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RECORD OF ORAL HEARING UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC., WRIGHT MEDICAL GROUP, INC., and WRIGHT MEDICAL TECHNOLOGY, INC., Petitioners,

v.

BONUTTI SKELETAL INNOVATIONS, LLC, Patent Owner.

> Case IPR2013-00629, Consolidated Patent 7,806,896 B1

Oral Hearing Held: Monday, October 27, 2014

Before WILLIAM V. SAINDON, MICHAEL R. ZECHER, and RICHARD E. RICE, *Administrative Patent Judges*.

RECORD OF ORAL HEARING

The above-entitled matter came on for hearing on Monday, October 27, 2014, at 1:00 p.m., in Hearing Room B, taken at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

1 PROCEEDINGS 2 (1:00 p.m.) 3 JUDGE SAINDON: Be seated. Good afternoon. We 4 are here for IPR2013-00629, U.S. Patent No. 7,806,896. This 5 proceeding was consolidated. We had joined in IPR2014-00354. I am Judge Saindon. With me here today are Judges 6 7 Zecher and Rice. We have allotted a half hour for each side. And we will start with the Petitioners who are granted one 8 9 30-minute block of time, and they may distribute that as they 10 wish. Just let me know how much you would like to reserve for 11 rebuttal. So, Petitioner, go ahead and introduce yourself. 12 13 MR. CAVANAUGH: Dave Cavanaugh for the Petitioner, Smith & Nephew. And with me is Jake Oyloe, also 14 15 from Wilmer Hale representing Smith & Nephew, and Sam 16 Apicelli, representing Wright Medical. 17 May it please the Board. Good afternoon. I would like to reserve five minutes of my time for rebuttal. 18 19 Last February when the Board instituted a trial on 20 the challenged claim 1, the Board credited the testimony of the Petitioner's expert, Dr. Mabrey, and found that there was a 21 22 reasonable likelihood that claim 1 was unpatentable on at least 23 one ground. 24 And in its response the Patent Owner raises just a few challenges. The Patent Owner didn't file a motion to amend 25

the claims. Nor did the Patent Owner challenge the admissibility
 of any of the evidence. And, finally, the Patent Owner has not
 introduced any evidence of secondary considerations such as
 commercial success.

5 The granted grounds in this IPR is based on
6 obviousness and, as the Board knows well, obviousness is a legal
7 determination based on the underlying facts.

8 My presentation today will focus on those narrow 9 issues. First I will address the Patent Owner's statements about 10 the references and, second, I will address the arguments that the 11 Patent Owner raises with regard to the combination of the 12 references to render the claims unpatentable.

The technology here is the same. It is the same as for the challenged patent and the references. It relates to total knee arthroplasty, or total knee repair, which is TKA or TKR, and it is a procedure used to replace part of a knee to improve mobility and it is something that has been around for a while.

18 Techniques improve. Techniques develop. But all 19 of the prior art cited by the Petitioner here and used by the Board 20 in the decision on institution relate to total knee repair.

The challenged claim 1, and I will get into the details of it in a moment, is a method claim, and as the '896, the challenged patent identifies, many of the limitations of challenged claim 1 are admittedly part of the prior art, by the '896 patent itself, determining a position, positioning a cutting

guide, removing a cutting tool. I will talk about these
 limitations in a moment.

And then the last limitation, attaching a replacement portion of the knee to the cut surface, and a specific limitation about the replacement portion and its dimension with respect to a cutting guide surface.

And so in the decision on institution the Board
agreed with the Petitioner that a reasonable likelihood of
unpatentability was raised with Stulberg, which taught, teaches,
the majority of the claim circumscribed in blue, and combined
with the secondary references of Turner and Scorpio which
disclose the limitation of the transverse dimension is larger than
the transverse dimension of the guide surface.

And so the two key limitations with respect to claim 15 1 are the transverse dimension or the width of the replacement 16 portion, the implant, and the width of the guide surface.

Delp in combination with Scorpio or Turner was also granted ground. Delp, an article describes the material circumscribed in blue, largely unchallenged by the Patent Owner, and the Scorpio and Turner reference are used to teach the replacement portion having a transverse dimension larger than the transverse of the guide surface.

JUDGE SAINDON: Counsel, I would like to jump in
for a second here.

25 MR. CAVANAUGH: Sure.

1	JUDGE SAINDON: Just to clarify the combinations,
2	the Stulberg combination, well, there is no picture there, but
3	that's the one where we have computer-assisted knee
4	replacement, and the modification is to take what was in Stulberg
5	and add the cutting surface or cutting guide of the secondary
6	references?
7	MR. CAVANAUGH: Actually the modification of
8	Stulberg is to put in a Stulberg describes that it can be used
9	with normal mechanical systems, so a cutting guide is clearly
10	disclosed.
11	What Turner and Scorpio provide is the particular
12	dimension that's recited in the last limitation. So kind of the
13	combination is the particular cutting guide surface that is
14	described in Turner and Scorpio can be used with Stulberg or
15	Delp to render obvious the claims.
16	JUDGE SAINDON: So what is being modified is the
17	cutting guide?
18	MR. CAVANAUGH: The cutting guide surface,
19	that's right. The claim limitation is the cutting guide surface.
20	And that's, I think, important to recognize that both Scorpio and
21	Turner have a cutting guide surface that meets that limitation of
22	the claim.
23	JUDGE SAINDON: And the same for the Delp
24	combination as well; it is the cutting guide surface that is being
25	added or modified to the base reference?

1	MR. CAVANAUGH: The cutting guide surface that
2	is being the cutting guide surface that is disclosed in Turner
3	and Scorpio is being applied to the cutting guide surface as
4	described in Delp, that's correct.
5	JUDGE SAINDON: Thank you.
6	MR. CAVANAUGH: The Board did identify a
7	couple terms to construe, and the cutting guide, a cutting guide
8	a guide that has a guide surface, and a guide surface is a
9	surface that guides a cutting instrument.
10	So the Patent Owner hasn't offered any different
11	construction and the Petitioners are comfortable with the
12	construction that the Board has selected.
13	Turner discloses information that is largely not in
14	dispute. It has a cutting guide. The Patent Owner and the
15	Petitioner agree on that. It has a guide surface. The Patent
16	Owner and the Petitioner agree on that.
17	It also, in view of the expert's deposition, the expert
18	agreed that the transverse dimension, the width of the guide
19	surface, is much smaller than the width of the implant. So
20	Turner as a reference is largely has the limitations, the
21	limitation of the claim that the Petitioner has alleged and the
22	Patent Office found in the decision on institution and it is
23	available for what it teaches.

1	JUDGE SAINDON: So Turner, I mean, it is just a
2	tiny little piece of metal there, whereas the Stulberg may have all
3	kinds of different parts going on.
4	So what exactly in Stulberg is being modified with
5	Turner and what does that look like?
6	MR. CAVANAUGH: The Stulberg reference, and
7	I have a I'm not sure I have a picture of it. I will orally
8	describe it and then, to the extent there are any additional
9	questions, I will kind of well, the structure of Stulberg is kind
10	of a mechanical kind of guide system.
11	And what is being modified is that guide system
12	using a guide system that uses a computer-aided alignment
13	without an IM or EM rod, which is why it satisfies the
14	limitations of the first part of the claim.
15	And because the identification of the guide surface is
16	a particular dimension, which is unclear from Stulberg, Turner
17	discloses that particular guide surface dimension.
18	And I think it is important for the Board to realize
19	that we are not looking at a physical combination of this
20	particular reference kind of combined with the mechanics of this,
21	of another particular reference. What we're doing is
22	understanding what someone skilled in the art would recognize
23	from the teachings of Stulberg and from Delp and be able to
24	combine that with Turner or Scorpio, each having a guide surface
25	that is a particular width.

1	Does that answer your question?
2	JUDGE SAINDON: So in Stulberg you are saying
3	that take that and then look at Turner. And Turner is saying,
4	well, whatever you have make it narrow. The teaching that one
5	is taking from Turner is the narrowness of it?
6	MR. CAVANAUGH: Is the narrowness, that's
7	correct, and also Scorpio. Scorpio has a narrow guide surface
8	which is a separate issue.
9	But I think it's important to recognize that, you
10	know, to the extent the Patent Owner identifies that there is a
11	particular width in the guide surface, that width of that
12	particular width of a guide surface was already available to those
13	skilled in the art.
14	If there are no more questions on Turner I will move
15	to Scorpio. And Scorpio has two guide surfaces. Each, as the
16	Board indicated in the decision on institution, have a dimension
17	that is smaller than the width of the implant.
18	And, you know, the reference, the particular surgical
19	technique is good for what it discloses. And the Patent Owner
20	really hasn't challenged what the reference discloses. And what
21	the Patent Owner has done, the Patent Owner has gone to has
22	obtained a particular commercial embodiment, a sample of the
23	device, and then made purported differences between that
24	commercial embodiment and what they believe their claim says.

1	So, you know, I think the first instance, it is
2	important to realize that the Scorpio device, as it is described in
3	the surgical technique, includes two guide surfaces with the
4	particular dimension that's recited in the claim.
5	And the Patent Owner has like obtained a particular
6	device from some source and identified that this
7	commercially-available device is not it doesn't meet the
8	limitation of the claim.
9	And how they get there is they look at the very
10	bottom of the triangle, which is in the center, and if I can orient
11	the Board, so we are looking face on I'm sorry, we are looking
12	at the femur face on, on the physician side, and so we see the
13	two left and right guide surfaces. And that physician side is
14	represented from the top down.
15	And on the bone side, where the femur is, is what is
16	represented looking up.
17	And the Patent Owner identifies a portion of the
18	triangle which is truncated and, as a result of that portion of the
19	triangle being truncated, alleges that Scorpio has a continuous
20	guide surface all across the width of the device that is wider than
21	the implant.
22	JUDGE SAINDON: Can we go back one slide,
23	please?
24	MR. CAVANAUGH: Sure.

1	JUDGE SAINDON: So you call these two slots in
2	Scorpio the left guide surface and the right guide surface. In
3	resecting the portion of the bone being shown here, does one use
4	only one of those guide surfaces or both for this particular bone?
5	MR. CAVANAUGH: For this particular photo the
6	Patent Owner has alleged that you need both. Our expert has
7	demonstrated that you only need one.
8	And that makes sense because there are two guide
9	surfaces. The guide surface is oriented toward a left knee and a
10	right knee. And our expert Dr. Mabrey demonstrated that you
11	can use one of the guide surfaces for the distal cut of the femur.
12	And that's where it is.
13	So the short answer to your question is only one
14	guide surface is needed for the femoral cut.
15	We have differences between the commercial
16	embodiment. If the Board would like to hear some of the
17	differences and some of the statements, we fully briefed them in
18	our reply.
19	If the Board would like to hear the differences
20	between a commercial embodiment on the one hand and what the
21	Patent Owner has said about the commercial embodiment, which
22	don't kind of that don't measure in truth, don't actually
23	accurately reflect the device, we can describe those, if the Board
24	is interested, otherwise we can talk about the combination.

1	JUDGE SAINDON: To clarify, the ground that you
2	have proposed is based on the disclosure in Stulberg, that actual
3	article. Do you rely on inherency at all in that ground?
4	MR. CAVANAUGH: We do not rely on inherency
5	for we have been talking about Scorpio.
6	JUDGE SAINDON: Oh, I'm sorry, Scorpio.
7	MR. CAVANAUGH: So we don't rely on inherency
8	at all for Scorpio. We believe the reference itself, the Scorpio
9	surgical technique guide, fully describes like what someone
10	skilled in the art would need in order to identify a guide surface
11	that is the right dimension, that is the dimension that's recited in
12	the claim.
13	The Patent Owner has tried to make allegations that
14	that guide surface, I'm sorry, that truncated triangle here, which
15	is illustrated in red, is an important feature of the device, of the
16	commercial device, and without it it would not work.
17	And our expert also demonstrated that that was
18	incorrect, that it certainly would work, that he was able to make
19	a cut on the distal end of the femur without the use of that
20	surface.
21	And I think as a claim construction matter, if like
22	even presuming that this commercial embodiment should be
23	considered probative to whether or not the reference itself meets
24	the limitation of the claim, even if someone were to consider the
25	claim construction of what a guide surface is, this, because that

de minimis portion of the triangle is not used, it doesn't really
 satisfy the limitation as recited by the Board. The guide surface
 must be used to kind of guide a cutter, as recited, or as claimed.

And I think the last point that I will make before I move on is that the de minimis size of this portion, although the Patent Owner's expert didn't measure it, we did, and it is a measurement that is one millimeter by half a millimeter which, to put that in perspective, at 14 point font, one millimeter is about the size of a period, and a half millimeter, of course, is about half of that.

11 So it is a very de minimis space. And this drawing 12 that the Patent Owner identifies, you know, the expert believed 13 that it kind of corresponded to the device but he couldn't verify 14 that he looked at them side-by-side and confirmed that it 15 corresponded to the device.

JUDGE SAINDON: Go back to the continuous guide 16 surface. Can you refresh me on why the guide surface is only 17 18 the bottom of the particular aperture that is in Scorpio depicted there? Maybe it will be clearer if you go back one more slide. 19 20 MR. CAVANAUGH: I'm sorry, the guide surface, 21 the left guide surface and a right guide surface? 22 JUDGE SAINDON: Right. You had called out the guide surface, which it is either the top or the bottom of the 23 24 particular slots that you see there.

1	But is there a reason why? You know, that slot
2	constrains a saw blade in many different ways, up, down, and
3	left and right. Is the guide surface limited to only the
4	lower-most portion of that slot?
5	MR. CAVANAUGH: I think that the guide surface
6	that is recited in the claim is the transverse dimension, so it is
7	the width, so it is the bottom surface of the guide surface which
8	would be relevant to the particular limitation in the claim.
9	And your question about why there is a single guide
10	two guide surfaces, a left guide surface and a right guide
11	surface, as opposed to a single guide surface, I think is
12	addressable in two ways.
13	One, as our expert has demonstrated, you only need
14	one of those guide surfaces in order to make the cut. And as a
15	corollary to that, you would not be able to go from the right
16	guide surface and move all the way to the left guide surface
17	without removing your cutter and reinserting it. So clearly that
18	is a separate guide surface.
19	JUDGE SAINDON: Let's say just one side. Just
20	pick one. We'll pick the right guide surface because we can see
21	the whole slot there. If somebody were to insert a saw blade,
22	their saw blade would be constrained for movement to the left
23	and to the right to a certain extent by that slide, as well as up
24	and down?
25	MR. CAVANAUGH: That's correct.

1	JUDGE SAINDON: So it constrains the blade, both
2	left, right and up, down. So my question is, why are we focusing
3	on just the bottom of that slot to be the guide surface when it
4	seemed like the top as well as the left and right also play a role
5	in guiding the blade?
6	MR. CAVANAUGH: I think that the limitation of
7	the claim relates to the lateral dimension of the guide surface.
8	And, you know, whether or not there is kind of an upper portion
9	or a lower portion or a side to side, the upper portion, you know,
10	is just not needed.
11	I mean, just from a practical standpoint, the fact that
12	there is an upper surface like there is, you know, there can be a
13	single kind of guide surface that is described, and is not
14	necessarily kind of the I'm not sure if I understand your
15	question to question whether or not the entire guide surface is
16	that kind of circumscribed area around the opening, that would
17	constitute the opening all of the way through.
18	I think the specification in the patent, in the '896
19	patent, describes the lateral dimension and it doesn't kind of
20	reflect that the guide surface would be the entire kind of
21	circumscribed area including the top and the bottom, the left and
22	the right.
23	JUDGE SAINDON: Turning here to column 21 of
24	the specification, at about line 44: The illustrated anterior

resection guide has a slot which forms the guide surface. This

results in the saw blade being captured so that the saw blade is
 restrained against both up and down movement.

So I guess what I am reading from that sentence is a slot forms the guide surface, which would be as you said kind of the entire aperture.

6 MR. CAVANAUGH: There are other embodiments 7 that have a single surface that the Patent Owner has also alleged 8 correspond to the guide surface limitation.

9 I think that as a matter of guide surface, it is unclear 10 then how, like, the guide surface of the disclosed embodiment, if 11 considering the entire circumscribed area, would be smaller than 12 the width. And that's just not a fact in evidence yet.

So the reading that you have of the specification and
the corresponding illustration, which I think is figure 13, if I
remember correctly, is, all right, 13, 14, is simply like the
circumscribed, like, area, including the top, the bottom. That's
simply not kind of identified.

And, you know, it is unclear whether if you were to 18 19 include that entire area -- in fact, it is pretty clear that it would 20 not, simply because if the top and the bottom of surface 178 -- I am looking at figure 13 right now -- if the top of the surface 178 21 22 and the bottom, just looking at the figure, like extend more than half the dimension, then under that interpretation that you've 23 24 articulated this particular device that's illustrated in figure 13 25 wouldn't meet the limitation of the claim.

JUDGE SAINDON: Figure 13 of which?
 MR. CAVANAUGH: Of the '896 patent.
 JUDGE SAINDON: Continue on. I've asked a lot of
 questions.

5 MR. CAVANAUGH: I would also like to note that 6 figure 54, which is another illustration of something that the 7 Patent Owner identifies as corresponding to the invention, and in 8 there, there is simply no top surface. There is no side surfaces. 9 It is just a single kind of surface that is used and similar to what 10 Turner is describing.

In my remaining minute and a half, I guess, I would like to just spend a moment on obviousness and I would like to focus on the references, the primary references in the Stulberg -and this, Judge Saindon, this goes to your question from earlier -- what in Stulberg provides an indication that someone would use a particular mechanical system.

And it is right in Stulberg. In a TKR surgical
technique, their alignment results, without the use of an IM or
EM rod, can be more accurate and reproducible than mechanical
systems. And the system uses currently-available mechanical
total knee instruments.

22 So it is casting a wide net in terms of what kind of 23 mechanical alignment -- what kind of mechanical total knee 24 instruments could be used with Stulberg, and that would include 25 Turner and it would include Scorpio.

1	Delp similarly has a similar disclosure in the Delp
2	article on page 50 and right now I am on slide 16 that the
3	mechanical alignment systems are identified as having issues
4	that want to be solved.
5	And, you know, the Delp article specifically
6	identifies that it augments mechanical instruments. It is using
7	mechanical instruments, i.e., the guides and guide surfaces in a
8	way to reduce the use of or to eliminate the use of an IM or EM
9	rod.
10	And the Delp '018 patent, as I think the Board has
11	already recognized, has kind of a good, concise kind of
12	co-location of relevant aspects of the disclosure of why someone
13	would want to combine the references.
14	The computer systems that are described in Delp and
15	also Stulberg kind of replace complicated alignment systems, IM
16	and EM rod, and allow smaller jigs to be used and, thus, a
17	smaller incision, and with a smaller incision it can be a less
18	invasive procedure, which kind of loops us back to why someone
19	would want to kind of reduce the size of a cutter, reduce the size
20	of a cutting guide or the cutting guide surface.
21	All of those make a less invasive procedure. All of
22	them result in a smaller incision. Thank you.
23	JUDGE SAINDON: Thank you.

1	MR. KAPPEL: May it please the Court, since I only
2	have 30 minutes, I want to focus on three points in my
3	presentation.
4	The first is whether Turner has an extramedullary
5	alignment rod, and I'm going to call that an EM rod from here on
6	out so I don't get totally tongue-tied.
7	The second question I think we touched on before
8	was what does Scorpio disclose with respect to the size of the
9	guide surface and the cutting guide.
10	And the last point I want to discuss is whether a
11	person of ordinary skill in the art in the 2000-2003 time frame
12	would have had an apparent reason to combine the references in
13	the manner urged by the Petitioner.
14	Let's start off on slide 2. And here we see the
15	femoral cutting guide of Turner along with Dr. Schoifet's
16	testimony regarding the EM rod.
17	And what we can see in figure 8 is that the
18	cutting guide consists of a long rod that terminates with the
19	guide surface, sort of a vertical guide surface, and that rod is an
20	extramedullary alignment rod.
21	It provides alignment for the cutting guide surface
22	because it rests along the femur, and that alignment is
23	extramedullary. It is outside the medullary canal of the femur.
24	Let's turn to slide 3. And when I took Dr. Mabrey's
25	deposition, I asked him about this, and he annotated figure 8 for

me. And he confirmed that what he labeled the guide extension
provides extramedullary alignment for the cutting guide surface.
Now, in their reply the Petitioners sort of backtrack
on that statement. What they do is they refer to the features of a
tibial EM rod that is shown in figure 11 of the Stulberg patent,
and they use that for the proposition that an EM rod has to have
fixed anatomical markers.

8 But the term extramedullary alignment rod has to be 9 given its broadest reasonable construction in light of the 10 specification of the '896 patent. And the Petitioner has provided 11 no citation in the specification and no other basis for reading 12 these limitations from a prior art reference into the claim term.

Another problem is that Turner is a femoral
alignment guide, whereas the alignment guide they rely upon in
Stulberg is for the tibia. It is a tibia EM road. And there is no
evidence in this case about what the structure of a femoral EM
rod will be.

The claim term in question simply calls for an
extramedullary alignment rod. Under its broadest reasonable
construction, Turner has an extramedullary alignment rod.

The second point I would like to address is Scorpio. And let's go to slide 4. And this is the figure that I have seen before. And the issue is, does Scorpio disclose a cutting guide surface that is smaller in the transverse dimension than replacing a portion in the knee.

1	And what Petitioner contends is that that surface,
2	that segment D1, that that is the guide surface. The problem is
3	that D1 is just the opening of the cutting guide looking from the
4	physician side. And there is no other figure in Scorpio that
5	shows it from the opposite side.
6	And if we look at the specification of the '896 patent
7	we see that not all portions of the cutting guide surface have to
8	extend all of the way to the physician side. And you can see that
9	by comparing figure 11 and figure 13.
10	Figure 11 is the same perspective as figure 15 of
11	Scorpio. And you see that the slot appears to the slot only
12	goes part way across. However, figure 13 shows the guide
13	surface in the cross-section. And you can see in figure 13 that
14	the guide surface 178 extends all of the way down to the bottom
15	of that cutting guide.
16	So you can't just look at the physician side of the
17	guide to determine the guide surface because, as we know, the
18	claim has to be read in light of the specification. And clearly in
19	the specification, cutting guide surface does not have to extend
20	completely over to the physician side.
21	JUDGE SAINDON: Counsel, just to jump in, the
22	same question as I asked Petitioner, column 21, that portion I
23	read, that the slot forms the guide surface.
24	MR. KAPPEL: Well, I think that in a captured
25	device there are several different embodiments of cutting

1 guide surfaces in the patent. And there is also a cutting guide surface, for example, in figure 54 that doesn't have a top portion. 2 3 And the construction that we have in this case from 4 the Board is that it is a surface that guides the cutting 5 instrument. So that could be captured or not captured. 6 In the case of Scorpio, is it, in fact, captured still on the bone side. There the slot continues from the left side to the 7 right side, although it gets smaller, it gets to have a depth of 8 only half a millimeter, but it is still a continuous slot. 9 10 Does that answer your question? 11 JUDGE SAINDON: I guess my question is why can't 12 we look at Scorpio, the figure that you have there, and we see the 13 slot is, from what we can see, yes, it broadens out in the back as 14 you pointed out, or at least that's what your declarant has shown. 15 Why can't we stop there and say that, well, there's 16 the slot right there and the slot is the guide surface? MR. KAPPEL: Well, I guess then we are kind of 17 18 parsing the word slot. But I would say the slot continues on the 19 back end. And you can't see the back end of this device. You 20 can't see if those two slots aren't connected as a single slot. And I think if you want to interpret claim 1 21 22 consistent with figure 13 of the patent specification, you can't 23 say that just because the opening doesn't come back to the 24 physician side that it is not part of the guide surface. Okay? So 25 what is Petitioner's response on this?

1	JUDGE RICE: Can I come back to that point? The
2	claim says a transverse dimension of the guide surface. Why
3	can't we just focus on D1 as a transverse dimension of the guide
4	surface, regardless of your position that the guide surface
5	extends all the way across?
6	MR. KAPPEL: Well, in that sense then I guess we
7	could stop anywhere along any slot and say, well, only the first
8	half of D1 is the guide surface.
9	But I think if you read the patent specification, the
10	guide surface is the surface that can guide the cutting guide.
11	JUDGE RICE: Well, you are physically stopped,
12	though.
13	MR. KAPPEL: No, I'm not stopped because I can
14	continue.
15	JUDGE RICE: Not beyond D1. You can't continue
16	beyond D1.
17	MR. KAPPEL: Not from the front but as I angle it I
18	can.
19	JUDGE RICE: Right. So why isn't the width D1 a
20	dimension of the surface?
21	MR. KAPPEL: Well, because the transverse
22	dimension across the width still continues. And, again, let's go
23	look at figure 13 and the transverse dimension would be going
24	from the top to the bottom. So the transverse dimension of that
25	guide surface would continue to the edge. Okay?

1	That's the same figure that you were quoting
2	previously about the you were asking about the capture. The
3	slot defines the guide surface. Well, in that same sentence they
4	are talking about this exact figure, and that guide surface is
5	clearly shown as going through to the bottom, despite the fact
6	that it is not visible from the front.
7	So I don't think that, consistent with the patent
8	specification, you could read Scorpio a different way than you
9	are reading figure 13.
10	JUDGE ZECHER: Counselor, just real quick, you
11	know, there is a rub there because we are looking specifically at
12	figure 13 and, as you said, there is different embodiments in the
13	spec, why that figure, in and by itself, should we be reading that
14	into the transverse?
15	MR. KAPPEL: I don't think you are reading it into
16	the transverse dimension. What I'm saying is you can't read the
17	claim term cutting guide surface inconsistent with what is taught
18	in that embodiment, because of the claim term's broadest
19	reasonable construction in light of the specification.
20	And I don't think that you can read I don't think
21	you can, in light of figure 11 and 13, I don't think you can look
22	at the front of Scorpio and know what the guide surface is. Just
23	like you couldn't tell from figure 11 what the transverse
24	dimension of that guide surface was.

1	JUDGE SAINDON: One more question on this issue.
2	Regarding the transverse dimension, you have been talking about
3	it being the width.
4	Looking at column 17 of the '896 patent, it is talking
5	about the transverse dimension perpendicular to a longitudinal
6	central axis of the femur.
7	Now, the longitudinal central axis of the femur in
8	figures 11 and in Scorpio figure 15, that is what is coming
9	straight out towards us.
10	MR. KAPPEL: Right, so it would be transverse
11	across.
12	JUDGE SAINDON: So it says the transverse is
13	perpendicular to that. Isn't the entire plane of the page
14	perpendicular to that axis?
15	MR. KAPPEL: Again, I think you need to look in
16	the context of the patent specification what we are talking about
17	the guide surfaces are.
18	And the guide surface 178 is perpendicular to the
19	axis in the femur as is the guide surface D1 which connects again
20	to the left side guide surface, left side of the slot in a single
21	guide surface.
22	Now, I would say that not necessarily, if you didn't
23	have this type of cutting guide, I'm not sure that you can read
24	that perpendicular into transverse in all of the embodiments, but
25	in this one, yes.

1	HIDOF CAINDON W 11 L
1	JUDGE SAINDON: Well, I guess because it
2	appeared that another perpendicular to that longitudinal axis
3	would be the up and down, as shown in figures 11 or 15 in
4	Scorpio, and there was another disclosure that I read previously
5	in column 21 that the slot captures the blade from up and down
6	movement as well?
7	MR. KAPPEL: Well, I think if you take a look at the
8	specification, the transverse dimension that they are talking
9	about in figures 11 and 13 is going across.
10	And, in fact, you don't even move the blade up and
11	down as captured in that one. When we talk about movement of
12	the guide surface, we talk about moving it across the width. And
13	so I think you have to look at the specification and read it in
14	light of the specification.
15	And, you know, I would also add that that is not an
16	argument that has been made in this petition or it's of record that
17	somehow the transverse dimension is top and bottom. And so
18	that is not something that the Patent Owner had an opportunity to
19	respond to in this proceeding.
20	So just getting a little bit back to their argument
21	about could we go to slide 5. So what is their argument?
22	There is nothing in Scorpio that shows it from the bone side.
23	And they can't establish that the Scorpio device inherently that
24	on the bone side of the Scorpio device it inherently doesn't have

a slot because both parties agree that in the actual Scorpio device
 there is a passage on the bone side.

And, in fact, Dr. Mabrey, Petitioner's expert, went and got his own version of the Scorpio device, and he measured it and he says, well, the truncated apex of the triangle is one millimeter wide by half a millimeter deep. All right?

So what is their argument? Well, they say, and they
said earlier, it is because Dr. Mabrey didn't experiment. He was
able to only use part of the guide surface and, therefore, that's
the end of the guide surface.

11 But that's not the test. They can't show that you 12 can't use that center portion of the passage to guide the cutting 13 guide.

And, in fact, Dr. Schoifet who, unlike Dr. Mabrey,
has used this device in surgery, he said that he, in fact, does use
that center portion of the slot in surgery. And so in our view,
broadest reasonable construction, you can't say that Scorpio has
shown a guide surface of the claimed dimension.

JUDGE SAINDON: Counsel, when performing an
operation using this particular device, does the surgeon, for
example, just cutting the left knee, does he use both?

MR. KAPPEL: He uses both sides. Dr. Schoifet testified about that very clearly in his deposition. You will notice he is the only expert in this case who has actually used that device in surgery. And I can get you --

1	JUDGE SAINDON: Is it in your response?
2	MR. KAPPEL: It is not because it was raised this
3	whole thing was raised in their reply brief. So we have not had
4	an opportunity to file responsive papers.
5	But his deposition testimony is in evidence. And on
6	transcript pages 123, lines 23 to 25, and 124, lines 18 to 125,
7	line 2, he says you use both sides.
8	And I will say that there is absolutely nothing in the
9	Scorpio reference that tells you, or even suggests that you only
10	use one side for a left knee and one side for a right knee.
11	What they point to is a statement in Scorpio that says
12	you can use this device in a left or right knee, which is true.
13	That doesn't go to the point that nowhere does it suggest, well,
14	this left slot is for the left knee and this right slot is for the right
15	knee. That's totally unsubstantiated, in our view.
16	All right. I think I need to move on to the
17	combination. Do you have any more questions on Scorpio?
18	JUDGE SAINDON: One more. So for Scorpio there
19	are two slots; they are just entrances onto the same guide
20	surface?
21	MR. KAPPEL: There is a single guide surface.
22	There are two openings on the physician side that a way that
23	you get at the continuous guide surface that goes across.
24	And if you look at Scorpio, as confirmed, it clearly
25	is connected. And if you look at the Scorpio reference, in

absence of this evidence of the Scorpio device, you have to say
 you can't say from the reference alone whether or not that those
 are two guide surfaces or one guide surface.

And the proof that we have is that you can't prove it
inherently because we went out and got the device, so did they,
and the fact is that they are connected on the bone side.

Okay? All right. So I'm going to move on just to
the issue of combinability. And in their reply brief Petitioners
variously argue that Patent Owner relies on unclaimed features,
physical combinability, or we argued against the
reference individually. But we do no such thing.

We argue that Petitioner has not proven that a person
of ordinary skill in the art would have an apparent reason or
motivation to combine the references in the manner urged by
Petitioner.

And to do that you need to consider the prior art references as a whole and assess what they teach to suggest to a person of ordinary skill in the art in the 2000-2003 time frame. You need to consider the prior art references as a whole, and assess what they teach to the person of ordinary skill in the art in the 2000 to 2003 time frame without the hindsight provided by the '896 patent.

And if you take a look at their brief, I think
Petitioner's assertion of motivation boils down to two things: To
be expected to increase accuracy or be expected to reduce

trauma. So let's take a look at that and start with Stulberg, and
 that's in slide 9.

And as we discussed previously, Stulberg is a computer-assisted technique. And what it is concerned with is improving the accuracy of the cuts, as compared with the mechanical alignment systems that were in use then, in 2000, the year 2000.

8 And they report that even with the instrumentation in 9 use then, the mechanical systems have unacceptable errors. And 10 you can see here on the right Stulberg also stressed that the goal 11 of total knee instrumentation procedure is to achieve cuts that 12 are perpendicular to the axis of the femur. So it is in that 13 context that they seek to improve accuracy.

Now, going to slide 10, we can see the Stulberg
cutting guide. And this is what is relied upon as the cutting
guide which is mounted, which is aligned without an
intramedullary or extramedullary alignment rod, and secured
without an intramedullary alignment rod.

And you can see the cutting guide surface is larger in the transverse dimension than the replacement knee portion. And that was found in the institution decision. I think it is not disputed by Petitioner.

But what won't we find in Stulberg? You will find no disclosure in Stulberg to suggest that you should reduce the length of the cutting guide surface.

1	And, in fact, if we go to slide 11 we will see Dr.
2	Mabrey's testimony where he agreed this is the case. And, in
3	fact, a person of ordinary skill in the art would not seek to
4	reduce the cutting guide surface of Stulberg to be less than
5	transverse dimension of the replacement femoral component,
6	because if you were to do that you would reduce you would
7	not be the cutting tool would not be guided throughout the
8	width of the cut that Stulberg is making.
9	And that, to a person reading Stulberg, you would
10	expect that to reduce the accuracy of cut and, according to
11	Stulberg, accuracy is of paramount importance.
12	Now, I want to step back a minute. You will not find
13	a discussion of the size of the cutting guide surface in Stulberg.
14	You won't find it in the Delp article. You won't find it in Delp
15	'018 and you won't find it in Turner or Scorpio.
16	None of these references in any way suggest the size
17	of the guide surface is a parameter of interest, much less
18	something that should be optimized or reduced in order to
19	increase accuracy or reduce trauma.
20	Let's take a look now at Delp for a minute, and that's
21	at slide 12. And Delp is very similar to Stulberg. Again, this is
22	1998 and they are talking about how accuracy is essential, okay,
23	and that even with state of the art guides you can't it is tough
24	to get a satisfactory result.

1	And, as I said, like Stulberg, Delp doesn't talk the
2	cutting guide surface of the claimed dimension, and it doesn't
3	have any discussion whatsoever of the cutting guide surface and
4	certainly doesn't indicate that it should be reduced.
5	And if we look on slide 13, we can see Dr. Mabrey,
6	he admits this is the case. And in that case, why would you
7	make the guide surface, looking at Delp and Stulberg, all
8	concerned with accuracy, all have guide surfaces that are larger
9	than the claimed dimension, why would you make the guide
10	surface, the thing that guides the cutting blade, why would you
11	make it shorter looking at Stulberg and Delp? You wouldn't.
12	JUDGE ZECHER: Counsel, real quick let me inject
13	here. Are you suggesting that we need a specific suggestion in
14	either one of those references to reduce the guide surface?
15	I mean, I'm sure you are well aware under KSR there
16	are different scopes of the way we can look at this. You are not
17	suggesting that motivation is not the sole reason here?
18	MR. KAPPEL: No, I don't think that you need to
19	find a specific suggestion in the references, but I think that the
20	complete lack of discussion of the guide surface, even a
21	parameter of interest, is instructive. It's not the end of the story.
22	All right?
23	But just because you don't have to find it doesn't
24	make the fact that it has no discussion about it irrelevant. It is

highly relevant. It may not be dispositive, I agree, but it is
 highly relevant.

So let's take a look at Turner, and that's slide 14.
And you have seen Turner before. Turner is an article from
1980. And this is not the type of state of the art mechanical
instrumentation that Stulberg and Delp were talking about.

And, in fact, as Dr. Schoifet testified, the Turner
knee and its associated cutting guide had long been abandoned
by the time of Delp and Stulberg.

10 And I refer you, for example, to Exhibit 2006. And 11 that's an article from 1998 which -- 1988, which stated that even 12 by that time the implant design and surgical technique of a 13 geometric knee -- which is what Turner is -- are considered 14 unacceptable.

And, again, is that the end of the story? No, but you have to look at that. When you are looking at the prior art as a whole, you have to look at what a person of ordinary skill in the art would think of these references in the year 2000.

Now, Petitioner's evidence, they pulled out an article
from 1976 saying, oh, Turner was -- the geometric knee was
successful. But that's not the inquiry. The inquiry is not what
some would have thought in 1976.

The question is what would a person of ordinary skill in the art have thought in the year 2000 to 2003. And he would have recognized this as an abandoned technique.

1	There is another problem. Turner, when we look at
2	the combination of Stulberg and Turner, or Delp and Turner, the
3	Turner guide is far more imprecise than the techniques that are
4	already criticized in Stulberg and Delp.
5	And, in fact, Dr. Schoifet testified what Turner
6	provides is basically a freehand or eyeball cut because the
7	cutting edge is very small, and the blade will actually pivot,
8	could pivot.
9	And you can see that, for example, in slide 14 how
10	the edge of the cutting guide is actually almost entirely above
11	the cut that they are making. So this is not going to give you the
12	kind of precision that Stulberg and Delp are looking for.
13	Another issue is the cut that Turner makes. As we
14	said earlier, what does Stulberg say? Stulberg says the goal of a
15	total knee instrumentation procedure is a perpendicular cut.
16	Well, let's look at the Turner cutting guide. It
17	doesn't make a perpendicular cut. Okay? And we you look at
18	slide 18 you can see, I asked Dr. Mabrey, and he admitted it. It
19	is not making a Turner cut.
20	So now someone in 2000 is looking at Turner,
21	Stulberg and Delp. Well, it looks like it is much more inaccurate
22	than the stuff Stulberg and Delp was talking about and it is not
23	even making the cut that Stulberg wants.
24	So why am I going to make that combination absent
25	the hindsight provided by applicant's disclosure? Well, we told

you, okay, that it actually is good to have a smaller cutting guide
 surface.

So just going to the -- let's just move on to slide 18.
So the question is -- let's move on to the motivation to combine.
And I think we have covered it a bit, which is Petitioner says,
well, you are going to combine Stulberg or Delp with Turner
because it is going to improve accuracy.

8 It is not going to improve accuracy because, as you 9 can see, the Turner cutting guide, it has got a much smaller 10 surface and provides much less control over the blade than 11 Stulberg. So it is certainly not going to get you a more accurate 12 cut.

And where are you going to get that motivation from? Okay. You are not finding it in Stulberg or Delp because they don't talk about reducing the cutting guide surface. You are not going to find it in Turner because Turner, although it has a short cutting guide surface, doesn't say anything about it. Okay.

There is no art that has been brought that is being relied on in this petition that draws any connection between the size of the cutting guide surface and accuracy or why you would want to do it. The only place you get that is from the '896 patent and Dr. Mabrey's testimony.

JUDGE SAINDON: Counsel, let's talk a brief
moment about Delp '018. You said there is nothing talking about
a cutting size.

1 I believe Delp '018 we talked about a little bit had to deal with the overall size of the tool. 2 3 MR. KAPPEL: Let's take a look at slide 21. I've got 4 the related portions of Delp '018. And, you know, what the 5 Petitioner points out is that Delp points out that Delp '018 said 6 the smaller cutting jigs will reduce trauma. 7 But you need to look at the language of Delp in context. And what they are talking to here as the cutting jig, and 8 they say it right there, cutting jigs that align the cuts. What they 9 are talking about the cutting jig is the alignment device. Okay. 10 There is no suggestion to even being -- making the 11 cutting guide smaller. They are talking about the alignment 12 13 guide. And they certainly can't jump from the fact that you might want to make the alignment guide smaller to now a 14 15 specific solution of making the cutting guide surface not only 16 smaller, okay, but to the claimed dimension. And if you want to see a smaller cutting guide 17 surface that satisfies Delp '018, you can look at Stulberg. It is 18 19 five years after Delp. And the cutting guide surface is smaller 20 than Scorpio, but it is still not the claimed dimension? Why? Because all of these patents say that the 21 22 primacy is accuracy. All they want is accuracy. The most important thing is extreme precision. The last thing you do, 23 24 according to their thinking, was making the cutting guide surface 25 smaller so you are not making as precise a cut.

1 You don't get that from the prior art. That is the 2 applicant's disclosure and that was applicant's insight. 3 JUDGE SAINDON: So you are saying that making the jig smaller or making a smaller incision doesn't speak at all 4 5 to the size of a component of that jig, the cutting surface? 6 MR. KAPPEL: No, because the jig, which is, if you 7 look at what they are talking about, they are saying that the jigs 8 are large because -- what they are saying is the jigs are large 9 because they have to cover certain anatomical alignment landmarks in order to align the cutting jigs. They are talking 10 11 about the alignment devices.

Okay. So you can reduce the size of the alignment devices because you don't need to deal with the anatomical markers. Okay. There is no reason -- that doesn't suggest to you that the cutting guide surface should be smaller and it certainly doesn't get you to the claimed cutting guide surface dimension. That's in the '896 patent.

I don't think you can jump from a generalized desire to reduce trauma to the very specific solution that we have got in this claim, which is cutting guide surface, small in the transverse dimension than the replacement portion. And I think the only way you get there is by looking at the '896 patent and going back in hindsight.

JUDGE SAINDON: Is the cutting surface a portionof the jig, though?

 you would say in that sense the cutting jig does not have to be I don't think you could make the assumption that the cutting jig includes the cutting guide, because they can be separate devices. They could be made integrally, okay, but the fact that they are focusing on the alignment portion of it and they are talking about the, you know, it is large because of the anatomical landmarks, you don't get to reducing the cutting guide surface. That's a very specific solution. And, in fact, it runs contrary to all this prior art, except Turner, which is from 1980 where, you know, they really weren't worried about computer-aided design and making something very precisely located. I will just, you know, go on. I have only got, it looks like two minutes. JUDGE SAINDON: We have asked you a lot of questions so I will give you another five minutes. We would like to hear about Scorpio and well, focus on the Scorpio and the reason. I think you were going there anyway. MR. KAPPEL: Let's go to Scorpio, and that is on slide 19. And the first thing you notice about Scorpio, when you look at Stulberg, is it is bigger. Okay. It wraps around the femur. You can see it right there. 	1	MR. KAPPEL: No well, if you look at Scorpio
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23 femur. You can see it right there.	22	look at Stulberg, is it is bigger. Okay. It wraps around the
	23	femur. You can see it right there.

A person of ordinary skill in the art looking at
 Scorpio and Stulberg isn't going to reduce the size of the cutting
 surface.

Rather, you are going to say, if I want to look at
Scorpio, you are going to say, oh, hey, look, that Stulberg
cutting surface is too small because it should wrap around the
femur. There is no way you get to that from there to reducing
the cutting guide surface of Stulberg.

Again, Scorpio, nothing about the size of the cutting 9 guide surface. Doesn't say it is too big. Doesn't say it is too 10 11 small. Nothing. You get that from the patent, from our 12 invention, not, you know, not -- also you can see there in this 13 case, your question about the alignment guides, you can see that 14 in there. The bottom portion with the handle, that's the 15 alignment guide. And then the top portion, which is the cutting 16 guide, is what drops in.

So in our view it's Petitioner's burden to prove thepresence of the elements, claim elements in the prior art.

I do not think that based on Scorpio you can say
Scorpio discloses the claim guide surface, not if you want to be
consistent with the way that term is used in the '896 patent. And
once you have that, it just falls away. It is actually larger.

I would also say, as we mentioned, you know, as Dr.
Schoifet testified, there is no really apparent way that you are
going to mount this cutting guide in the system of Stulberg

without the intramedullary alignment rod. That's really integral
 to this whole design. Especially if you look at the greater width
 and size of Scorpio as compared with Stulberg.

But I would say, you know, in the end, Scorpio does
not teach the guide surface length. And so you can't -- and
neither does Stulberg and neither does Delp. And so the
combination, you can't do it anyway.

8 And you can't get from any of them a suggestion to 9 make the guide surface length smaller than the transverse 10 dimension of the replacement portion. Nobody is talking about 11 it. Only the '896 patent.

12 Are there any questions?

JUDGE SAINDON: Questions? No? Thank you.
MR. CAVANAUGH: I will limit my rebuttal
remarks to a few.

First, with regard to the reply and what the Patent Owner has said about the arguments in the reply and the reply declaration, the Patent Owner had an opportunity to depose the reply declarant and elected not to. So his testimony is in the record unrebutted and good for what it stands for.

Now, I would like to focus my remarks on what you
have heard and then what you haven't heard. First, you heard a
lot about the references. And despite the Patent Owner's
protestation that they are not arguing the physical combinability
of the references, that's essentially what's going on.

1	They look at issues with Turner. Turner is a
2	geometric knee. It was a groundbreaking kind of seminal
3	technology when it was created. People that had extreme pain
4	after the surgery didn't have extreme pain. People that needed
5	assistance walking could walk without assistance.
6	So the characterization that the knee replacement
7	system that Turner describes as being outmoded or somehow
8	irrelevant to what someone skilled in the art would consider is
9	belied by the facts. The surgery worked. Two years out people
10	were still benefiting from the surgery.
11	And in a 10-year study, like time goes on, and there
12	are particular patient populations that are not always well
13	serviced. Sometimes the knee is associated with the knee
14	replacement is associated with an elderly population, that they
15	can have other issues that are going on.
16	So I think that it is important to realize
17	JUDGE ZECHER: Mr. Cavanaugh, do you mind if I
18	step in real quick?
19	MR. CAVANAUGH: Sure.
20	JUDGE ZECHER: To say the surgery worked, I
21	mean, is it specifically attributed to the size of the cutting guide?
22	Is there any evidence that that was the key component or key
23	reason why it worked or is it just simply because it was an
24	innovative procedure with no specific attribution to one thing
25	involved?

1	MR. CAVANAUGH: I'm not sure that there is any
2	specific attribution to the width of the cutting guide. Clearly it
3	is relevant to its success because that's what was aligning the
4	cutting device to make the appropriate cut. So it is certainly
5	relevant.
6	Did the articles that we have that Turner produced
7	say that it is because of the width of the cutting guides? I'm not
8	aware of any, if there are. And so I don't think that that's I
9	think the Board asked an appropriate question, that it doesn't
10	necessarily have to identify that that narrowness is kind of the
11	reason why it is successful.
12	I think that someone skilled in the art has to look at
13	the reference and understand what it is good to teach.
14	And what we hear with Turner is that there is a
15	successful surgery with a narrow cutting guide and, you know,
16	whether it has an EM rod or an IM rod, you know, the Patent
17	Owner makes a statement this is my second comment on
18	Turner is listen carefully, because, like, Stulberg and Delp,
19	like, teach someone not to use an IM or EM rod, teach someone
20	how to do that.
21	And the fact that the Patent Owner alleges that
22	Turner has an EM rod because it is aligned with the femur but
23	not inside the femur, is largely irrelevant because, like, that's not

what the reference is used for. That's not what someone skilledin the art would appreciate from that particular teaching.

1	With regard to Scorpio, we have addressed the issues
2	that the Patent Owner has raised with regard to the commercial
3	embodiment of Scorpio in our reply, and I will rely kind of
4	largely on that.
5	But I will focus on two unsupported positions that
6	the Patent Owner made in their response, and that they had to
7	either agree as not being accurate or unsupportable.
8	First they said the cutting guide could not make
9	the the cutting guide of Scorpio could not make the anterior
10	skim cut required. And as we identify in our reply, you can.
11	And that's on page 37 of their response.
12	And, secondly, on page 38 of their response, they say
13	the Patent Owner alleges I'm sorry, the surgeon accessing the
14	femur from only one slot could not make the femoral cut, could
15	not make. And our expert could.
16	The statements that they are making about this
17	commercial embodiment of Scorpio are unsupported and
18	demonstrably false, and demonstrated to be false in a declaration
19	that they elected not to take the deposition of.
20	JUDGE SAINDON: Counsel, we are about out of
21	time. I have a question for you about Delp '018.
22	MR. CAVANAUGH: Okay.
23	JUDGE SAINDON: Patent Owner was discussing
24	how Delp's disclosure of the size of the jig was not necessarily
25	germane to the size of the cutting surface.

1	I just wanted your comments as to why Delp what
2	Delp '018 does teach?
3	MR. CAVANAUGH: Delp '018 teaches, and I think
4	that I'm going to go to the particular section, because it teaches
5	the use of a smaller jig and the benefits of a smaller jig.
6	And so I'm going to answer your question with an
7	observation of what the Patent Owner hasn't said. What the
8	Patent Owner hasn't said is, like, where does it say that the guide
9	surface needs to be a particular dimension? Yes, like clearly
10	Delp and Stulberg are concerned with accuracy.
11	But, like, it doesn't say you make a big hop in, like,
12	the guide surface in order to make it the most accurate. I mean,
13	if they would say that, then the Patent Owner may have a point,
14	but they don't say that.
15	They recognize that a guide surface is a guide
16	surface and could be kind of adjusted, just like our expert has
17	described.
18	And with the Delp '018 it specifically recognizes that
19	without an IM rod, and without an EM rod, you are able to
20	reduce the size of the jig.
21	And, as our expert has identified to the Board's
22	question, the jig does include the guide surface. The jig is the
23	guide. It includes the guide. And that's in paragraph 22 of the
24	Petitioner's reply declaration.
25	JUDGE SAINDON: Okay. We are out of time.

MR. CAVANAUGH: Thank you.
 JUDGE SAINDON: Thank you. Okay. We are
 adjourned. Have a good afternoon.
 (Whereupon, at 2:10 p.m., the hearing was
 concluded.)

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