. BUNIS: Yeah, I hope not, absolutely.
2 Actually --
3 THE COURT: Maybe I'm glad you're doing it on
4 Zoom, huh?
5 MR. BUNIS: Judge, so obviously, as Ms. Pirozollo
6 mentioned, the plaintiffs believe that you don't have to get
7 passed out of Step 1 in order to find these patents
8 patent-eligible, and let me help you with that. These
9 claims, whether you use the '346, the '141, the '817,
10 et cetera, all direct you to a multistep, very detailed
11 process that is a practical solution to a technical problem
12 that existed before, and let me explain.
13 So the patient who is suffering from cancer will
14 have different kinds of scans performed. Those scans, as
15 Ms. Pirozollo mentioned, include things like a CAT scan. It
16 can also include a PET scan. As Ms. Pirozollo said, the CAT
17 scan is what's referred to in the patent as an "anatomical
18 image." The PET scan is referred to as a "functional image."
19 What happens when that patient in the prior art
20 goes to see the doctor is that the radiologist reads those
21 images and makes determinations about the state of the
22 cancer, the treatment plan, the progression of the cancer,
23 et cetera, all based on, as the Court was saying -- I think
24 I was interpreting -- for comparing in the one instance the
25 functional image and the anatomical image; and, of course,

using her own subjective experience as a radiologist in saying, "Here is where I believe the boundaries are. Here is where the segmentation occurs. Here is where the tissue is. Here is where the organ is." And as a result, they make determinations about treatment plans, staging cancer, et cetera.

Now, in Massachusetts we're lucky, right? You can go to the Dana Farber, and the likelihood is that you're going to find a radiologist that is experienced and knows, when they see an artifice on a particular scan, "Oh, I know that, I've had experience with that," and they can make determinations based on their experiential review of these functional and anatomical images.

That created a problem, of course. The problem was that if you weren't lucky enough to be located where a radiologist had a ton of experience, but you were in a place or just happened to be that you got a radiologist who didn't have that much experience -- and, by the way, it's not only based on experience -- I'll come back to that -- you were at the mercy of the reading of those functional and anatomical images by the radiologist. That was subject to recency bias. It was subject to all different things in addition to just the number of images or scans that a particular radiologist may have read in the course of her career.

Here, with this invention, in this multistep

1 process, what the patent's claim is, "a process by which the
2 images of the patient are reviewed." Then --
3 THE COURT: Can we stop off on the comparison one?
4 MR. BUNIS: Sure.
5 THE COURT: So Ms. Pirozollo said that those,
6 though, are typically 3D, or can be 3D. Let's put it that
7 way.
8 MR. BUNIS: Yeah, the display of the image, I
9 think what you might -- I don't know if you've ever had this
10 experience, but you very often look at a CT image or a
11 functional image on a radiologist's computer where they can
12 manipulate it. And so by 3D, I think the Court should keep
13 in mind that you can see volumes, right? They're represented
14 in the 2D image, which can't hold the volume, but it's a
15 representation of volume more than just in two dimensions,
16 so that you can see, for example, the depth of the cancer
17 within the tissues, et cetera.
18 THE COURT: I see.
19 MR. BUNIS: Right? Does that answer the Court's
20 question?
21 THE COURT: Yes, so it's --
22 MR. BUNIS: It's a 3D representation of something
23 that's --
24 THE COURT: But I guess the key point is, it did
25 preexist?

MR. BUNIS: Well, yes, 3Ds did exist defined for CT and defined for functional, but as -- I can continue in explaining --

THE COURT: Yes, keep going. So what you're saying is, it didn't, 3D, exist for composite?

MR. BUNIS: Yes, that's right, but let me explain how it works, if I can.

THE COURT: Yes, go for it.

MR. BUNIS: So in the patent claim, the claim discusses the collection of the images for that patient, right? In particular, the anatomical images. Then the machine learning is applied. This convolutional neural network is applied to those images.

And, your Honor, you should think of that as a very distinct rule set that has the benefit of an algorithm that's been trained in looking at thousands of previous CT images, CT scans. And rather than having an inexperienced radiologist, you now have an algorithm that can make judgment calls.

THE COURT: But who sets the algorithm?

MR. BUNIS: The algorithm is set by the convolutional neural network that is used and claimed in the patent.

THE COURT: I don't know what that -- sorry. Is it something that is in the patent that sets the rule?

MR. BUNIS: The patent discloses in claims the use of machine learning and describes in the embodiments that that machine learning is a convolutional neural network.

THE COURT: I don't know what that is.

MR. BUNIS: Well, it's a particular application of machine learning. And what it means for these patents, Judge, is that the model, the algorithm has been trained by looking at thousands of CT images in the past, and, like an experienced radiologist, can make logical judgment calls about the placement of that segmentation, about where the map should exist on that particular patient.

THE COURT: But just to answer my question really directly, it isn't your client that trained AI, right? It's been trained by -- I don't know whether iRobot did it, but not your people? I mean, it was written by some other people?

MR. BUNIS: Well, make no mistake: Convolutional neural networks did exist before. They were not used in connection with reading of images in this way at the date of the filing of the patent, but the patent is using the logic, the rules of that machine learning, of those convolutional neural networks, to make those judgment calls in reading the anatomical image of the patient. And then it uses the anatomical image and the functional image and produces that 3D map, right, that risk map, which your Honor was correct

1 in pointing out, in focusing initially on the generation of
2 that thing which did not exist before. And it produces
3 something which has the benefit of the evaluation of the
4 patient scan and the application through the patient scan of
5 that machine-learning logic to create something that never
6 existed before.
7 And that is the solution. That is the technical
8 solution to the industry problem that these patents were
9 solving. And that's why a patient who is in a place where
10 you may not -- I don't want to cast aspersions on
11 geography -- but in a place where you may not find a
12 radiologist with that much experience, now, by virtue of
13 these inventions, the determinations about where the risk
14 map and where the overlays are, or where the cancer is and
15 the treatment plan, has the benefit of the most experienced
16 of radiologists. It lowers the playing field.
17 Now, the multistep process creates something that
18 never existed before, but in doing so, it uses an automation.
19 Now, the Federal Circuit has been very clear that when you
20 incorporate an automation, when you incorporate, for
21 example, a known algorithm or mathematical formula into a
22 multistep process, that doesn't render it patent ineligible,
23 and I would point the Court to *Diamond v. Diehr*. In the
24 *Diehr* case, Judge --
25 THE COURT: That old, old case?

1 MR. BUNIS: That's right, Judge. In that case,
2 the patent was directed to a process I think for curing
3 rubber, and one of the steps in the process used a
4 particular mathematical formula. And I don't know the name
5 of the formula; it begins with an A. But, anyway, the Court
6 said specifically, simply because the claim and the process
7 incorporated a step of a known formula, that doesn't render
8 it ineligible. That's the same thing that's going on here,
9 and so that's what the claims are directed to.
10 Now, with respect to the 3D visualization, Judge,
11 the Federal Circuit in both the *CardioNet* case and in the
12 *McRO* case -- and McRO is very relevant here, it's extremely
13 relevant -- what they said was: You should be careful not
14 to presume that the patent is claiming the automation of
15 what the prior art previously did.
16 Now, in the *McRO* case, what they're talking about
17 there is sort of a technology directed to lip-syncing and
18 the creation of models around when certain sounds are formed
19 in the face. It wasn't doctors there. It was artists who
20 actually created 3D manipulations, and they did it by art,
21 right? They did it by saying, "Oh, I know when you make the
22 O sound what the face looks like, and so I create the lips
23 to do a certain thing," right?
24 And in the *CardioNet* case, it was doctors. They
25 said, "Oh, I can make a judgment call about when I see a

1 particular flutter or a particular rhythm, and I can make a
2 judgment call."
3 And in both of those cases, the court said that
4 was sufficient. And in the *McRO* case, the output of those
5 determinations that were done automatically was a 3D
6 animation; no different, I would offer, your Honor, than the
7 3D animation that is the output of the process that's claimed
8 in these patents, right?
9 And in fact the court in *CardioNet* said that it
10 didn't matter that it wasn't a tangible image, it didn't
11 matter that it was a 3D image; that it was sufficient enough
12 to move it away from simply automating a process that had
13 previously been done in the prior art.
14 Now, doctors previously, as you pointed out in the
15 very beginning, they had compared one to the other, right?
16 But they had not previously used machine learning to create
17 these overlays, these 3D risk maps, for the purposes of
18 making diagnosis decisions involving cancer.
19 Now, I'm reluctant to move on, but I'll check in
20 with the Court to make sure that that is sort of a practical
21 understanding of what's going on here.
22 THE COURT: It is a practical understanding, but
23 going into claims, Claim 1, so do you agree that really
24 the -- I don't know whether it's Step 1 or Step 2 -- I find
25 that piece of it impenetrable in the case law -- but whether

1 it's Step 1 or Step 2, that the issue here is the creation
2 of a -- well, basically the "wherein" clause?
3 MR. BUNIS: Correct. That is correct, Judge. I
4 do agree with you. I would say to you, Judge, that you have
5 a multistep process that includes receiving an anatomical
6 image of the patient. You apply to that anatomical image
7 machine learning in the form of convolutional neural networks
8 that makes this heretofore analysis, an analysis that had
9 not been done but an analysis using thousands of previously
10 read CT images, and then it considers the functional image,
11 and it produces or generates that 3D map, right? It's a
12 multistep process that uses a real tool.
13 Now, let me pause for a second. Judge, in the
14 cases that the defendants cite where the Federal Circuit and
15 other District Courts have found that the claims are drawn
16 to abstract ideas, those claims all read data and then spit
17 it out in another form. In other words, they just
18 reformatted the data. And in fact the Court looked at this
19 very same kind of thing in the *Ocean* case not too long ago.
20 I'm reluctant to bring it all back to you, Judge, but there
21 you were looking at patents related to metrology --
22 THE COURT: No, it's not bringing it back. It's
23 blossoming as we speak. It's very much still -- I've got
24 two *Ocean* cases now, so it's not bringing it back. But I do
25 remember the analysis which I found so difficult, even in

that context, but what saved it were, at least two of them were dependent claims.

MR. BUNIS: Right. And you said in that case, you said, if you just look at collected data related to metrology and filter it, that's not good enough. That doesn't do it. That doesn't get you to -- I think you said the guillotine, the *Alice* guillotine. But what you found saved those dependent claims was that in the claims, they recited matters in which you could solve the problem that had previously been identified in the prior art.

Here, the problem in the prior art was that you couldn't get a reliable way to diagnose cancer that took advantage of, or at least weren't dependent upon, the relative experience of the radiologist who was making the determination. Here, by virtue of the application of the automation, of the machine learning or convolutional neural network, you get the benefit of all of that logic, those rules, right? And you create something with it that heretofore never existed, and that something was a 3D visualization.

Now, the defendants may say, well, now that's --

THE COURT: Can I jump in. So that's the '346. I think that's what it is. Yes. And you also wanted me to look at the, what was it, the --

MR. BUNIS: The '141. Judge, it's the very same

1 thing that's created in the '141 with nuances. The '141
2 describes with specificity, for example, the type of scan
3 that you're using. Ms. Pirozollo explained how in a
4 functional image, you can have a radiopharmaceutical. And,
5 again, you know, there's the situation -- perhaps the Court
6 is familiar with it -- where the patient is injected with a
7 particular substance that would bind to the cancer, and then
8 on the back side of that substance there's a radionucleotide
9 that lights up.
10 THE COURT: Yes.
11 MR. BUNIS: So those claims in the '141 include
12 more detail around those examples or those embodiments in
13 the invention. But the notion, conceptually it's all the
14 same, and that is to say, you collect patient's images; you
15 apply to those patient's images machine learning in the form
16 of a convolutional neural network that has the benefit of
17 having been trained on thousands of images to make
18 determinations and judgment calls about where the map
19 segmentation should be done; and then it produces an overlay
20 that is that sedimentation that is smart, Judge. It is
21 smarter than any radiologist --
22 THE COURT: So why are they different? I mean,
23 I'm just trying to -- wouldn't one encompass the other?
24 MR. BUNIS: Well, no. They each have nuances.
25 For example, in the '141 patent, there's descriptions of how

1 the 3D boundaries are placed within the risk map, which
2 doesn't exist in the '346 patent.
3 THE COURT: Like where? Like where?
4 MR. BUNIS: Well, for example, in the "wherein"
5 clause, there's a subclause (a) that says "Using the
6 composite image to graphically identify the 3D boundary for
7 each one or more of the regions of imaged tissue within the
8 nuclear medicine image." It also describes the nuclear
9 medicine image by name; yet it's calling it the functional
10 image in the '346. In the '035 patent, it recites in the
11 independent claim the presence of the --
12 THE COURT: This is where I started getting lost
13 in your briefings. I mean, each one of them sound quite
14 similar. So if I say the first patent, the '346, is enough,
15 does that, in your view, automatically say the Claim 1 -- in
16 other words, when you create these patent thickets, each one
17 is slightly different, and it's very confusing for a judge
18 trying to walk through the differences.
19 MR. BUNIS: Your Honor --
20 THE COURT: So why wouldn't Claim 1 pick this up?
21 MR. BUNIS: So it does. Claim 1 of the '346 alone
22 doesn't, but it does -- let me try to explain it this way:
23 Certain portions of the dependent claims in the first set of
24 patents pick up or capture the concepts that are claimed in
25 the subsequent patent. So, for example, in dependent

1 Claim 3 of the '346, Judge, you have the claiming of the PET
2 scan, and you name the functional image. In Claim 1, it
3 just talks about functional, but in Claim 3 you're talking
4 about the specific type of functional image. So to the
5 extent the Court is concerned, "How do I manage all these
6 various claims and nuances --"
7 THE COURT: There are so many claims and so many
8 patents. I'm not going to go through each claim.
9 MR. BUNIS: So long as you consider all of the
10 claims, both independent and dependent, you'll be fine
11 looking at the '346, and you can use that. It may be
12 clearer if you look at some of the other independent claims
13 of the other -- I guess there's three patents -- because
14 they are more specific with respect to what's going on. But
15 conceptually, Judge, so long as you can appreciate that even
16 Claim 1 of the '346 claims a multistep process whereby the
17 claims include looking at the images of the patient, applying
18 to those anatomical images machine learning in the form of
19 convolutional neural networks that makes determinations
20 based on having been trained on thousands of previous images
21 about where a map should be drawn, and then actually
22 produces that 3D visualization. It actually creates
23 something.
24 Now, if you look at those cases that the defendants
25 cite, those are cases standing for the proposition that

simply reading data in one form and spitting it out in another form -- if you read tabular data and then show it as a graphic, if you read data in the form of -- for example, in the *AI Visualize* case, all the claim was directed to there was taking a look at whether some particular frames were present locally in the database that the computer was reading; and if they weren't present locally, then the patent claims sending a version, a lighter version of those frames to the client or to the computer.

THE COURT: But why did you flag the '141? Is that because it was just --

MR. BUNIS: It's just a little more specific with respect to -- it would make it easier for the Court to sort of see what specifically was going on.

THE COURT: Because this involves the prostate, right?

MR. BUNIS: Correct, Judge. That's right.

THE COURT: And you have other ones that include the, I don't know --

MR. BUNIS: That's right, Judge. Like, the prostate is a perfect example because what you're able to do --

THE COURT: But there's nothing new about the prostate that isn't provided in the first one, right?

MR. BUNIS: Well, no. I mean, for the purposes of

1 this analysis, why I'm reluctant to say "no" is because I
2 don't like that -- for the purposes of the 101 analysis, the
3 answer is "no."
4 THE COURT: Okay, for the purposes of 101. I
5 mean, there may be different things that are --
6 MR. BUNIS: That's right.
7 THE COURT: Okay.
8 MR. BUNIS: Judge, I just want to leave you with
9 this understanding that like you did in the *Ocean* case,
10 right, when the claim is simply directed to collecting images
11 or collecting data, filtering the data, and then making a
12 determination based on that filtration, that filtering step,
13 that's not enough, right? That's not what's going on here.
14 The claims are very clear: You look at images. You apply
15 machine learning in the form of convolutional neural networks
16 to those images. Then you create something -- or you also
17 consider functional images when you're creating the risk
18 map, and then you produce something that is a tool that is a
19 very practical solution to a technical problem that existed
20 and was identified in the prior art.
21 And to be clear, Judge, yes, radiologists were
22 conducting these segmentations, but they were doing so, just
23 as you -- I don't want to presume. I got the impression,
24 Judge, in the beginning that you were holding one image in
25 one hand and one in the other and comparing. That's what

the prior art describes, right? This claim is not simply automation of the prior art. It produces something new that never existed before.

THE COURT: All right, thank you.

Do you want to, Ms. Pirozollo, respond with five minutes?

MS. PIROZOLLO: Yes. I can respond briefly, your Honor, because I know Ms. Butler, I know that we have our other aspect --

THE COURT: We do have another aspect.

MS. PIROZOLLO: So just three quick points. So, first of all, in response to the question you asked me earlier, the *AI Visualize* case did involve 3D virtual views, and it said the creation of 3D virtual views was still an abstract idea, abstract data manipulation. So that's my first point.

The second point is, Mr. Bunis referred to machine learning and the benefits of using machine learning over subjective analysis of medical images, and your Honor asked about where are the rules, who trained the AI? You know, and the answer to that question is, there is no information about the machine learning claimed, in the claims or in the patent itself. If you look at Column 25 of the '346 patent at Lines 32 to 35, so that's three lines of the patent --

THE COURT: Wait. I've got to get there.

MS. PIROZOLLO: Okay.

THE COURT: What column?

MS. PIROZOLLO: It's Column 25, Lines 33 to 35.

THE COURT: I have so many patents here.

(Pause.)

THE COURT: Okay, line?

MS. PIROZOLLO: 33, the word says "Other approaches." And it says, "Other approaches based on machine learning techniques -- e.g., artificial neural networks (ANNs), e.g., convolutional neural networks (CNNs) -- may also be used." That is the total description of AI that appears in this patent. As Mr. Bunis conceded, convolutional neural networks and artificial neural networks were already known. The patent doesn't teach anything new about machine learning or neural networks. It has that very limited disclosure. And the claims don't require any specific machine learning, and there's no description of any specific training on medical images that appears in this patent.

So the limitation of "use machine learning" is really just the same thing as "use a computer." There's no specific rules or information about the machine learning in the patent or the claims, and that isn't permissible, and we've cited some cases on that. This is an issue that's coming up more recently with AI, but we cited the *Power Analytics* case which was affirmed by the Federal Circuit,

1 which held that just adding machine learning to a claim
2 doesn't turn an abstract idea into a patentable invention.
3 I didn't want to go back to the *Diehr* case, but
4 very unlike the *Diehr* case, which had a specific equation in
5 the claims, these claims don't have any specific rules.
6 They just say "use machine learning," which is the same
7 thing as saying "use a computer," which *Alice* says you can't
8 do. And the problem is, one company shouldn't get a patent
9 to use of machine learning to analyze medical images.
10 That's just not permissible under *Alice*.
11 And, lastly, I will just say we agree with you
12 that there is no difference for the 101 analysis between the
13 '346 and the '141 patent. The issues Mr. Bunis was pointing
14 to --
15 THE COURT: They both rise or fall?
16 MS. PIROZOLLO: It's the same thing. The more
17 specifics that Mr. Bunis referred to are things that were in
18 the prior art. The different types of medical images are
19 the same types of medical images that we talked about in
20 connection with the '346 patent. CAT scans, PET scans,
21 these are all things that have been used. As you pointed
22 out, prostate cancer, different cancers, you know, this type
23 of technology doesn't add anything inventive to the claims.
24 References to radiopharmaceuticals don't add anything to the
25 claims. The Background of the Invention section of the

1 patents talks about radiopharmaceuticals being known. So
2 the issues are all the same on these patents. They're all
3 directed to, and this includes the '817 patent, to the
4 abstract idea of using machine learning to analyze medical
5 images.
6 THE COURT: All right, thank you. Let's move on
7 to Part B. Did you want two seconds?
8 MR. BUNIS: Just two seconds, Judge, very quickly.
9 Number one, I want to point out the fact that Ms. Pirozollo
10 mentioned that there's no further description or analysis of
11 what it means to use convolutional neural networks. That's
12 a problem for claim construction, Judge. A person of
13 ordinary skill in the art would understand what it is when
14 they read CNN in the specification. But, your Honor, we're
15 way before that. All right, that's number one.
16 And number two, Judge, the cases that say that 3D
17 imaging is not enough, that's because those are cases where
18 the patent claim is directed to just the presentation in the
19 3D form of a re-formation, a reformatting of the data that
20 was evaluated. That's not what's going on here. The images
21 are considered in the claims; then the machine learning is
22 applied, and something new is created by virtue of applying
23 that machine learning, and you're creating a 3D visualization
24 that never existed before in any form. It's not a
25 reformatting of that. We're not claiming, you know, math.

We're not claiming to occupy or preempt all applications of a machine learning to medical images. No. We're very specifically targeting a solution to applying machine learning to a situation and producing something that didn't exist before.

THE COURT: Thank you. All right, we need to move on to the next thing. So maybe if the two of you turn off your computers and we just go to the new folks up at bat, it would be really helpful, although I don't want you to leave because my favorite topic is going to be at the end, which is potential settlement. So there we go.

MS. BUTLER: All right, are you ready for me to proceed?

THE COURT: Yes.

MS. BUTLER: Okay. So the discussion that you just heard --

THE COURT: Mr. Bunis, turn off so -- you're not arguing on this, right, Mr. Bunis? All right, so just turning off your video would be great. Perfect. Now I've got the two of you.

MS. BUTLER: Good morning, your Honor. Marla Butler for MIM Software. So the discussion that you just heard was about four of the patents, and we're moving to dismiss those patents on 101 grounds. This discussion relates to the other three patents where we didn't move to

1 dismiss under 101, but we're moving to dismiss for failure
2 to state a claim.
3 So plaintiffs purport to accuse four MIM products
4 of accusing (Sic) seven patents, and the four MIM products
5 at issue are Contour ProtegeAI, SurePlan MRT, LesionID, and
6 LesionID Pro. And the complaint is long with a lot of
7 quotes from articles and websites and product literature,
8 and purports, your Honor, to address a representative claim
9 from each patent on an element-by-element basis. So that's
10 important because that's what the complaint purports to do.
11 It walks through, purportedly, each element of each claim.
12 What the complaint actually does is, for any
13 representative claim, because they use a representative
14 claim for each of the patents, address one or more products
15 as to some limitations and other products as to other
16 limitations of a claim. So, for example, just as an
17 example, in their allegations with respect to representative
18 Claim 1 of the '508 patent, for the first claim limitation --
19 THE COURT: Wait a minute. Whoa. I'm sitting
20 here with piles of patents, so -- so where do you want me to
21 be?
22 MS. BUTLER: And I don't need it. For purposes at
23 this point, your Honor, this is just as an example, and I
24 think you'll understand why I say I don't even think you
25 need to look at the claim because I'm not going to get into

1 the meat of what the claim says at this point. But I just
2 want you to understand that they use this patchwork pleading
3 where -- so, for example, for the '508 patent, for the first
4 limitation, Progenics addresses LesionID but says nothing
5 about the other three products, right? They don't address
6 Contour ProtegeAI, SurePlan MRT, or LesionID Pro at all.
7 And then they get, for example, to the fourth
8 limitation, and they do the opposite. So in the complaint
9 they're putting out these facts that address SurePlan MRT,
10 Contour ProtegeAI, and LesionID Pro, but they say nothing
11 about LesionID. And when I say that they addressed these
12 particular products, I don't mean that they've adequately
13 alleged infringement. All I mean is that they pointed to
14 some document or article that mentions the product. And so
15 the result is that for each asserted claim in the patent
16 where they pick a representative claim for each patent, they
17 make no attempt to show that all four products practice all
18 the claim elements.
19 THE COURT: Can I say this: The Federal Circuit
20 law on this is not so crystal clear. In other words, they
21 think it's pretty standard Federal Circuit law that you
22 don't have to go limitation by limitation.
23 MS. BUTLER: So -- and this is -- and a hundred
24 percent I agree with you, but I don't think that that means
25 that a plaintiff can waive, completely fail to address, a

1 claim limitation, especially, your Honor, in a situation
2 like this where the plaintiff does purport, if you look at
3 how they laid out their complaint, does purport to address
4 each claim on an element-by-element basis. So while the
5 Federal Circuit has certainly said that a plaintiff does not
6 need to plead infringement on an element-by-element basis,
7 what the Federal Circuit has also said and what *Iqbal*
8 directs is that --
9 THE COURT: So you think this is another example
10 of Federal Circuit -- I mean, that's the thing, is that
11 *Iqbal* has been applied across many fields but somehow hasn't
12 hit the Federal Circuit yet.
13 MS. BUTLER: Understood, but I think that they do
14 make sense together, right? Because what *Iqbal* says is that
15 the plaintiff has to plead factual content that allows the
16 court to draw a reasonable inference that the defendant is
17 liable; here, for infringement. And of course, to infringe,
18 a product has to meet all elements of the claim of the
19 asserted patent --
20 THE COURT: -- each limitation, so it's
21 complicated.
22 MS. BUTLER: I agree it's complicated, but here is
23 why I don't think in this case it's that complicated,
24 because the plaintiff purports to walk the Court through
25 every single element of every single claim, right? But for

1 some of those elements, the plaintiff has done a big kind of
2 hand wave or just said that they addressed the element; but
3 when you actually look at what they pled, they haven't
4 addressed the element. And in that type of situation where
5 the plaintiff says the accused products -- and I'll try to
6 give you an example of this -- the accused products perform
7 Element A of Claim 1 of this patent, and then they cite
8 literature for two of the four accused products but they
9 leave the other two, they just completely ignore the other
10 two, and then the accused products perform Element B of
11 Claim 1, and now they're going to cite literature for two
12 different products, right? So what the plaintiff has done
13 is build this fabric of allegations that has obvious holes
14 in it. And when those obvious holes are present, when the
15 plaintiff purports to address the claims on a element-by-
16 element basis, the Court cannot draw a reasonable inference
17 that those elements that they don't address, at least for
18 some products -- here, for the three patents that I'll
19 address here for all products -- the Court can't draw a
20 reasonable inference that there is infringement. And
21 certainly when the plaintiff alleges facts that are the
22 opposite of what the claim requires, the Court can't draw
23 such an inference in that situation either.
24 And as to this last point, with the Court's
25 permission, I'd like to address the '508 patent first, if

that's okay. And so that is 11,657,508. It was Exhibit 5 --

THE COURT: I've got it, I've got it. I've got my binder with all the patents in it. So where do you want me to go?

MS. BUTLER: Very good. So I think they use representative Claim 1, so it's going to be Claim 1 that we're going to talk about, but I'm going to call your attention --

THE COURT: Where do you want me to go?

MS. BUTLER: I'm going to call your attention to the very last claim limit of Claim 1. So it's in Column 80 starting at around Line 48. But I want to just, even before we get to the claim, your Honor, I just want to talk about at a high level what the '508 patent is about, and when the Court's ready, I'll proceed with that.

THE COURT: Okay.

MS. BUTLER: So the '508 patent relates to measuring what's referred to as "radiopharmaceutical uptake." It's how much of -- and Ms. Pirozollo and Mr. Bunis talked about injecting these agents, and they bind to different tissues in the body.

THE COURT: Right.

MS. BUTLER: Radioactive uptake is just how much of this agent has bound. So the '508 relates to measuring radiopharmaceutical uptake in the body. And, for example, a

lesion, a cancerous lesion, the purported invention of the '508 patent is to measure not just the radiopharmaceutical uptake or the intensity level at the lesion, which the claim refers to as a "hot spot." So you're not just measuring how much was absorbed at that lesion, but you're also identifying reference volumes so that you can compare, right? So different tissues are going to absorb at different levels. And so if you have reference volumes of what you expect to be normal tissue, you can see where the hotspot sits relative to those reference volumes.

And in the '508 patent, and particularly in representative Claim 1, they're using reference volumes from the aorta, so blood from the aorta and the liver. And then what the claim requires, and the point that I pointed you to starting at about Column 80, Line 48, what the claim requires is, you determine an index level from the hotspot. And the way you determine that index level is -- so there's a -- and I'm going to use an example that's not in the patent, but I think it does just help to explain what this patent is about -- there's an industry standard called PROMISE. And in fact Progenics has a product called aPROMISE -- this is a small "a" in front of PROMISE -- because they're automating this industry process. And what it does and what the '508 patent describes is, you know that a functioning liver, a normal functioning liver would have a

higher uptake than the blood pooled in the aorta. And so the '508 patent and this PROMISE method uses the liver and the aorta as references. And then you take --

THE COURT: Wait a minute. Where does it say --

MS. BUTLER: So Column 80 starting at, say, Line 45. I'm sorry, Line 48.

THE COURT: Okay, the aorta and the liver.

MS. BUTLER: Right. So at Line 48, "For each individual detected hotspot, determining a corresponding individual hotspot intensity level based on the measure of intensity value at the detected hotspot." So that is basically, what's the intensity level? How much has that hotspot absorbed of this radiopharmaceutical agent? And then determining a corresponding individual hotspot index level from the hotspot intensity level, the aorta intensity referenced, or the aorta-referenced intensity level, and the liver-referenced intensity level.

So the way this works, and, for example, in this PROMISE method, is that you have the, and I've got a sheet on this, but there's an index from 0 to 2. And because we know that the liver is expected to be high, that liver is 2. So anything that's over what the liver's kind of uptake level, how much that liver has absorbed, would be 2. We expect the blood aorta to be lower. And so this index is used to measure where does the hotspot intensity level sit

relative to the liver and the aorta?

The most important thing here, your Honor, is that this claim requires using both the liver and the aorta for the reference values of both of those. But if you look to what -- well, even before we look to see what Progenics has alleged here, in addressing this claim element, I'll point out that Progenics only talks about one product, and that's the LesionID. This is a perfect good example. They make no reference, they point to no documents, nothing about Contour ProtegeAI, SurePlan MRT, or LesionID Pro. And where they --

THE COURT: Back up because I don't know this by heart. So they're claiming that which products violate this patent, all four or just one?

MS. BUTLER: That is the question, your Honor, because they say that the accused products perform this particular claim element. They make that statement, but then they only point to documentation related to one of the products and point to nothing as to the other three.

THE COURT: So you're just saying dismiss the other three on this claim but keep the one?

MS. BUTLER: No. So I'm saying at a minimum for this claim, the other three should be dismissed, right?

THE COURT: So what is the one that they did allege violated this?

MS. BUTLER: LesionID. And here's why we say that

1 even for LesionID, this claim should be dismissed, because
2 what they point to is documentation, and they quote it in
3 Paragraph 102 of their complaint.
4 THE COURT: Wait, wait, wait. I don't know this
5 as well as you do, so let me get to 102.
6 MS. BUTLER: And it starts on, if it helps, Page 55
7 of the Second Amended Complaint.
8 THE COURT: All right, here we are, 102.
9 MS. BUTLER: And if you scan and if you turn -- so
10 you see they say the infringing products also possess the
11 7th limitation, so that kind of broad statement about the
12 infringing products. For example, MIM Encore's Web page
13 lists LesionID. They talk about LesionID, use of PERCIST.
14 It's a method that is used by this particular product. And
15 then they talk about what PERCIST is, what PERCIST does.
16 And if you look through the remainder of Paragraph 102, what
17 they're actually doing is quoting language from the literature
18 that says that PERCIST doesn't use a reference level for the
19 aorta or the liver. PERCIST uses the reference -- or excuse
20 me. They don't say that PERCIST uses --
21 THE COURT: Anyway, you're going too fast for me.
22 So I'm reading this. So PERCIST, PERCIST isn't a separate
23 product?
24 MS. BUTLER: It's a method, and they describe it
25 as a method for measuring tumor burden. It's a method for

figuring out kind of the stage of a tumor, for example.

THE COURT: Well, it does refer to "and/or aorta reference."

MS. BUTLER: So what is described, if you look at, for example --

THE COURT: I can't do this on a motion to dismiss. I understand your point about the other products, but it's saying aorta and liver.

MS. BUTLER: So while measurements might be taken from the aorta and the liver, the index value is determined from one of them. And Claim 1 of the '508 patent requires that the --

THE COURT: It says "liver and/or."

MS. BUTLER: Where are you reading, your Honor?

THE COURT: Am I wrong? "Involves, among other things, comparing lesion peak standardized update values --" at the very bottom of Page 55 -- "to cut off thresholds derived from liver and/or aorta reference intensities."

MS. BUTLER: So that's what Progenics says, but then they go on to quote the actual literature that says you use one or the other. They say --

THE COURT: I know. I can't do that on a motion to dismiss. You may win the ballpark. You're asking too much of me at this point. I mean, as long as -- I do get your point about the other three products. That seems fair

enough.

MS. BUTLER: Understood, understood. So, yes, at a minimum, where those other three products have not been addressed at all as to this particular claim element, we'd suggest they be dismissed. And even for LesionID, and I'll just make the point last and we can move on to another patent --

THE COURT: Okay.

MS. BUTLER: Even for --

THE COURT: I don't have that much time to move on to all the patents, so --

MS. BUTLER: Okay, so --

THE COURT: But is it the same kind of thing where you're saying they're making certain claims, but it's inconsistent with the actual literature? Is that what's happening here?

MS. BUTLER: So in the '508 patent, what they're alleging, what they point to in the literature in their allegations is actually the opposite of what the claim requires.

THE COURT: So they make the allegations in the complaint, but the literature --

MS. BUTLER: That they quote, what's actually in the -- and you don't have to go to the literature. All you need to do is read the rest of Paragraph 102, right, and the

1 parentheticals that they have in 102 which say, for example,
2 if the liver is damaged -- you get both, so that if the
3 liver is damaged, you can use the aorta instead. So I'm not
4 suggesting that your Honor look at the literature. All I'm
5 suggesting is that you look at the parentheticals that they
6 have quoted from the literature, which make it clear that --
7 so there is, just because I have it underlined, if you are
8 on Page 56 of the Second Amended Complaint, there is a
9 parenthetical that says, you know, "the intensity for each
10 hotspot, which will be compared with liver or aorta
11 references," right? And about five lines from the bottom on
12 Page 56, "PERCIST compares the peak SUL intensity for each
13 hotspot with liver or aorta references."
14 My whole point, your Honor, is that what the claim
15 requires is that it be compared with liver and aorta. And
16 when they are saying that the literature says it's "or,"
17 that's the opposite of what the claim --
18 THE COURT: But then later on they use "and,"
19 like, later on in the next sentence down.
20 MS. BUTLER: So the next sentence down says, "See
21 id. When the activity and the descending thoracic aorta is
22 measured instead --"
23 THE COURT: No, no, the one that says "Retain
24 those hotspots with SUL peak values above the liver and
25 aorta-derived thresholds." So I do agree it's confusing.

I --

MS. BUTLER: Understood. I hear you, your Honor. I think, and what I would just ask the Court, if you look at that Paragraph 102, again, while those values might be measured and even retained, whenever you're talking about comparing, which is what you're doing with an index, it's the liver or the aorta, not the liver and the aorta as the claim requires.

THE COURT: Okay, thank you. So at the very least, I have to be clear, I'm not going to probably -- it's "when all reasonable inferences" kind of thing. I mean, it's --

MS. BUTLER: Understood.

THE COURT: But you're saying the other three products aren't named?

MS. BUTLER: They're not. As to this particular claim element, they don't address them at all. And where you address one claim element and purport to say all the accused products and you've given the Court nothing from which the Court can infer that these other three products do the same thing, right, then that claim element hasn't been met; a plausible claim of infringement has not been met.

THE COURT: All right, I will look at that through this prism.

So let me turn to opposing counsel on this.

MS. SPIETH: Absolutely, your Honor. Anita Spieth on behalf of the plaintiff. The Court expressed some frustration about dealing with the seven patents at this stage of the case, and I think what you're running into is the fact that MIM just didn't have 101 arguments for these three patents, so they're trying to shoehorn them in somewhere in here, and you'll find that their arguments really just do not hold up to the 12(b)(6) --

THE COURT: The point she just made, though, take that particular claim. I mean, it does strike me that at most, we're talking about one product here.

MS. SPIETH: So absolutely, your Honor, and that can be easily swiped away. What is accused in the complaint -- and you don't have to look now, but for your record, it's in Paragraphs 5 and I believe 52 of the complaint -- is a suite of products. So imagine, like, does your Honor --

THE COURT: Wait, wait. There's a reason I have all of you sitting in front of me. What do you mean a suite of products?

MS. SPIETH: Does your Honor use the Microsoft Word suite which includes Microsoft Word, Excel? It includes PowerPoint. It includes Keynote, depending on what you buy. Are you familiar with the concept, your Honor?

THE COURT: The concept, yes. Do I use those?

No.

MS. SPIETH: That's okay, that's okay. I'm analogizing to that concept so that it might be more clear. What is accused is MIM's suite of software, all of which it sells, all of which it advertises, and all of which can be bought by MIM customers to do this radiologic imaging task.

One customer might turn on a particular module of that suite and might buy it. I don't know that. That's something we'll have to uncover through discovery, but what is accused in this case is the MIM suite of software.

THE COURT: I can't do it that way. I have to do it product by product.

MS. SPIETH: Actually, your Honor, I'll tell you why you can. The product is MIM's product, so when you think of it in that context, we have endeavored to fast forward some of the infringement allegations. As MIM points out, they know exactly what's accused. It's perfectly clear from the complaint. It certainly meets the *Iqbal* standard as the *Iqbal* standard has been interpreted by the Federal Circuit.

THE COURT: Well, can I just say, your colleague listed four specific MIM products; Contour, you know, et cetera, LesionID, that sort of thing. So each one of those is a separate product, right?

MS. SPIETH: No, your Honor. They're modules.

1 This is where I think you're getting tripped up here by a
2 factual distinction. They're modules within MIM's software
3 products, so customers buy multiples of those and use them
4 together. For example, this is in the complaint --
5 THE COURT: Can you buy them separately?
6 MS. SPIETH: That's for us to learn through
7 discovery. We don't know the answer to that, but I suspect
8 the answer is that most of MIM customers use them together.
9 For example, just to give you a specific example --
10 THE COURT: Why don't you know that? Why don't
11 you just buy it?
12 MS. SPIETH: I don't believe that --
13 THE COURT: -- collaboration. So, I mean, I don't
14 know that I --
15 MS. SPIETH: I don't believe that they would sell
16 it to us, but our complaint alleges in fact that, for
17 example, one of the products is a part of the other product;
18 Contour ProtegeAI is a part of MIM's SurePlan MRT.
19 So it's not the case that these are -- so let me put it
20 in a way that might be easier to understand. MIM cites one
21 single case for this proposition that you can dismiss, you
22 know, an allegation of infringement with respect to one
23 product over another. That was about spray cans. In that
24 case, the plaintiff listed ten spray cans, but its
25 allegations were only about one single spray can. So the

1 court said, "Well, you didn't tell me about these other
2 spray cans. They're totally separate products. I'm going
3 to dismiss the nine spray cans from the case."
4 Actually, what we have here is a suite of products. We've
5 identified infringement with respect to all of the products
6 across the seven accused patents. And in fact what the
7 Court does when it has exemplary --
8 THE COURT: I'm just trying to -- for example,
9 given your example, I don't have Excel. I have some Microsoft
10 products but not others.
11 MS. SPIETH: Right.
12 THE COURT: So they're separate patents. It may
13 be that you can get a bundle. If you buy them in a certain
14 way, maybe it's cheaper or something, but they're separate
15 products. And I do get your point; you don't have to go
16 limitation by limitation. I don't know whether the Federal
17 Circuit has read *Iqbal*, but at least right now, you don't
18 have to go limitation by limitation. So I don't know that I
19 can say, for example, the example that was just given:
20 Well, there's enough in the liver/aorta distinction to get
21 you infringement, but that's going to get you infringement
22 on all the others in the suite.
23 MS. SPIETH: Well, there is guidance in the case
24 law, and it's cited in our brief. It's the *Windy City* case,
25 and then there's an *ASUSTek* case which can give you guidance

that exemplary infringement allegations from overlapping products are sufficient at this stage. And I think what you have to do is, you have to do it --

THE COURT: You're saying they're all the same -- it's different than Microsoft then. Those aren't overlapping products. You're saying these are overlapping. It's just like having, oh, I don't know, that you only buy them in a suite. Is that what you're saying?

MS. SPIETH: That is our understanding of how they're sold is in a suite of products.

THE COURT: And where does it say that here in the complaint?

MS. SPIETH: It's in Paragraph 5 of the complaint says it's a suite of products.

THE COURT: Okay, let me get there.

(Pause.)

MS. SPIETH: And to be clear, your Honor, I don't know that MIM would sell their products to us.

THE COURT: So you here say "Software products like Contour Protege, MIM's SurePlan, Lesion, the infringing products." So you're separating them out.

MS. SPIETH: So let me also point you to Paragraph 52 which discusses that the products, those four infringing products, the Contour ProtegeAI, MIM's SurePlan MRT, LesionID, and LesionID Pro -- I'm reading from

1 Paragraph 52 which is on Page 16 of the Second Amended
2 Complaint -- "are part of MIM's broader software suite."
3 THE COURT: Yes, but "Infringing Products" is
4 capitalized, and then you parenthetical it, which makes me
5 feel quite clear that each one of them is a separate
6 product. You're defining them by the parenthetical.
7 MS. SPIETH: And perhaps, you know, this will
8 become more clear in the infringement contention stage of
9 the case, which is coming up in a few weeks. And that's the
10 reason why the burden is not as high at the complaint stage
11 as it is at the infringement contention stage of the case.
12 THE COURT: Well, can I just ask you this: Assuming
13 for a minute you've defined each product as four separate
14 products, I don't think that's an unfair reading of this
15 complaint, and so what I'm trying to understand is, have you
16 alleged that it's not all for one or one for all, and you
17 don't have to go limitation by limitation? But as it was
18 just shown on the one that we talked about, there may be
19 enough with respect to one product; but are you just sort of
20 assuming that because you got it on one, you got it on all
21 four?
22 MS. SPIETH: So, again, the complaint is laying
23 out exemplary allegations of infringement that are designed
24 to meet the *Iqbal* standard, which is to put the defendant
25 reasonably on notice of the claims and create a plausible

entitlement to relief.

THE COURT: I get it. So you did that on one.

MS. SPIETH: But I want to point out to you that I think we've been a little quick in saying what's accused here. LesionID is mentioned for the '508 patent, but there's also allegations involving Contour ProtegeAI and MIM's SurePlan MRT, which I can point the Court to --

THE COURT: Excuse me. With respect to which patents?

MS. SPIETH: The '508. So if I can just point you to Paragraph 97, which is talking about the second limitation of Claim 1 of the '508.

THE COURT: Wait. You're going faster than I can go because I have to get there. You know it by heart and I really don't. I'm learning. So, all right.

MS. SPIETH: Sure. So Page 50, which is part of Paragraph 97, it quotes from the 510K application, which is an FDA regulatory application for MIM's Contour ProtegeAI product. So, in other words, this is explaining how MIM's Contour ProtegeAI product meets the limitation of the '508 patent. And then continuing --

THE COURT: I don't understand that.

MS. SPIETH: Yes, continuing on, just so the record is complete, Paragraph 99 is also about Claim 1 of the '508 patent, and it's describing how MIM's SurePlan MRT

meets the limitation of the '508 patent. There's a quote from MIM's marketing material for MIM SurePlan MRT.

THE COURT: Where does it talk about aortas and livers?

MS. SPIETH: So, again, all of these things work together. They are designed to work together for MIM's customers. So MIM can't avoid infringement by saying, "Oh, well, we only have one piece of software, one piece of the piece of software that does the liver piece. We have one piece of the software that does the aorta piece, and we have another piece of the software that puts all the pieces together and makes the 3D visualization." They can't get out of infringement because they call their products by different tradenames.

THE COURT: Well, yes, they can if they -- I mean, you have to plead something with respect to each product and each patent, and it's very hard to read. Let me just put it this way: Usually, in most patent cases, they claim one product, and then they claim which patent, and so I'm just having a hard time with this.

But, in any event, I will read your brief, and I will go through each one and see where you've cited to because it's all about going back to the complaint.

MS. SPIETH: And I just point the Court to the *ASUSTek* and the *Windy City* cases because I think they

provide good guidance about exemplary allegations of infringement where there's multiple products that are infringed.

THE COURT: But don't you just win on that exemplary product?

MS. SPIETH: Yes, yes. In fact, we're being held to a higher standard because as everyone on this hearing agrees, there is no obligation to plead infringement element by element. So I think what's happening here is that the plaintiffs are being punished for clearing the bar too high.

THE COURT: Well, I don't know if that's true. In any event, I'm not going to go through each one of them now. I think, unfortunately, you've charged so many patents, it is making it a burden on the Court to sit and sift through all of them.

MS. SPIETH: Can I respond --

THE COURT: I'm going to assume for a minute that you've been able to -- I'll read the complaint, and I'll read your motion in opposition to the motion to dismiss. I am not going to go back into the literature. That's what I'm not going to do. But it may be that I -- you've defined accused products as the four of them, and so I'm going to look at them. And if it doesn't work, it will be without prejudice to your amending. So that's how it will go. And I can't really go through each one of them here now. We're

already close to noon. So if you're sensing some -- I will look through every -- in your motion to dismiss, your opposition to the motion to dismiss, I will go through each claim. And I will not micromanage it, I will not go limitation by limitation, but you at the very least have to make it plausible, based on what I've read. So that's what I'm going to do.

Can I just have everyone back on now. I know you were talking in terms of -- and maybe go off the record here for settlement discussions.

(Discussion off the record.)

THE COURT: All right, thank you very much, and have a nice lunch.

MS. PIROZOLLO: Thank you, your Honor.

MR. BUNIS: Thank you, your Honor.

MS. SPIETH: Thank you, your Honor.

MS. BUTLER: Thank you, your Honor.

THE COURT: Bye-bye.

(Adjourned, 12:05 p.m.)

1 C E R T I F I C A T E

2

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UNITED STATES DISTRICT COURT)
4 DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

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7 I, Lee A. Marzilli, Official Federal Court
8 Reporter, do hereby certify that the foregoing transcript,
9 Pages 1 through 66 inclusive, was recorded by me
10 stenographically at the time and place aforesaid in CA
11 No. 24-10437-PBS, Progenics Pharmaceutcals, Inc., et al v.
12 MIM Software Inc., and thereafter by me reduced to
13 typewriting and is a true and accurate record of the
14 proceedings.
15 Dated this 5th day of November, 2024.

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19

20 /s/ Lee A. Marzilli
_____
21 LEE A. MARZILLI, CRR
OFFICIAL COURT REPORTER

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