

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUSION ORTHOPEDICS, LLC,

Petitioner

v.

EXTREMITY MEDICAL, LLC,

Patent Owner.

IPR2023-00894
Patent 11,298,166 B2

Record of Oral Hearing
Held: September 13, 2024

Before ROBERT A. POLLOCK, TIMOTHY G. MAJORS, and
JAMIE T. WISZ, *Administrative Patent Judges*.

APPEARANCES:

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The above-entitled matter came on for hearing via video on Friday, September 13, 2024, commencing at 1:00 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P R O C E E D I N G S

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2 JUDGE POLLOCK: Good afternoon. This is the final hearing in
3 IPR2023-00894, which relates to U.S. Patent Number 11,298,166.
4 Petitioner is Fusion Orthopedics, LLC, Patent Owner is Extremity Medical,
5 LLC. This hearing is open to the public and a full transcript of the hearing
6 will be made part of the record. I'm Judge Pollock. With me are Judges
7 Majors and Wisz.

8 Counsel for Petitioner Fusion Orthopedics, do kindly identify
9 yourself and your colleagues.

10 MS. BRINKERHOFF: Yes. Good morning, Your Honors. I'm
11 Jennifer Brinkerhoff, lead counsel for Petitioner Fusion Orthopedics, and my
12 co-counsel is Mr. Scott Kamholz.

13 JUDGE POLLOCK: Good afternoon. Also for Patent Owner
14 Extremity Medical, would you kindly identify yourself and your colleagues?

15 MR. BAPNA: Good afternoon, Your Honors. My name is Abhi
16 Bapna, and I'm the only one here today for Patent Owner.

17 JUDGE POLLOCK: All right. Our July 8 order setting oral
18 argument allotted each side 60 minutes to present its case. We subsequently
19 granted Petitioner's request that Ms. Brinkerhoff be permitted to participate
20 in the oral hearing as a LEAP practitioner and, accordingly, allotted
21 Petitioner an additional 15 minutes of argument time.

22 We have before us the claims originally challenged in the petition,
23 Patent Owner's contingent revised motion to amend and Patent Owner's
24 motion to exclude. Both parties are welcome to address all or any subset of
25 the issues before us and in the order they prefer.

1 Counsel for Petitioner, would you like to reserve any of your 75
2 minutes for rebuttal?

3 MS. BRINKERHOFF: Yes, Your Honor, we'd like to reserve 15
4 minutes for rebuttal.

5 JUDGE POLLOCK: Counsel for Patent Owner, you may have the
6 last word today if you wish. Would you like to reserve any of your 60
7 minutes?

8 MR. BAPNA: Yes, Your Honor, I'd like to reserve 10 minutes,
9 please.

10 JUDGE POLLOCK: Very good. I'm looking forward to the parties'
11 presentations today, but I'd like to cover just a few things before we begin.

12 To maintain clarity of the record please identify yourself each time
13 you speak. We have access to the entire record, including demonstratives.
14 When referring to each demonstrative paper or exhibit, please do so by slide
15 or page number and allow us time to locate it.

16 To minimize electronic interference and reduce strain on our
17 bandwidth, please mute your microphone when not speaking. Should you
18 wish to lodge an objection, please do not do so while opposing counsel is
19 speaking. To the extent there are objections to today's argument or
20 demonstratives, we will take them under advisement and address them in our
21 final decision to the extent necessary.

22 At the conclusion of the hearing, I ask the attorneys to stay on the
23 line in case the court reporter has any questions.

24 Petitioner will go first as it bears the burden of showing
25 unpatentability of the challenged claims. Counsel, you may begin.

1 MS. BRINKERHOFF: Thank you, Your Honor. Mr. Kamholz will
2 be presenting the case regarding the challenged claims for which the Board
3 instituted trial. And I will be addressing the revised motion to amend.

4 JUDGE POLLOCK: Very good. Thank you.

5 MR. KAMHOLZ: Good afternoon. Can everyone hear me? Can
6 anyone hear me?

7 MS. BRINKERHOFF: I can hear Mr. Kamholz, but I can't hear
8 anybody else.

9 MR. KAMHOLZ: Judge Pollock, I saw your lips moving, but I did
10 not hear you speak.

11 JUDGE POLLOCK: I'm sorry, I'm having trouble with the mute
12 button. Please, please go ahead. We can hear you.

13 MR. KAMHOLZ: Thank you. Good afternoon. I am Scott
14 Kamholz, backup counsel for Petitioner, and I'll be presenting the case in
15 chief for Petitioner.

16 On slide 1, we present an outline of the issues Petitioner will address
17 today. Petitioner has organized its presentation to address a series of what it
18 considers to be the dispositive issues in this case. First, I will address the
19 construction of the claim term "bore," which is central to the anticipation
20 and obviousness challenges based on *Cognet*. Then I will apply that claim
21 construction to the *Cognet* challenges. Petitioner intends to stand on its
22 briefs as to construction of the term "at a terminal end," and the challenge is
23 based on *Simon*. Ms. Brinkerhoff will then take up the revised motion to
24 amend and discuss Petitioner's prior art challenges to the patentability of the
25 proposed claims.

1 Slide 2 addresses construction of the claim term "bore". I think the
2 history surrounding the construction of bore is well known to the Board and
3 parties. The Board construed bore as not excluding, quote, "holes or
4 passages having tapered or stepped longitudinal cross-sections." This was
5 on page 13 of the Institution Decision. The Board invited the parties to
6 develop the record on the construction of bore.

7 The next substantive paper filed after the Institution Decision was, of
8 course, the Patent Owner response, which is paper 22. In its response at
9 pages 17 to 18, Patent Owner argued that the Board's construction is
10 unreasonable because in Patent Owner's view, the term "bore" encompasses
11 only regular, that is, precisely, cylindrical holes. Patent Owner argued in the
12 alternative that bore could encompass tapered holes, but not holes with
13 stepped longitudinal cross-sections. That's at the Patent Owner's response,
14 pages 15 and 18.

15 But Patent Owner did not support its arguments with very much
16 evidence. Patent Owner did not identify anything in the specification that
17 justifies the exclusion of whole -- with stepped longitudinal cross-sections.
18 In fact, the word "bore" does not even occur anywhere in the '166 patent
19 specification. Nor did Patent Owner submit any prior art uses of the term
20 "bore" consistent with either of its preferred constructions. Instead, they
21 cited expert testimony, which in turn was based on one patent reference, we
22 call it the '299 patent, exhibit 2017, which actually post dates the '166 patent
23 effective filing date.

24 In its reply, paper 28, Petitioner showed that the Board's construction
25 is on all fours with how the term "bore" is used in a wide swath of prior art.
26 Petitioner identified numerous examples of the phrase "the bore" in the prior

1 art -- in actual prior art to the '166 patent that are used to describe a void
2 with stepped longitudinal cross-sections. They are described with annotated
3 drawings at pages 3 to 7 of the reply. Some of that art is shown here on slide
4 2, with relevant portions of the bores annotated in blue and red to show their
5 various stepped longitudinal cross-sections. I don't think we need to go
6 through those. There are several others addressed as well in Petitioner's
7 reply, culminating in the primary reference that is *Cognet*, exhibit 1004,
8 which describes its stepped longitudinal cross-section bore as V tunnel 2 at
9 page 4, line 20.

10 In slide 3 it shows that even Patent Owner's own expert, Dr. Eric
11 Ledet, used the phrase "a tunnel," in this case a transosseous tunnel, in his
12 own prior art published work to refer to the hole made to receive a bone
13 implant having stepped longitudinal cross sections. This is discussed on
14 reply page 8 with reference to exhibit 1023, a paper Dr. Ledet published in
15 2006.

16 And even exhibit 2017, the '299 patent, the one and only piece of
17 documentary evidence Patent Owner cites in support of its exclusionary
18 Board construction, exhibit 2017 shows a bore having stepped longitudinal
19 cross-sections made by a single reamer that is rotated to cut the hole. This is
20 discussed on page 7 of the Petitioner reply.

21 JUDGE POLLOCK: Mr. Kamholz, excuse me. On slide -- your slide
22 3, you're talking about Dr. Ledet's description of a transosseous tunnel?

23 MR. KAMHOLZ: Yes.

24 JUDGE POLLOCK: Can you point out a little more clearly how this
25 thing is a step -- has a step aspect? I'm not seeing it.

1 MR. KAMHOLZ: Sure. Let me turn on the pen if I may. You'll see
2 that there is a metallic piece here and it steps in here. Forgive my poor
3 freehand drawing. There's a better picture of this implant in the reply brief.
4 And you can see about in the middle of the figure there is a step down in the
5 diameter of the implant.

6 JUDGE POLLOCK: All right. Thank you very much.

7 MR. KAMHOLZ: Sure. Turn off the pen. On slide 4, perhaps the
8 most telling piece of prior art in the entire case on the proper construction of
9 bore is the *Small* reference exhibit 2025. This was an exhibit submitted by
10 Patent Owner in its surreply, which describes a surgical screw having axial
11 bore 125, which "extends through the entire length of the screw," as shown
12 in the annotation of this patent reference on slide 4 and in Petitioner's sur-
13 surreply. That's paper 50 at page 1. *Small* axial bore 125 is made up of
14 multiple steps longitudinal cross-sections annotated here in multiple colors.

15 The evidence marshalled by both Petitioner and Patent Owner
16 clearly shows that the prior art contemplates the use of the term "bore" to
17 describe precisely the stepped longitudinal cross-section structures included
18 by the Board in its construction of bore. And another reference Patent
19 Owner cites, exhibit 2035 to Grafton, reproduced here on the right side of
20 slide 4 in annotated form, shows that the prior art described stepped
21 longitudinal cross-sections as "tapers". Recall that Patent Owner has argued
22 that the term "bore" may encompass tapers. The Patent Owner does not
23 explain how there is any meaningful difference between tapered bores and
24 bores having stepped longitudinal cross-sections in light of its own Grafton
25 reference, which ties together tapers and steps.

1 On slide 6 we now turn to anticipation by *Cognet*. Patent Owner's
2 argument, Patent Owner's sole argument, against *Cognet* is that *Cognet* does
3 not disclose one bore extending from the first aperture to the second
4 aperture, but instead has two bores, an upper bore and the lower bore, as
5 they argued in their preliminary response, or a counter bore and a bore, as
6 they express it in their full Patent Owner response. The Board did not find
7 this argument persuasive when instituting the proceeding. Yet Patent
8 Owner, despite the Board's invitation to develop the construction of the term
9 "bore" has done little to defend its argument. To the contrary, it cited even
10 more evidence to bolster the Board's construction that bore can encompass
11 stepped longitudinal cross-sections. I refer to Small exhibit 2025, Grafton
12 exhibit 2035, and the '299 patent exhibit 2017.

13 On slide 7, as I mentioned earlier, Patent Owner's sole argument
14 against *Cognet* is that it discloses two distinct bores, a bore and a
15 counterbore, that are joined up in order to extend from the first aperture to
16 the second aperture. So Patent Owner does not dispute that a void extends in
17 *Cognet* from one aperture to the other. Instead, Patent Owner disputes what
18 names to call different parts of that tunnel. They call the wider part the
19 counterbore and the narrower part the bore.

20 But as Petitioner pointed out at reply page 17, Patent Owner's
21 argument amounts to mere verbal fencing. *Cognet* doesn't name different
22 parts of the void different names. *Cognet* just calls the whole thing "the
23 tunnel". That's exhibit 1004, page 4 at line 20.

24 Petitioner also cites numerous pieces of prior art that describe similar
25 voids to bores that include or have a counterbore. A couple of examples are
26 presented on slide 7, *Laps*, exhibit 1028, describing a bore 16 that includes a

1 counterbore; and *Martinez*, exhibit 1029, that describes a bore that has a
2 counterbore. In this case, the counterbore and bore are shown in blue and
3 red, respectively.

4 On slide 8, Petitioner also came forward with evidence of another
5 way the prior art makes clear that a bore and its counterbore form one
6 structure. That is the combination is referred to in the prior art as a
7 counterbored bore. This is seen, for example, in *Seo*, exhibit 1031, in the
8 middle of slide 8; and in *Exner*, exhibit 1032, as shown on the right side of
9 slide 8. Even Patent Owner's expert Dr. Ledet in one of his own patents
10 describes an aperture or a hole as being "counterbored," as can be seen
11 toward the right on slide -- I'm sorry, to the left on slide 8, which is taken
12 from exhibit 1022.

13 JUDGE POLLOCK: Mr. Kamholz, I'm sorry, I've looked at this
14 Ledet picture and is the only point you're making is that the word
15 "counterbore aperture" was used or is there something from the picture itself
16 we're supposed to take?

17 MR. KAMHOLZ: There's really nothing in the picture you're
18 supposed to take except the identification of the holes. That number is used
19 in the specification to refer to them as being counterbored. But yes, the
20 illustration doesn't really make any point in that direction. I apologize if
21 that's caused confusion. But column 29, lines 3 to 5 of exhibit 1022 clearly
22 describe those holes as counterbored apertures.

23 All of this evidence, *Laps*, *Martinez*, *Seo*, *Exner*, Dr. Ledet,
24 demonstrates that the Board's construction is correct in all respects and is
25 grounded in a significant body of evidence in the record. The evidence also
26 demonstrates the Patent Owner's argument is superficial because it dwells on

1 names rather than on structures. Anticipation is not, of course, an *ipsis*
2 *verbis* test. It's a structure test. *Cognet* discloses the structure recited in
3 claim 1 of the '166 patent. The labels Patent Owner tries to attach to parts of
4 *Cognet's* tunnel do not change that fact.

5 On slide 9, I will now address an argument directed specifically to
6 claim 3. Claim 3 requires that "the exterior surface of the head portion of
7 the first member abuts the interior surface of the first bore at the first
8 aperture." The issue is whether *Cognet* screw head abuts at the first
9 aperture. The Patent Owner argues that Petitioner has not shown that
10 *Cognet* discloses this relationship. Patent Owner says that Petitioner
11 identified the first aperture as lying on *Cognet's* surface, that is at the blue
12 arrow in the annotated *Cognet* figure on the left side of slide 9, but that the
13 abutment instead takes place at the green arrows in that annotated figure.

14 Patent Owner complains that Petitioner is trying to have it both
15 ways, that the aperture is at the surface for the analysis of claim 1, but at the
16 deep location for the analysis of claim 3. Patent Owner makes this argument
17 at pages 26 to 34 of their response, but as Patent Owner -- sorry, as
18 Petitioner explained in its reply as well as in the preliminary reply, if there's
19 any confusion here about the location of the first aperture, it was created by
20 Patent Owner in how it conflated the terms "bore" and "aperture".

21 I start by noting that the word "bore" does not occur -- does not occur
22 -- anywhere in the specification of the '166 patent. It appears only in the
23 claims. Now, during prosecution of the parent case, the '680 application,
24 Patent Owner presented their claims that also included the term "bore". And
25 it argued during prosecution of the '680 patent application that the recited
26 bore extends, and I quote "along a third axis 1102 from the first aperture

1 1130 to a second aperture on an exterior surface 1135," unquote. That is
2 from the '680 prosecution history, which is exhibit 1015, page 109, lines 11
3 to 13. Patent Owner there is describing figure 11, which is shown here on
4 slide 9 in annotated form on the right side.

5 But that description I just quoted of how the bore traverses the third
6 member is essentially the same as how the '166 patent describes the aperture
7 in the '166 patent specification. That's exhibit 1001, column 9, lines 46
8 through 49. Patent Owner states that tapered aperture 1130, and I quote,
9 "traverses tapered portion 1110 along axis 1102, which causes tapered
10 aperture 1130 to emanate from surface 1135," unquote. Thus, Patent Owner
11 has used the words "aperture" and "bore" to refer to the same structure, a
12 void penetrating all the way through the third member.

13 So, yes, the first aperture is at the surface, and it's also deep, just as
14 Patent Owner said in the '166 patent that the aperture traverses element
15 1110. Petitioner is not being inconsistent when it argues that *Cognet's*
16 abutment is at the first aperture because by Patent Owner's own usage of the
17 term "aperture," that structure can be deep. You can see that right here in
18 figure 11, as shown on slide 9. Patent Owner positioned aperture 1130 deep
19 to the surface, just as *Cognet's* abutment is deep to the surface.

20 And I didn't discuss it today, but recall the Board's construction of
21 "at a terminal end," which made clear that the aperture need not be at the
22 very end, but could simply be near the end. Aperture 1130 is near the end.
23 Patent owner has not disputed that *Cognet's* abutment is at least near the end.

24 And slide 10. I would also just like to note that Patent Owner has
25 continued to maintain inconsistent positions on the location of the first
26 aperture and has even aggravated the inconsistency in its surreply, which is

1 paper 43. At the bottom of slide 10 is another excerpt from the '680
2 prosecution history in which the Patent Owner stated on the record that the
3 first aperture has the element number 1130 and is at a terminal end 1120.
4 This is exhibit 1015, page 109, lines 10 to 11.

5 But in Patent Owner's surreply, that's paper 43 at page 14, which was
6 Patent Owner's last statement on the merits of the case in chief, Patent
7 Owner now says that the first aperture is not element 1130. Rather, element
8 1130 is now some other structure that is, quote, "below the first aperture,"
9 unquote. Patent Owner just continues to play games with words, just as it
10 did for the construction of bore.

11 The solution in situations like this where Patent Owner has said one
12 thing to obtain the patent and another thing to defend its patent is to toll the
13 inconsistency against the Patent Owner. They can't have it both ways.
14 Patent Owner has said that the aperture can be at the surface. Patent Owner
15 has said the aperture can be deep. Petitioner is simply holding Patent Owner
16 to its word. For these reasons, Patent Owner has shown *Cognet* anticipates
17 claim 1 and also anticipates claim 3.

18 And now slide 11. Petitioner addresses anticipation of claim 4 by
19 *Cognet*. The issue here is whether *Cognet* discloses its screw head as having
20 a "torque transmitting aperture". Petitioner submitted expert testimony that
21 a person of ordinary skill would assume that *Cognet* discloses this feature on
22 the basis that almost all screws have them in order to allow them to be
23 turned. Patent Owner argues that almost isn't enough to show anticipation,
24 but this argument misses the point because it's not considering the
25 underlying evidence. The underlying evidence of Petitioner's expert is that

1 the person having ordinary skill would have assumed this feature to be
2 present in its near universal ubiquity.

3 Patent Owner does not challenge this evidence. I want to emphasize
4 that Patent Owner does not challenge the accuracy of that evidence. Patent
5 Owner does not dispute Mr. Dominguez' testimony that the person having
6 ordinary skill would have assumed the feature to be present. Mr.
7 Dominguez testified further that several other aspects of *Cognet's* disclosure
8 indicate that *Cognet's* screw has a torque transmitting aperture. In particular,
9 he based this on the indications in *Cognet* that the screw head does not have
10 any sides to it. As shown in the center and right side portions of slide 11,
11 Mr. Dominguez reaches this conclusion from his observation that *Cognet's*
12 illustration of the screw includes surface features such as the screw threads
13 and the head lip, but does not include any surface features such as lines in
14 the screw head that would indicate the presence of sides.

15 Mr. Dominguez also notes that *Cognet* describes the head as having
16 a diameter, a term that, in Mr. Dominguez's opinion, has meaning only in the
17 context of a circular shape. Patent Owner does not dispute this testimony
18 either. The consequence of *Cognet* having a circular head is that it must
19 have a torque transmitting aperture, as Mr. Dominguez testifies, because
20 there are no sides to the head to grip with, say, a wrench to twist it. Mr.
21 Dominguez testifies and Patent Owner again does not dispute that the only
22 way for a roundhead screw to be driven in is by way of a torque transmitting
23 aperture, and that testimony is in exhibit 1018, paragraph 49.

24 JUDGE POLLOCK: Mr. Kamholz, I don't mean to be flip with this
25 question, but how do we exclude the possibility this isn't intended to be
26 hammered with a mallet like a spike?

1 MR. KAMHOLZ: I think the screw threads make it very clear that it's
2 not intended to be hammered because then the screws would just strip
3 through the bone. And probably -- I don't want to inject expert testimony
4 here, but would probably --

5 JUDGE POLLOCK: Do you have expert testimony that screws are
6 not hammered? It's hard -- I mean, seriously, I'm not trying to be flip, I'm
7 just trying to exclude a vague idea I had.

8 MR. KAMHOLZ: I am not aware of anything that says screws must
9 be screwed and not hammered. I can look for that and get back to you later
10 in the hearing if you'd like, but at the moment I'm not aware of any.

11 On slide 12, Petitioner addresses obviousness of dependent claims 4,
12 8, 10, 11, 14, and 15 over *Cognet* and *Brumfield*. These claims all recite, in
13 Petitioner's view, conventional screw features such as the torque transmitting
14 aperture, self-tapping ends, and a tapered head. These features are also
15 conventional screw features in the opinion of Mr. Dominguez.

16 Petitioner argued that these conventional screw features are well
17 known in the art, as exemplified by *Brumfield*, and argued that their
18 inclusion in *Cognet* would involve the mere substitution of one element for
19 another known in the field and yields a predictable result. That's on pages
20 25 to 26 of the reply.

21 Patent Owner does not dispute this argument and instead makes
22 bodily incorporation arguments that address the references individually than
23 rather as a combination. That's on their surreply at pages 17 to 18.

24 If there are no questions about the case in chief, I'd like to turn the
25 presentation over to Ms. Brinkerhoff to address the revised Motion to
26 Amend.

1 JUDGE POLLOCK: Judge Majors, any questions? Judge Wisz?
2 Very good.

3 MR. KAMHOLZ: Thank you.

4 JUDGE POLLOCK: Ms. Brinkerhoff, you have the floor.

5 MS. BRINKERHOFF: I apologize. I shared my screen first and then
6 I can't unmute while sharing the screen. Let me try that again.

7 Okay. Slide 13 shows the amendment in the revised Motion to
8 Amend, which add the limitations highlighted here, which requires substitute
9 claims 16 and 27 to have the first aperture on a portion of a first exterior
10 surface and on a portion of a second exterior surface of the third member.
11 Claims 20 and 28 further limit the surfaces to be the top and side surfaces of
12 the third member. Our arguments will focus on the top and side exterior
13 surfaces because of claims 20 and 28.

14 On slide 14 *Mazur* is an anticipatory reference to the substitute claim
15 because figure 16 embodiment has all the features recited in the amended
16 claims. Although figure 16 illustrates a curved hub, *Mazur* discloses that the
17 curved hub can be straight in paragraph 94, which Patent Owner does not
18 dispute. Patent Owner does argue that the disclosure -- that the curved head
19 can be straight does not apply to figure 16 because paragraph 94 is referring
20 to the above combinations. That's on reply, page 2.

21 JUDGE POLLOCK: Ms. Brinkerhoff?

22 MS. BRINKERHOFF: Yes.

23 JUDGE POLLOCK: Would you unpack a little bit why it's important
24 to your case that this hub may be straight?

25 MS. BRINKERHOFF: Yes, because the hub may be straight, then
26 figure 16 alone displays all of the claim limitations.

1 JUDGE POLLOCK: I'm sorry, I didn't quite catch that. Would you --
2 why is it required to be straight? Or why are you talking about a straight
3 hub?

4 MS. BRINKERHOFF: The claims require that the third member be
5 straight.

6 JUDGE POLLOCK: I'm sorry, the claims 20 and 28 require a straight
7 third member?

8 MS. BRINKERHOFF: I'm sorry. So claims 16 and 27.

9 JUDGE POLLOCK: Ah, okay. Thank you.

10 MS. BRINKERHOFF: You're welcome. Okay. Sorry, give me one
11 second. Okay. So their argument is unreasonable for two reasons. The first
12 reason is because figure 16 is mentioned above paragraph 94 in paragraph
13 55. Another reason is figure 16 is the same as or similar to figure 11. Patent
14 Owner's expert Dr. Ledet acknowledges that figure 16 is the same as figures
15 12G through I, which show a curved hub that is the same as or similar to
16 figure 11. This testimony is located at exhibit 2037, paragraph 34.

17 Figures 11, 12, and 16 are reproduced here on slide 14 on the right.
18 It is immediately apparent that they all show the same or similar curved hubs
19 consistent with *Mazur's* disclosure. Since figure 16 is a curved hub that is
20 the same as or similar to figure 11, and *Mazur* discloses that figure 11 is a
21 curved hub that can be straight, it follows that figure 16 is also a curved hub
22 that can be straight. And a straight figure 16 discloses all of the substitute
23 claim limitations.

24 Petitioner also challenges the substitute claims with obviousness
25 over *Mazur*. Paragraph 94 at the very least suggests to a person of ordinary
26 skill to modify figure 16 to have a straight hub and describes how to

1 implement a straight hub embodiment with a reasonable expectation of
2 success.

3 On slide 15, the second issue Patent Owner raises is whether *Mazur's*
4 side notch can form part of the aperture. Patent Owner contends that the
5 notch cannot be part of the aperture because the notch does not participate in
6 fulfilling the purpose of the aperture, which is to be an opening for a first
7 member to enter the third member and a surface of the bore for the first
8 member to abut and rest on. However, the claim does not recite any
9 purposes that the aperture must fulfill, so *Mazur* is not required to disclose
10 them.

11 Patent Owner argues that *Mazur's* screw does not engage with the
12 notch when entering the third member and abutting the bore surface. Patent
13 Owner does not dispute that *Mazur's* screw does enter the third member
14 through the hub opening and does abut the bore surface. So Patent Owner's
15 argument amounts to asserting that all portions of the aperture must
16 participate in receiving the first member and providing abutment, but this
17 cannot be the case. Patent Owner's showing a support for the proposed
18 claim amendments, shows an aperture, a significant portion of which is not
19 involved in receiving this group. I'm referring to the figure at the bottom left
20 on the slide 13 -- or sorry, slide 15 taken from the revised Motion to Amend.
21 The aperture is outlined in green and the top portion is not involved in
22 receiving the screw.

23 Slide 16. Petitioner's next challenge to the proposed claims is
24 obviousness over *Cognet* and *Zhang*. Patent Owner critiques this challenge
25 on two grounds. One of those grounds is similar to the Patent Owner's

1 arguments that *Mazur's* notch is not fulfilling the purpose of the aperture.
2 That argument has no basis in the claim for the reasons already discussed.

3 The second issue Patent Owner raises here is whether *Zhang's* nail
4 tail discloses separate top and side surfaces. The Patent Owner's argument is
5 not responsive to the obviousness challenge as Petitioner framed it.
6 Petitioner argued that *Cognet* discloses the use of an ancillary, which is the
7 device that is keyed to the top of the nail in such a way that would allow
8 force and torque applied to the ancillary being transmitted to the nail.

9 JUDGE POLLOCK: I'm sorry, what is an ancillary? Are we talking
10 screwdriver?

11 MS. BRINKERHOFF: It can be a screwdriver, yes.

12 JUDGE POLLOCK: Okay.

13 MS. BRINKERHOFF: Petitioner presented evidence that a common
14 way to key an ancillary is a slot in the top structure, as shown in *Brumfield*,
15 *Marcus*, and *Chandran*. *Cognet's* disclosure of an ancillary suggests that
16 *Cognet* could have a similar thought. *Zhang* also has this thought and has it
17 for the same purpose, to receive an ancillary. Petitioner cited *Zhang* to show
18 that the result of providing a slot in the top of the nail already having a screw
19 bore would be an aperture opening to both the top and side surfaces of the
20 nail.

21 *Zhang* is also evidence that a person of ordinary skill would have a
22 reasonable expectation of success with this structure, even with a bore
23 through the top surface of the nail. Instead, Patent Owner is attacking the
24 *Zhang* reference individually rather than the combination. Petitioner's
25 argument was that the inclusion of a slot on *Cognet's* nail top, as suggested
26 by *Cognet*, called to an ancillary, would have resulted in the recited first

1 aperture opening to the top and side. And Petitioner cited *Zhang* as evidence
2 that the person of ordinary skill would have known that that combination
3 was workable.

4 Patent Owner's focus on the precise structure of *Zhang* -- oh, sorry.
5 In any event, *Zhang* discloses a flat top portion as distinguished from a
6 curved side portion, as shown in the figure here. Even Patent Owner's
7 expert in his alternative models shows a flat top surface distinct from a
8 curved side portion.

9 To the extent Patent Owner argues that *Zhang* has a singular surface
10 that is not divided into top and side portions, the art of record contradicts
11 them. For example, *McKay* discloses number 80, as you can see here on the
12 bottom of slide 16 on the right, discloses number 80 having top surface 84
13 and end surface 83, which are smoothly continuous with one another and
14 which, when inserted into channel 71, form a uniform exterior surface.

15 Slide 17. Petitioner's next challenge --

16 JUDGE POLLOCK: Counsel? Counsel, could you back up a slide?
17 I'm trying to understand this picture here.

18 MS. BRINKERHOFF: Yes.

19 JUDGE POLLOCK: All right. The *McKay* -- well, *McKay*, we're not
20 looking at a sphere. We're looking at it more of a disk, is that correct?

21 MS. BRINKERHOFF: Yeah. It's not a sphere. That's correct.

22 JUDGE POLLOCK: That's right. Okay, thank you. Go ahead.

23 MS. BRINKERHOFF: Okay. Slide 17. Petitioner's next challenge to
24 the proposed claims is obviousness over *Cognet* and *Melkent* or *Gooch*.
25 Patent Owner argues that Mr. Dominguez's proposed modification to the
26 bore angle in *Cognet* risks penetrating the articular surface and harming the

1 patient. Patent Owner addresses this argument to both the combination of
2 *Cognet* with *Melkent* and *Cognet* with *Gooch*, but this is the only argument
3 Patent Owner raises with respect to the *Cognet-Melkent* combination. Patent
4 Owner does not address the *Melkent* reference on its merits at all.

5 Patent Owner's argument is nonresponsive to Petitioner's challenge
6 because it amounts to a bodily incorporation. Mr. Dominguez's angle
7 modification was presented for illustrative purposes only. Petitioner's
8 challenge was premised instead on the combination of *Cognet*'s instruction
9 to vary angles and dimensions as necessary and evidence from *Melkent* or
10 *Gooch* that a person of ordinary skill understood how to make these
11 variations and also that apertures could be on tops, sides, or both tops and
12 sides.

13 Patent Owner's argument is also in tension with its own definition of
14 a person having ordinary skill in the art. Patent Owner doesn't explain why
15 a person that is capable of performing various design tasks and that also has
16 an appreciation for the medical issues and concerns faced by a surgeon
17 would not have understood how to apply the teachings of *Melkent* or *Gooch*
18 to *Cognet* safely and effectively.

19 Patent Owner presents one further argument against the *Cognet-*
20 *Gooch* combination. Petitioner showed that *Gooch* discloses that its groove
21 can be inserted through the top, through the side, or through the top and side.
22 In particular, Petitioner showed that *Gooch*, figure 20, shows an insertion
23 through the top and side. Patent Owner argues that figure 20 does not
24 necessarily show a top and side insertion, but may instead be showing just
25 another view of a side insertion presented from a perspective that distorts the
26 true relationship between the screw and the anchor.

1 Patent Owner does not dispute that one of the two possible
2 interpretations of figure 20 is a top and side insertion. Patent Owner merely
3 argues that a top and side insertion or a side only insertion are equally
4 plausible interpretations. Patent Owner's side only interpretation is not
5 possible because it would mean that *Gooch* is introducing redundancy and
6 confusion for no reason. Figure 18 already shows a side only embodiment.
7 Showing it again from an angle that obscures this relationship serves no
8 purpose. It is more likely that the figure is what it appears to be, which is an
9 aperture on the top and side surfaces.

10 In any event, Patent Owner acknowledges that side only and both top
11 and side are the only plausible interpretations that a person of ordinary skill
12 would have appreciated from figure 20. Since by Patent Owner's own
13 acknowledgement, a person of ordinary skill would have at once envisaged
14 to these two possibilities, they are both disclosed and, therefore, *Gooch*
15 meets the limitation.

16 And we -- if there's no questions, then we yield our time.

17 JUDGE POLLOCK: Very good. You still have 36 minutes to go.
18 But on that, Mr. Bapna?

19 MR. BAPNA: Thank you, Your Honor. Are you able to hear me?

20 JUDGE POLLOCK: I can hear you.

21 MR. BAPNA: Okay. May I share my demonstratives, please?

22 JUDGE POLLOCK: Please do.

23 MR. BAPNA: Are you able to see the demonstrators now, Your
24 Honor?

25 JUDGE POLLOCK: We can see them.

1 MR. BAPNA: Thank you. Turning to slide 2, this slide shows all of
2 the topics that Patent Owner's demonstratives cover. In the interest of time,
3 I will not be able to cover every slide today, of course.

4 I start with claim construction, slide 5. The term "first aperture at a
5 terminal end" should be construed to exclude apertures along the shaft.
6 During prosecution while distinguishing the *Chang* prior art reference,
7 Patent Owner clearly and unmistakably disclaimed apertures that are
8 provided merely along the shaft of a nail. In *Chang's* figure, Patent Owner
9 distinguished through holes 101 and 102 as merely along the shaft of the nail
10 distinguished from the terminal end.

11 Slide 6. Petitioner's expert also admitted, with reference to *Chang's*
12 figure, that it is through hole 103 that is actually at the terminal end. Now,
13 the various prior art references Petitioner sites cannot overcome Patent
14 Owner's clear and unmistakable disclaimer or Petitioner's expert's admission
15 here.

16 JUDGE POLLOCK: Mr. Bapna, I'm really not grasping the
17 admission here. The expert says it's referring to the very top of the terminal
18 end. I'm not sure how that is specific to the tip. It's a little vague to me.
19 How much is the top?

20 MR. BAPNA: Yes, Your Honor, there's nothing in the '166 patent
21 that describes the terminal end as having depth. And here, when Petitioner's
22 expert was asked about his interpretation of figure 2 in *Chang*, he says bullet
23 103, I think he's referring to part 103 there in the figure, he says that's
24 referring to the very top of terminal end. I would represent that as the
25 terminal end of the nail. You know, as you can see, he did not allude to parts
26 101 or 102 when he was referring to the terminal end in this figure.

1 JUDGE POLLOCK: And did this expert affirmatively exclude 101 as
2 being at the terminal end?

3 MR. BAPNA: I don't believe he did that, Your Honor.

4 JUDGE POLLOCK: So things seem just a little vague here with this
5 testimony, but please continue.

6 MR. BAPNA: Thank you. Your Honor, as I was saying, the various
7 prior art references Petitioner cites cannot overcome the disclaimer and the
8 admission here. Thus, first aperture at a terminal end should be construed to
9 exclude apertures that pass through only the side of the shaft of the third
10 member.

11 Moving to the construction of bore, Patent Owner's expert opined
12 that a skilled artisan would understand the term "bore" does not include two
13 sections of a hole separated by a ledge or stepped longitudinal cross-
14 sections, as did exhibit 2012 at paragraph 41. And Petitioner's experts
15 opined that a bore is a cylindrical hole made by the spinning rotation of a
16 twist drill cutting tool. Thus, bore should be construed as a cylindrical hole
17 made by the spinning rotation of a twist drill cutting tool. That would be
18 consistent with both experts' opinions.

19 Alternatively, Patent Owner submits that the Board's preliminary
20 construction should be modified to be a cylindrical hole or passage made by
21 or as if by the turning or twisting movement of a tool, not excluding holes or
22 passages having tapered cross-sections.

23 JUDGE POLLOCK: Mr. Bapna?

24 MR. BAPNA: Yes, Your Honor.

25 JUDGE POLLOCK: Sorry, I'm having trouble with my mute
26 function. It occurs to me that the spinning rotation of a twist drill cutting

1 tool could cut a stepped hole if it were a stepped cutting tool, and I'm pretty
2 sure I saw one of those illustrated in Petitioner's papers. Would you address
3 that?

4 MR. BAPNA: Yes, Your Honor. Your Honor, Patent Owner -- well,
5 let me start with the '166 patent. First of all, in the '166 patent, there's no
6 disclosure of a stepped cross-section.

7 Secondly, Patent Owner's expert has opined that a skilled artisan
8 would not consider stepped longitudinal cross-sections to be included within
9 the definition of a bore. Patent Owner's expert has opined that that would be
10 considered a counterbore and a bore, two separate elements. And that's
11 based on his understanding of what a skilled artisan would consider to be a
12 bore.

13 JUDGE POLLOCK: All right. I'm sorry, before you go any farther
14 into bore, would you step back to "at the terminal end"? I understand the
15 construction from the District Court in a related case. Would you unpack
16 that a little bit for me? It seemed to me that the District Court seemed to
17 think that the "at the terminal end" was not just the very tip, but some
18 distance down the shaft. And I thought maybe you could address that.

19 MR. BAPNA: Yes, Your Honor, of course. So this is also covered on
20 -- in the footnote 2 in page 3 and 4 of Patent Owner's surreply. And the
21 District Court here merely held that the scope of Patent Owner's disclaimer
22 does not support construing the terminal end as the very tip. But the District
23 Court did not hold that there was no disclaimer to support excluding
24 apertures that passed only through the side of the shaft of the third member.

25 And so here, Your Honor, the issue is whether the terminal end
26 should be construed to include or exclude apertures that are merely along the

1 shaft. And the District Court's construction is consistent with Patent
2 Owner's position there.

3 JUDGE POLLOCK: What do you mean by "merely along the shaft"?

4 MR. BAPNA: Your Honor, the disclaimer here, looking again at slide
5 5, it points to holes 101 and 102, and not 103. As you can see, holes 101
6 and 102 are along the side exterior surface of the shaft of *Chang's* nail. And
7 that's in contrast to hole 103, which is at the top of the nail of *Chang's*
8 assembly. And so, Your Honor, "merely along the shaft" of the nail means
9 what it implies, it's the side exterior surface of the nail. If the aperture is
10 along just that side exterior surface, then it is not at the terminal end.

11 Going back to the construction of bore, slide 7. Now, the Patent
12 Owner cites several references where a bore is treated as distinct from
13 counterbore and those are exhibits 2024 to 2027. And the Patent Owner's
14 counsel discussed references that disclose particularized uses of the term
15 "bore". But those references are divorced from the teachings of the '166
16 patent and none of those references indicate that the term "bore" ordinarily
17 and customarily includes stepped longitudinal cross-sections.

18 Petitioner's counsel also cited exhibit 1023, which was Dr. Ledet's
19 journal article. And Petitioner argues there that Dr. Ledet describes a
20 transosseous tunnel. And when Judge Pollock asked counsel where in figure
21 3 of that article a stepped bore is shown, Counsel pointed to the bone screw
22 that is shown in the figure. But that's clearly wrong. Transosseous tunnel
23 refers to a tunnel in the bone as the bone screw is drilled through the bone.
24 And this is clear, Your Honor, because the article states, "A transosseous
25 tunnel formed through the sacrum across the L5-D1 disc space." That's on
26 page 330 of exhibit 1023.

1 So, therefore, transosseous tunnel does not refer to the bone screw
2 itself that counsel pointed to. It actually refers to the tunnel that is created in
3 the bone. And the figure, figure 3 of that exhibit, shows no stepped cross-
4 section in the bone tunnel itself.

5 Finally, Your Honors, Petitioner's expert actually doesn't ever opine
6 that the ordinary and customary usage of bore does include stepped
7 longitudinal cross-sections.

8 Slide 8, moving on. Petitioner fails to establish any ground of
9 unpatentability as to original claims 1 through 15.

10 Slide 9. This is a summary of Patent Owner's response to each of
11 Petitioner's seven grounds.

12 Slide 10, ground 1, "Petitioner fails to show anticipation by *Cognet*
13 for claims 1 through 7, 9, 12, and 13."

14 Slide 11. Regarding claims 1 and 12, *Cognet* does not disclose or
15 suggest a single bore that extends from the first aperture to a second
16 aperture. Instead, it discloses two bores: a larger diameter bore and a
17 smaller diameter bore. Thus, Petitioner fails to show, by preponderance of
18 the evidence, that *Cognet* anticipates claims 1 in 12.

19 Slide 15, moving to claims 3 and 7. Petitioner has taken inconsistent
20 positions as to the location of the first aperture for its anticipation analyses
21 for claim 1 on the one hand and claims 3 and 7 on the other. This figure
22 here on the slide is lifted right from the petition with Petitioner's own
23 annotations. And you can see that the first aperture is indicated with a blue
24 arrow at the very top of the bore. That's what Petitioner argues for claim 1.

25 So what does Petitioner do for claims 3 and 7? It instead indicates
26 the abutment that's required by claims 3 and 7 with green arrows at a

1 different location, that is, the shoulder between the larger and smaller
2 diameter bores.

3 Slide 16. This shows screenshots of Petitioner's expert confirming
4 that he's pointed to two different locations for the first aperture.

5 I'm going to go back to slide 15 here for the enlarged view of this
6 figure. You heard counsel Petitioner argue that, it was unclear, but he
7 seemed to imply or argue that the entire blue portion here can be the first
8 aperture. It can be where the blue arrow is pointing and it can be where the
9 green arrows are pointing. Well, first of all, Petitioner did not clearly make
10 this argument in the petition and, therefore, it is waived.

11 But second, if the first Petitioner -- excuse me, if the first aperture is
12 that entire blue area, that would raise other questions that Petitioner has not
13 addressed. For example, claim one requires the first four extending along a
14 first floor axis from the first aperture to a second aperture on the exterior
15 surface of the third member. So under Petitioner's new theory, where does
16 the bore exactly lie? Does it begin at the very top, including the blue area,
17 or does it begin at the shoulder? It's entirely unclear.

18 And in fact, Your Honor, when -- if you look at the petition, when
19 Petitioner was to point to where that bore lies -- excuse me, I'm going to
20 find. Okay. So if you look at slide 12, this is from the petition, page 17, for
21 the limitation that requires the bore to extend from the first aperture to the
22 second aperture, petitioner actually pointed to that entire area in orange right
23 there as the bore. And so it is clear that Petitioner is trying to have it both
24 ways when it comes to claims 3 and 7 as distinguished from claim 1.

25 Turning back to slide 17, this slide summarizes the at least three
26 independent reasons that Petitioner fails to show *Cognet* anticipates claims 3

1 and 7. First, if it were a Petitioner's intention to present one theory of
2 unpatentability for claim 1 and an alternative theory for claim 3 and 7, it was
3 required to expressly state so in the petition. Because it did not do so, that
4 alternative theory is waived under at least the Federal Circuit's *Netflix v.*
5 *DivX* decision.

6 Second, Petitioner cannot succeed on its challenge to dependent
7 claims 3 and 7 without also addressing how its alternative theory impacts the
8 patentability of independent claim 1 as required under at least the Federal
9 Circuit's *Microsoft v. IPA Technologies* decision. Again, Petitioner has not
10 addressed claim 1 under its alternative theory that the first aperture is
11 actually at the shoulder where the larger and smaller bores meet.

12 Third, Petitioner points to this statement on the slide here from -- this
13 statement by Patent Owner from the prosecution of a related patent, and
14 from this Petitioner analogizes that shoulder and *Cognet's* nail to element
15 1130 in figure 11 of the '166 patent, and that element 1130, if you recall, is
16 recessed from end 1120. And in this analogy, Petitioner fails to mention that
17 the '166 patent refers to element 1130 not as a first aperture, but as a tapered
18 aperture.

19 But more importantly, Petitioner's argument completely misses the
20 mark. Whether you look at element 1120 or 1130 in the '166 patent, there is
21 abutment of the nail head at both locations. Patent Owner cannot say the
22 same for the terminal or top end of *Cognet's* nail, where there is no abutment
23 between the screw and the nail.

24 Moving on to claim 4, slide 18, Petitioner can point to no express
25 disclosure in *Cognet* of a torque transmitting aperture. Now, Petitioner
26 appears to argue that *Cognet* inherently discloses a screw having a torque

1 transmitting aperture, but clearly fails to meet the exacting standard for
2 inherency under the *Trintec v. Top-U.S.A.* Federal Circuit decision. Again,
3 that decision holds that a mere possibility, or even a probability of a screw
4 having a torque transmitting aperture is not sufficient. Petitioner can assert
5 only that almost all screws have a torque transmitting aperture. Now, even if
6 this argument is assumed to be correct, it clearly fails to meet the standard.

7 Also, Patent Owner's expert has provided an opinion that there are
8 screws that don't have such an aperture. For example, a hex lag screw,
9 which a skilled artisan would understand could be used in an assembly such
10 as *Cognet's*.

11 JUDGE POLLOCK: Mr. Bapna, you're showing a hex lag screw
12 there. It looks like something from a construction site. Are we clear that
13 this is something you would put in a person's body?

14 MR. BAPNA: Your Honor, this is an exemplary photograph that
15 Petitioner's -- I'm sorry, Patent Owner's expert has provided to show the
16 structure of a hex lag screw and the fact that it doesn't have a torque
17 transmitting aperture. But to your point, this is not to be taken as exactly a
18 screw that would be placed into a human body.

19 JUDGE POLLOCK: Has your expert -- excuse me, has your expert
20 affirmed that hex lag screws are used in implantation in a person's body?

21 MR. BAPNA: Your Honor, yes, he has. If you look at this slide cites
22 exhibit 2012, paragraph 59, the expert does opine that a hex lag screw a
23 skilled artisan would understand could be used in *Cognet's* assembly. That's
24 what he says.

25 JUDGE POLLOCK: Okay. It could be used. Have these been used
26 in surgeries?

1 MR. BAPNA: I don't know that he uses those words, Your Honor.
2 But I believe the inference to be made from this statement is that they are
3 used in medical procedures.

4 JUDGE POLLOCK: Very well. Please continue.

5 JUDGE MAJORS: I have a question.

6 MR. BAPNA: Yes, Your Honor.

7 JUDGE MAJORS: Mr. Bapna, we heard some argument earlier to the
8 effect that as depicted, the screw is shown as having a round head and,
9 similarly, that it's described as having a diameter. Do you have any support
10 for the notion that this hex head screw, like depicted here in your slide, that
11 that would be described as either round or having a diameter?

12 MR. BAPNA: Your Honor, I don't think there has been any opinion
13 that a hexagonal shape could be considered to have a diameter. No, I don't
14 think there's that in the record.

15 But your question brings me to my next point, Your Honor. You
16 heard Petitioner's counsel make the argument that -- I'm sorry, I'm going to
17 move to slide 19. You heard Petitioner's counsel make the argument that
18 *Cognet* shows surface features of the screw or discloses that the head has a
19 diameter. And Judge Pollock asked Counsel, how do we know that the
20 screw isn't simply hammered into the nail? And Counsel pointed to the
21 surface features of the screw. And Your Honors, this argument must fail, at
22 least because Petitioner did not make these arguments in the petition, and
23 thus they are waived under at least the Federal Circuit's *Netflix* decision.

24 JUDGE MAJORS: Seemed to me it's fairly responsive, that a
25 response coming back from Patent Owner is that this could be some other
26 type of attachment mechanism beyond a typical screw with, you know, like

1 a Phillips head insert or flathead or the hex head that's internal to the screw.
2 Why is that not a responsive argument on Petitioner's part?

3 MR. BAPNA: I'm sorry, Your Honor, could you rephrase that
4 question?

5 JUDGE MAJORS: Yeah. As I understand the argument, you're
6 saying that their point about this screw not being tapped in is a new
7 argument that they were -- that wasn't made in the petition itself. And I'm
8 posing to you the question explain why that's not responsive to the
9 counterargument coming back that this isn't inherently shown and there's
10 other fixation mechanisms that could be at play here.

11 MR. BAPNA: Your Honor, the hex lag screw that Patent Owner
12 pointed to does not have a torque transmitting aperture, and that's just one
13 example of such a device. And *Cognet* is entirely unclear whether the screw
14 has an aperture or not.

15 Moving to slide 20, claim 9. Claim 9 recites that the first bore axis
16 and the second bore axis intersect outside the third member. Now, Petitioner
17 relies merely on this annotated figure, but does not expressly argue or
18 provide any evidence to support that the two axes necessarily lie on the same
19 plane which would be required for them to intersect. Thus, Petitioner fail to
20 show that *Cognet* anticipates claim 9.

21 Moving to slide 22, ground 2, "Petitioner fails to show obviousness
22 over *Cognet* and *Brumfield* for claims 4, 8, 10, 14, and 15."

23 Regarding slide 23, regarding the combination of *Cognet* and
24 *Brumfield*, Petitioner fails to address a motivation to combine, an
25 expectation of success, or potential challenges or difficulties in making the

1 combination. Thus, Petitioner fails to show obviousness by preponderance
2 of the evidence.

3 Now, Petitioner merely argues that the screw and the nail in
4 *Brumfield* are performing the same function in the same way as the screw
5 and nail in *Cognet*. But even this is wrong.

6 Turning to slide 26. In fact, as Patent Owner's expert has opined, a
7 skilled artisan would not consider replacing *Cognet*'s screw with a screw
8 having the beveled head that is disclosed in *Brumfield*. The beveled head of
9 *Brumfield*'s screw would not mate with the shoulder in the tunnel of *Cognet*'s
10 nail. Instead, the beveled head would only contact the edge of the aperture
11 at the shoulder of *Cognet*'s nail, resulting in increased resistance to the
12 rotation of the screw, and this is supported by Patent Owner's expert's
13 opinions at exhibit 2012, paragraph 69 to 70. On the other hand, a
14 Petitioner's expert does not opine on these issues at all, and thus Petitioner
15 fails to establish ground 2 by preponderance of the evidence.

16 Slide 28, ground 3, "Petitioner fails to show obviousness over
17 *Cognet* and *Ferrante* for claim 11."

18 Slide 31, Petitioner concedes in the petition, and this is on pages 34
19 and 36 of the petition, that *Cognet* does not disclose or suggest the
20 limitations of claim 10 or claim 11, the latter depending from claim 10.

21 Slide 32. Petitioner does argue that *Ferrante* teaches a self-tapping
22 edge as to claim 11, but Petitioner entirely fails to address claim 10.

23 Slide 33, The failure to address claim 10 is a fatal flaw as to claim
24 11 due to its dependency on claim 10 under at least the Federal Circuit's
25 *Microsoft v. IPA Technologies* decision. Thus, Petitioner fails to establish
26 ground 3 by preponderance of the evidence.

1 Slide 34, ground 4, "Petitioner fails to show anticipation by *Simon*
2 for claims 1, 4, 5, 8, 10 to 12, 14, and 15."

3 Slide 35. "Petitioner can point to no express disclosure in *Simon* of a
4 first member" comprising a head portion as required by claims 1 and 12.
5 Again, here Petitioner appears to argue *Simon* inherently discloses a screw
6 having head portion without stating that it is arguing inherency. But
7 Petitioner has not met the exacting standard for inherency. Again, a mere
8 possibility or even a probability of the screw having a head portion is not
9 sufficient.

10 Slide 36. The Board acknowledged for this -- on this issue that the
11 petition is not a model of clarity as to support for a head portion in *Simon*.
12 While the Board found Petitioner's evidence sufficient to identify a screw
13 head for the purposes of Institutions, that evidence is not sufficient now to
14 meet Petitioner's burden on unpatentability, and new evidence that has come
15 to light also undermines Petitioner's theory.

16 First, starting with the evidence at the time of Institution, Petitioner's
17 expert opined that while most screws have a head, some screws are headless.
18 Now, the Board limited this opinion as referring to screws that are intended
19 to be fully sunk in bone and concluded that it does not apply to *Simon*. This
20 is on the Institution Decision at page 23. But Petitioner's expert's opinion
21 here does apply to *Simon* screws because they are intended to be fully sunk
22 into the metatarsal bone, as seen clearly in figure 1 of *Simon* and shown here
23 on this slide.

24 Slide 37. Second, none of the Petitioner's or its expert's statements
25 that the Board cited in the Institution Decision establish that *Simon* screws
26 necessarily have a head portion.

1 Slide 38. Third, since Institution, Petitioner's expert admitted that if
2 a screw has no bulbous portion, meaning that there is no part of the screw
3 that is larger, presumably in diameter, than the rest of this crew, then it is a
4 headless screw. Now, that's exactly how *Simon's* figure 1 depicts its screws
5 and, therefore, Petitioner has failed to meet its burden to show that *Simon's*
6 screws have a head portion.

7 Slide 41. There is yet another reason to find that *Simon* does not
8 anticipate claims 1 and 12. *Simon's* figures clearly disclose the apertures are
9 not at a terminal end, but instead along merely the shaft of the device. These
10 figures here are figures -- I'm sorry, these are figures that Petitioner itself has
11 annotated in Petitioner's expert's declaration at exhibit 2012, paragraph 80.
12 And as you can see here, Petitioner and its expert points to the first aperture
13 at a different location than where it points to the terminal end and first end.
14 Thus, Petitioner fails to establish ground 4 by preponderance of the
15 evidence.

16 Slide 42. As to claim 4, which requires a torque transmitting
17 aperture, Petitioner makes the same argument as it did for *Cognet*, so I won't
18 repeat myself in detail, but the short of it is that Petitioner fails to meet the
19 standard for inherency.

20 Slide 43. As to claims 10 and 11, Petitioner can point to no express
21 disclosure in *Simon* of a self-tapping edge. Again here, Petitioner appears to
22 argue that *Simon* inherently discloses screws having a self-tapping edge
23 without stating that it is arguing inherency. And again, to establish
24 inherency requires Petitioner to show that the screws necessarily have a self-
25 tapping edge, not merely that the screws possibly or even probably do.
26 Petitioner can assert only that a certain type of screw commonly has a self-

1 tapping edge. Now, even if this argument is assumed to be correct, it clearly
2 fails to meet the inherency standard.

3 Slide 44, ground 5, "Petitioner fails to show obviousness over *Simon*
4 and *Ferrante* for claims 4, 8, 10, 11, 14, and 15."

5 Slide 45. Claim 4 depends from claim 3, which in turn depends from
6 claim 2. Now, Petitioner fails to assert anywhere in the petition that *Simon*
7 or *Ferrante* discloses the limitations of claims 2 and 3. This is a fatal flaw to
8 claim 4 due to its dependency on claims 2 and 3 under at least the Federal
9 Circuit's *Microsoft* decision.

10 Slide 46, ground 6. Petitioner fails to show obviousness over *Simon*
11 and *Cognet* for claim 9.

12 Slide 47. Again, claim 9 requires the first and second bore axes to
13 intersect. Here, Petitioner relies entirely on *Cognet*'s disclosure, not *Simon*'s.
14 I already discussed Patent Owner's response to this with respect to ground 1.
15 But again, the short of it is that there is no basis to assume that the two axes
16 lie on the same claim, and thus no basis to conclude that they intersect.
17 Thus, Petitioner fails to establish ground 6 by preponderance of the
18 evidence.

19 Slide 48. Now I will discuss an argument that applies to each of the
20 obviousness grounds that involve *Simon*, namely grounds 5 through 7.

21 Slide 49. Regarding the combination of *Simon* and any of *Ferrante*,
22 *Cognet*, and *Leu*, Petitioner failed to address any motivation to combine, an
23 expectation of success, or potential challenges or difficulties in making the
24 proposed combinations. Thus, Petitioner fails to establish grounds 5, 6, and
25 7 by preponderance of the evidence.

1 Unless the Board has any questions with respect to grounds 1 through
2 7 and the original claims 1 through 15, I now move to the third topic, which
3 would be Petitioner's failure to establish that any of substitute claims 16 to
4 30 are unpatentable.

5 Slide 55. This is a summary of Patent Owner's response to each of
6 Petitioner's alleged bases of unpatentability for substitute claims 16 to 30.
7 First, Petitioner fails to show anticipation by *Mazur* for substitute claims 16
8 to 30.

9 Slide 57. Petitioner relies primarily on figure -- on the figure 16's
10 curved embodiment to show anticipation, but seemingly asks the Board to
11 envision modifications based on the figure 7 straight embodiment. When
12 combining different embodiments for purposes of anticipation, the burden
13 that the Petitioner has to meet is to show, by preponderance of the evidence,
14 that the reference is sufficiently clear in disclosing the combinability of
15 those embodiments such that a skilled artisan would at once envisage the
16 claimed combination. That's from the Federal Circuit's decision in
17 *Chamberlain Group v. Tektronic Industries*, cited in Patent Owner's reply.
18 As I will discuss, Petitioner never acknowledged the *Chamberlain* standard
19 and never articulated an argument addressing this standard and in fact fails
20 to meet its burden.

21 Slide 58. Let's look at what Petitioner does in Petitioner's claim
22 charts seen here. Depending on the particular limitation it's addressing,
23 Petitioner vacillates between the figure 7 straight embodiment and the figure
24 16 curved embodiment.

25 Slide 60. Let's look at another example. I believe Judge Pollock
26 asked Counsel what's the significance of the straight embodiment here with

1 respect to claims 16 to 30? And slide 60 here shows at least two limitations
2 that require the third member to be straight. Now, for one of these
3 limitations, Petitioner relies on figure 7 and for the other it relies on figure
4 16A.

5 Now, the figure 16 embodiment as shown does not have a straight
6 third member, it has a curved one. So what does Petitioner do? Well, it
7 seeks to modify that embodiment based on a single sentence from *Mazur's*
8 paragraph 94, which states further a straight, curved, flexible, rigid, or no
9 hub at all may be used with the above combinations.

10 Now, this sentence requires context, context that Petitioner ignores.
11 For example, what does the phrase "above combinations in this sentence"
12 refer to? So let's turn to *Mazur's* paragraph 94, slide 61. The phrase "above
13 combinations in this paragraph" refers to combinations discussed within the
14 paragraph as highlighted here, and that's in the context of device 300. And
15 which embodiment is device 300 part of?

16 Slide 62. It is part of the figure 11 embodiment, not the figure 16
17 embodiment.

18 Now, as an initial matter, Petitioner does not even address figure 11
19 in its opposition. It does so only in its sur-reply after Patent Owner pointed
20 out the fact that paragraph 94 is referring to a different embodiment than the
21 figure 16 embodiment. So Petitioner's expert provides no opinion about
22 figure 11.

23 In any event, going back to slide 57, under the *Chamberlain v.*
24 *Tektronic* decision, the issue here is whether *Mazur* is sufficiently clear in
25 disclosing the combinability of the figure 16 curved embodiment with the

1 figures 1 to 9 straight embodiment, such that a skilled artisan would at once
2 envisage the claimed combination.

3 Now, Petitioner makes a few conclusory statements about using a
4 straight hub for the figure 16 embodiment, but does not explain the why or
5 the how. In particular, Petitioner says nothing about the differences in
6 design and application between the figures 1 to 9 straight embodiment and
7 the figure 16 curved embodiment.

8 Patent Owner's expert, on the other hand, explains that the figures 1
9 to 9 straight embodiment is configured and dimensioned for the proximal
10 ulna, while the figure 16 curved embodiment is configured and dimensioned
11 for the distal radius. That's at exhibit 2037, paragraphs 32 to 33. And Patent
12 Owner's expert further explains that if the figure 16 curved embodiment was
13 made straight, it would have to be inserted through the articular surface of
14 the distal radius, which would completely disrupt the risk. And that's at
15 exhibit 2037, paragraph 34.

16 Now, even if a straight hub could somehow be used with the figure
17 16 embodiment in the distal radius, Patent Owner's expert explained that the
18 hub would require additional modifications, and that's at exhibit 2037,
19 paragraph 35. Now, *Mazur* does not tell us the modifications necessary to
20 combine the figure 16 curved embodiment with the figures 1 to 9 straight
21 embodiment. All of this undercuts any argument that *Mazur* is sufficiently
22 clear in disclosing the combinability of the two distinct embodiments, such
23 that a skilled artisan would at once envisage combinations, an argument that
24 Petitioner has not even expressly made.

25 Slide 65. There's yet another reason to find that Petitioner fails to
26 show anticipation for substitute claims 16 to 30, and that's that *Mazur* does

1 not disclose an aperture that is on both a first exterior surface and a second
2 exterior surface. Figure 16A is shown here with annotations in red to mark
3 where Patent Owner's expert has opined the aperture is actually formed, that
4 is on only the top exterior surface of the hub, not the side. That's at exhibit
5 2037, paragraph 20.

6 Slide 66. Now, both parties' experts agree that the aperture described
7 in the '166 patent serves at least one and sometimes two purposes. One is to
8 provide an opening for the screw to be recessed within the nail, and two is to
9 provide abutment of the screw head.

10 Slide 68. *Mazur's* figures show that it is the open end on the top
11 surface of *Mazur's* hub and not the notch on the side surface that serves these
12 purposes.

13 Slide 69. *Mazur's* notch serves an entirely different purpose, which is
14 to allow the nail to mate with an ancillary tool, for example, an insertion
15 tool, and that's described in *Mazur* as shown on this slide.

16 JUDGE POLLOCK: Mr. Bapna?

17 MR. BAPNA: Yes.

18 JUDGE POLLOCK: Would you point to the claim language that
19 requires a particular purpose to the aperture?

20 MR. BAPNA: Your Honor, in claim 1, there is no particular language
21 that requires purpose, but a skilled artist would understand that an aperture is
22 not, as taught by the '166 patent, is not any hole, but a hole with certain
23 purposes. And I'll also add, Your Honor, that claim 3, for example, does
24 require -- I'm going to bring up slide 66, claim 3 of the '166 patent. "The
25 head portion of the first member abuts the interior surface of the first floor at
26 the first aperture."

1 And Your Honor, if you look here at slide 66, even Petitioner's
2 expert has opined and talked about the purposes of the aperture. He says
3 here, "The aperture serves the intended purpose to provide abutments for the
4 screw head and a recess in which to hide all or part of the screw head. The
5 importance of the aperture's function to enable abutment is common practice
6 when seating the bone screw's head into the nail implant."

7 And although it's not highlighted here, if you read that last sentence,
8 he actually goes on to opine that these purposes are, in his view, you know,
9 more important than the actual limitation that requires the aperture to pass
10 through the first and second exterior surfaces of the nail.

11 JUDGE MAJORS: Mr. Bapna, I have a question, just as a follow-up
12 to Judge Pollock's question, what structurally, though, are you distinguishing
13 relative to the substitute claims and the aperture with the notch that's shown
14 here?

15 MR. BAPNA: Yes, Your Honor. So, as I explained, so the '166
16 patent, a skilled artisan would understand that the aperture has these
17 purposes, and Patent Owner's expert has opined that the notch here in
18 *Mazur's* figure 16A does not serve either of these purposes.

19 JUDGE MAJORS: Yeah, but I'm not asking about the purpose. I
20 want to know what structure that's claimed is missing.

21 MR. BAPNA: So, Your Honor, the structure that's missing is that
22 claim 16 requires the aperture to be on not just one, but two surfaces, two
23 exterior surfaces of the third member. And Patent Owner's expert has
24 opined that here in *Mazur*, the aperture is only on the top -- or I should say
25 only on a first exterior surface, specifically the top.

1 And if I go back to slide 65, this figure here with the annotation,
2 that's right from Patent Owner's expert's opinion. The red is what he's
3 pointing to as where the aperture lies. And his opinion is that is only on the
4 top, first exterior top surface.

5 JUDGE POLLOCK: Mr. Bapna, is it my understanding that you are
6 interpreting *Mazur's* hub as having a two top surfaces, one a step lower than
7 the other, and the lower one is not a side, it's another top?

8 MR. BAPNA: Your Honor, I don't know that there's been expert
9 opinion on this. Our expert has said that is a top -- a single exterior surface,
10 top surface.

11 JUDGE POLLOCK: But you would agree with me that the surface
12 labeled red on the right side is higher than the one on the left side labeled
13 red?

14 MR. BAPNA: Yes, Your Honor. That is correct.

15 JUDGE POLLOCK: There are two levels to what your expert is
16 calling the top?

17 MR. BAPNA: That's correct, Your Honor.

18 JUDGE POLLOCK: Okay. Mr. Bapna, how does that differ from
19 your figure 11 from the patent? Couldn't we describe that exactly the same
20 way as having one top with two levels?

21 MR. BAPNA: Your Honor, that -- no, Your Honor, in figure 11 -- let
22 me just pull up the patent, one second. Figure 11, Your Honor, are you
23 referring to the elements 1120 and 1130?

24 JUDGE POLLOCK: Perhaps I'm referring to figure 18. Hold on, let
25 me figure it out. Yeah, figure 18. I'm sorry.

1 MR. BAPNA: Figure 18. Your Honor, this figure 18 in Patent
2 Owner's view and its expert's opinion, that -- where you see element 1850 --

3 JUDGE POLLOCK: Yes.

4 MR. BAPNA: -- around there, where the screw is entering the nail,
5 that area is part of both the side surface and the top. And not just the top,
6 because there's a cutout along the side exterior surface.

7 JUDGE POLLOCK: Uh-huh. And so there is a cutout in *Mazur's*
8 figure 16? I'm just not seeing the difference.

9 MR. BAPNA: No. Yes, Your Honor, there is a cutout, but I think
10 that would be the notch and the notch is not serving the purposes that we
11 spoke about for the aperture. Whereas here the notch, if I may call it that, in
12 figure 18, is providing abutment for the screw as well as providing an
13 opening for the screw to enter.

14 JUDGE POLLOCK: We're back to function and not really any
15 difference in structure is what I'm hearing.

16 MR. BAPNA: Well, Your Honor, Patent Owner's expert has also
17 opined that there is a difference in how the cutout here is -- well, if your
18 question is whether the notch is on the side exterior surface in *Mazur*, then I
19 don't think there has been testimony to dispute that. I think it's more that it's
20 not an aperture, not that it's not on the side, if that answers your question.

21 JUDGE POLLOCK: Okay. Thank you.

22 MR. BAPNA: Going back to slide 70. Now, here the parties' experts
23 agree about the purpose of *Mazur's* notch, which is again to provide mating
24 with the ancillary devices. And in addition, Petitioner's expert -- I'm sorry,
25 in addition, Patent Owner's expert opines that the notch in *Mazur's* assembly,

1 unlike the claimed aperture, can be configured and dimensioned
2 independently of the bore. And that says exhibit 2037, paragraph 23.

3 For all of these reasons, Petitioner has not shown by preponderance
4 of the evidence that a skilled artisan would consider the notch in *Mazur's*
5 nail to be part of the claimed aperture.

6 Slide 71, claim 24. Claim 24 requires the first and second bore axes
7 to intersect just like it does as to *Cognet*, Petitioner mistakenly assumes that
8 in *Mazur's* figure 16A, the two axes necessarily lie on the same plane. Thus,
9 Petitioner fails to show that *Mazur* anticipates claim 24.

10 JUDGE POLLOCK: Mr. Bapna, you have a total of 12 minutes left,
11 just as a note.

12 MR. BAPNA: Thank you, Your Honor. Second, Petitioner fails to
13 show obviousness over *Mazur* for claims 16 to 30.

14 Slide 73. Petitioner has not shown a motivation to modify *Mazur's*
15 figure 16 curved embodiment to have a straight hub with a reasonable
16 expectation of success.

17 Slide 74. As to motivation, Petitioner has not provided the requisite
18 motivation because it points to paragraph 94, which merely suggests the
19 possibility of a modification to the figure 16 embodiment without providing
20 a reason to make it.

21 Slide 75. As to a reasonable expectation of success, as discussed
22 earlier, Petitioner fails to consider that a straight hub could not be used in the
23 distal radius for which the figure 16 embodiment is configured and
24 dimensioned. And even if a straight hub could be somehow used there, it
25 would require additional modifications. Again, *Mazur* doesn't tell you how
26 to make those modifications and Patent Owner's expert explains that because

1 of those modifications, the modified embodiment could not possibly meet
2 the new limitations of the substitute claim. That's at exhibit 2037, paragraph
3 35. As for Petitioner's expert, he provides no opinion on this issue.

4 Slide 70 -- well, slide 76. Third, "Petitioner fails to show that the
5 original prior art discloses or suggests the original limitations contained in
6 the substitute claims."

7 Slide 77. For disclosure of the claim limitations carried over from
8 the original claims into the substitute claims, Petitioner relies on
9 incorporation by reference to show how the original prior art discloses or
10 suggests the limitations. And under 37 CFR 42.6(a)(3) this is improper.

11 Slide 78. The Federal Circuit has repeatedly blessed the Board's
12 disregarding incorporated arguments and the Board should do the same here.
13 If it were to do so, then all the Petitioner's grounds of unpatentability as to
14 substitute claims 16 to 30 that involve a combination of references fail.

15 Slide 79. Petitioner fails to show obviousness over *Cognet* and
16 *Zhang* for the substitute claims. *Zhang*'s singular figure has very limited
17 detail because it's in very low resolution and does not focus on the nail head
18 as shown in slide 80.

19 Accordingly, the figure does not clearly show where and whether --
20 whether and where, excuse me, on an exterior surface of the nail and
21 aperture is formed. Assuming *arguendo* that *Zhang*'s figure is considered to
22 disclose an aperture, Petitioner still fails to show that the aperture is on both
23 a first and second exterior surface. The aperture would be formed entirely
24 on that nail tail region, which is bulbous and potentially spherical, and
25 accordingly has a single surface.

1 Slide 81. Even if, however, *Zhang's* nail tail region is considered to
2 have multiple surfaces, Petitioner still fails to meet its burden to the extent it
3 relies on group 4 to show that the aperture is not only on a first exterior
4 surface, but also a second exterior surface. And that's because *Zhang's*
5 group 4 is not a part of the aperture for the same reasons discussed earlier
6 with respect to purpose and geometry of the claim aperture. These are these
7 measures notch.

8 Slide 82. Fifth, Petitioner fails to show that it would be obvious to
9 modify *Cognet* based on *Melkent's* or *Gooch's* disclosures.

10 Slide 83. This slide here on the left shows how Petitioner contends
11 *Cognet's* tunnel can be -- the angle can be varied to meet the new claim
12 limitations, and on the right-hand side shows Patent Owner's expert's further
13 annotation to show that, you know, there's actually a very strong motivation
14 not to modify *Cognet's* nail in that manner. And that's the fact that if that
15 was done, there's a very strong risk that the screw would partially or
16 completely protrude through that articular surface of the bone. That's that
17 curved surface in the top right, or come dangerously close to doing that.
18 And the risk is if the screw would drill through that surface, there would be
19 irreparable joint pathology resulting in great harm to the patient. And
20 Petitioner's expert opines on this -- I'm sorry, Patent Owner's expert opines
21 on this topic at exhibit 2037, paragraphs 48 to 50.

22 Slide 84. Petitioner, on the other hand, fails to acknowledge this risk
23 at all. And the screenshots here are of Petitioner's expert admissions that he
24 did not consider this risk in his obviousness analysis.

25 JUDGE POLLOCK: Mr. Bapna, claims 16 to 30 don't require drilling
26 through any particular bone in the body, do they?

1 MR. BAPNA: That is correct, Your Honor.

2 JUDGE POLLOCK: So why is it so important to focus on the
3 particular bone arrangement where you might drill through the articular
4 joint?

5 MR. BAPNA: Well, Your Honor, Petitioner has relied on *Cognet's*
6 figure and *Cognet's* disclosures to show how *Cognet*, as modified by
7 *Melkent* or *Gooch's* disclosures, would meet the claim limitations. And
8 Your Honor, this figure on this slide 83 shows that that cannot be done
9 without considering the risk to the patient here, at least in *Cognet*.

10 JUDGE POLLOCK: So your position is that *Cognet* is specific to this
11 bone and this bone alone and a POSA wouldn't think to use it someplace
12 else?

13 MR. BAPNA: Yes, Your Honor, there hasn't been any opinion from
14 Petitioner's expert at least that *Cognet's* assembly could be used in other
15 bones.

16 JUDGE POLLOCK: And you have five minutes of your time left.
17 You're welcome to use it now or save it for rebuttal.

18 MR. BAPNA: Thank you, Your Honor. Finally, Petitioner fails to
19 show obviousness over *Cognet* and *Gooch* for substitute claims 16 to 30.

20 Slide 86. Petitioner contends that *Gooch's* figure 20 shows an
21 assembly where a nail is inserted into an aperture that's on two exterior
22 surfaces of the nail. But figure 20 is drawn in such a way that a skilled
23 artisan would have no certainty as to whether the figure shows the aperture
24 on both a top and side, or whether the aperture is only on the side of the
25 bone anchor. Now, specifically, figure 20 may reflect a perspective such
26 that the screw is inserted entirely into the side surface and then it obscures

1 the top surface of the nail because it's in front of it rather than being, you
2 know, inserted into the top surface.

3 Slide 87. To illustrate this point, Patent Owner's expert created a
4 model, a 3D model, which arguably appears to show a gray post going
5 through the top and the side of the green nail.

6 Slide 88. In reality, however, the model is constructed such that the
7 post enters the nail through an aperture that lies entirely on the side exterior
8 surface, and this is discernible only with multiple perspective views, which
9 *Gooch* does not provide. In other words, *Gooch*'s figure 20 alone does not
10 indicate one way or the other whether the screw actually enters the bone
11 anchor from the top and side.

12 Slide 89. Petitioner's expert in his deposition did not dispute that
13 *Gooch*'s figure 20 might show something other than what he has opined it
14 shows.

15 Slide 90. At least under the Federal Circuit *Samsung Electronics v.*
16 *Neonode Smartphone* decision, because the parties' and their experts'
17 competing interpretations of figure 20 of *Gooch* are arguably equally
18 plausible, Petitioner fails to show by preponderance of the evidence that
19 *Gooch* discloses or suggests the new limitations.

20 Your Honors, in the interest of time, I will just note that Patent
21 Owner has a motion to exclude irrelevant and prejudicial evidence, but I
22 won't be discussing that in detail today. I'll reserve my remaining time for
23 rebuttal.

24 JUDGE POLLOCK: Thank you, Mr. Bapna. Turn back to Petitioner,
25 and who's speaking for Petitioner? Mr. Kamholz?

1 MR. KAMHOLZ: This is Scott Kamholz, the backup counsel for
2 Petitioner.

3 JUDGE POLLOCK: All right. Before you begin, we do have some
4 questions I'd like you to address during your talk. It doesn't have to be right
5 away. If you would address the alleged disclaimer over *Chang* relating to
6 "at the terminal end," and with respect to claim 9, address your evidence that
7 the axes intersect in *Mazur*.

8 With that, you have 36 minutes.

9 MR. KAMHOLZ: Thank you, Judge. Before I touch on those
10 questions, you asked a question during our presentation about whether
11 there's any evidence in the record of screws being hammerable. The only
12 thing that we found that is potentially relevant is in the *Zhang* reference, and
13 I'm going to share that with you if you'd like.

14 JUDGE POLLOCK: Please.

15 MR. KAMHOLZ: This is page 5 from *Zhang*, exhibit 1058. Is it
16 visible on the screen? As you can see at line 13 on page 5 of *Zhang*, *Zhang*
17 discloses that a hammer may be used to tap the nail tail of the intramedullary
18 nail into the bone. So it is sunk about, as it says on line 17, about three-
19 quarters of the distance in. So for at least a portion of the nail driving, it can
20 be hammered in.

21 Then *Zhang* says that the last quarter is actually screwed in. I don't
22 want to extrapolate reasons, but it would seem to me that *Zhang* suggests
23 that the last bit of the insertion be screwed to ensure that the bone that is
24 going to receive the screw threads is not damaged. But as far as we can tell,
25 that is the only evidence of record that's relevant to the question.

1 As to the two questions that you have asked us to address, the first is
2 the disclaimer over the *Chang* reference. We address that in our reply at
3 page 14 through 17. The major point there is not so much to quibble over
4 the extent of the disclaimer, but whether there was any disclaimer at all.

5 The governing case law makes it clear that that disclaimer must be
6 explicit. I believe the phrase is "so clear as to show reasonable clarity and
7 deliberateness, and so unmistakable as to the unambiguous evidence of
8 disclaimer." Our point simply is that Patent Owner's argument during
9 prosecution to distinguish over *Chang* can be interpreted in more than one
10 way.

11 One way is simply to emphasize that *Chang* is further from the end
12 than the '166 patent disclosure. That does not amount to a disclaimer. That
13 is simply distinguishing the art. And we really did not attempt to make any
14 further point than that on the disclaimer.

15 As to claim 9, the argument is presented in the claim chart in
16 Petitioner's opposition to the revised Motion to Amend, which is paper 49,
17 and it occurs on -- excuse me, it occurs on page 10 of paper 49.

18 The simple point to be made there is that *Mazur* shows this
19 relationship, the intersection of the angles, at least as well as the patent does.
20 The patent doesn't actually illustrate the intersection of the axes. It's implied
21 to by the presentation of those axes in figure 18.

22 In figure 16, of course, *Mazur* does not call it out either. But from
23 other disclosure in *Mazur* that shows how a second screw would be inserted
24 through that second pair of holes, that distal pair of holes through which the
25 green line moves. It would necessarily intersect with the screw as it is

1 moving through the open end of *Mazur's* hub, and for that reason, they
2 necessarily intersect outside the third member.

3 Patent Owner's concern that *Mazur's* figure 16 shows a curved hub
4 and, therefore, the angles cannot be determined is irrelevant in this context
5 because the change of even if there was some concern about the change of
6 the angle, that would still not change the fact that the intersection occurs
7 outside the third member.

8 JUDGE POLLOCK: And how is your argument applied to *Cognet*?

9 MR. KAMHOLZ: Oh, in the case in chief?

10 JUDGE POLLOCK: Yes.

11 MR. KAMHOLZ: In the case in chief that is addressed in the
12 petition. Allow me to -- the point there, and this is addressed on pages 62 to
13 63 of the petition as filed, *Cognet* shows that there's a second screw at the
14 bottom of the implant that is aligned in the same plane as the screw 4 that is
15 going through tunnel 2. Now, this was an issue in Patent Owner's expert's
16 testimony, but as we explained in the reply brief, Patent Owner's expert does
17 not actually take the position that these two screws lie -- do not lie in the
18 same plane.

19 Figure 2 of *Cognet* shows a side -- sorry, I should say a front view of
20 the implant, revealing that the hole for that lower screw, indicated by
21 number 5, lies in the median plane of the implant, the same as screw 4
22 through tunnel 2. As a result, because those two screws lie in the same
23 median plane, they intersect outside the third axis.

24 JUDGE POLLOCK: And this theory comes only from the figures in
25 *Cognet*? There's nothing in *Cognet* explaining that these are on the same
26 plane?

1 MR. KAMHOLZ: That's correct. *Cognet* does not expressly state
2 that. It is a conclusion drawn from the presentation of the figures, notably
3 figure 2.

4 JUDGE POLLOCK: Thank you. Judge Majors, do you have a
5 question?

6 JUDGE MAJORS: No, I -- well, I suppose I do. How do we know,
7 maybe it's evident from the figure, but how do we know that the upper screw
8 and the lower screw that are moving in lateral directions, that they're not at
9 different depths in the vertical nail? Does that make any sense? In other
10 words, you could have -- if you're looking at it in cross-section as depicted
11 there, you could have the upper and lower screws be offset to some extent,
12 and, therefore, even if one is going perpendicular and the other one is
13 angled, you're not going to necessarily have an intersection.

14 MR. KAMHOLZ: I think the answer is that in Mr. Dominguez's
15 opinion, the hole that is shown in figure 2 is in the midline of the implant.
16 And the natural reading of that is that the screw is moving through the
17 middle of the implant, directly out of the plane of the paper. Dr. Ledet did
18 not actually dispute that in his testimony, and so I think we're left with that
19 being the most reasonable interpretation of the drawing.

20 JUDGE MAJORS: Okay, thank you.

21 MR. KAMHOLZ: If there are no other questions, Petitioner yields its
22 time.

23 JUDGE POLLOCK: Thank you very much, Mr. Kamholz. Mr.
24 Bapna, you have, let's say, three minutes when you're ready.

25 MR. BAPNA: Yes, Your Honor. Regarding claim 9, as discussed,
26 Counsel for Petitioner just argued that, you know, that's the most reasonable

1 interpretation of the figures as annotated. However, you know, it's not just
2 the depth of the apertures. The figures don't show exactly the orientation of
3 the apertures. If the apertures are moved in a direction, even by a degree or
4 two, right, the two axes would not intersect. And so the burden is on
5 Petitioner to show that they do intersect. And it just had not met the burden
6 by clear and -- sorry, by preponderance of the evidence.

7 Regarding saying -- I think as mentioned before, the figure does not
8 clearly show a flat top surface, and *Zhang* actually refers to the nail tail
9 region is hemispherical, and that may indicate that there is no flat surface
10 and, therefore, *Zhang* does not show an aperture that's formed on two
11 exterior surfaces of the nail.

12 And Patent Owner also cited the *McKay* reference to argue that a
13 hemisphere can be considered to have a first exterior surface and a second
14 exterior surface, but that's inconsistent with how the terms are used in the
15 '166 patent and ordinarily and customarily. The figures of the '166 patent
16 show a discontinuity between two surfaces, and a skilled artist would
17 ordinarily and customarily understand that for there to be two distinct
18 surfaces, there must be a discontinuity between the two.

19 Regarding *Gooch*, in its surreply Petitioner cites the *Petering* case to
20 argue that if a skilled artisan would have envisaged both of the parties
21 competing interpretations for figure 20, then *Gooch* meets the limitation. I
22 just want to note that the *Petering* case is actually inapplicable here. The
23 holding in that case was where a skilled artisan would envisage each
24 member of a class based on a prior art reference, and the reference discloses
25 the class. That case does not speak to whether Petitioner here meets it's
26 burden by preponderance of the evidence if two mutually exclusive

1 interpretations of figure 20 are equally plausible. Again, it's the Federal
2 Circuit *Samsung v. Neenode Smartphone* decision that is applicable here.
3 And under that case, Petitioner fails to meet its burden.

4 Unless the Board has any other questions, I'll rest for the time being.

5 JUDGE POLLOCK: Before we finish, I want to apologize to my
6 panelists. Judge Majors, Judge Wysz, did you first have any questions for
7 Petitioner?

8 JUDGE MAJORS: Nothing further from me for either party.

9 JUDGE WYSZ: Nothing from me as well.

10 JUDGE POLLOCK: For either party?

11 JUDGE WYSZ: For either party.

12 JUDGE POLLOCK: Very well. We thank the parties for your
13 presentations today. Ms. Brinkerhoff, as a LEAP practitioner, you did very
14 well. Thank you.

15 And this matter is submitted to the panel for determination in
16 preparation of the final written decision. We are now adjourned, but I would
17 ask the counsel to remain on the line for any questions the court reporter
18 may have.

19 MR. KAMHOLZ: All right. Thank you, Your Honor.

20 MS. BRINKERHOFF: Thank you, Your Honor.

21 (Whereupon, the proceedings at 2:56 p.m. were concluded.)

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