**No. 20-440**

IN THE

# Supreme Court of the United States

MINERVA SURGICAL, INC.,
*Petitioner,*

v.

HOLOGIC, INC., CYTYC SURGICAL PRODUCTS, LLC,
*Respondents.*

**On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## JOINT APPENDIX – VOLUME II


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PETITION FOR CERTIORARI FILED SEPT. 30, 2020
CERTIORARI GRANTED JAN. 8, 2021

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NOTICE

The following documents have been omitted from the printing of this Joint Appendix. They may be found in the Appendix to the Petition for a Writ of Certiorari at the following pages:

[317] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

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CIVIL ACTION NO. 15-1031-JFB-SRF

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HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
*Plaintiffs and Counterdefendants*,

vs.

MINERVA SURGICAL, INC.,
*Defendant and Counterclaimant.*

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Wilmington, Delaware
Tuesday, July 17, 2018
9:00 o'clock, a.m.

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VOLUME 2

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BEFORE: HONORABLE JOSEPH J. BATAILLON,
U.S.D.C.J., and a jury

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[467] PLAINTIFFS' TESTIMONY

. . . EDWARD GORDON EVANTASH, having been duly sworn/affirmed as a witness, was examined and [468] testified as follows . . .

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DIRECT EXAMINATION

BY MR. WOLF:

* * * *

[511] Q. Now, you were here an hour ago when there were slides on the screen showing 2001 data for

NovaSure compared to 2017 data for the success of Minerva; is that right?

A. I was.

Q. In your opinion, in your experience, was that a fair comparison?

MR. BISH: Objection, Your Honor. Asking for opinion.

MR. WOLF: Your Honor, he submitted a statement and it's also corporate designee. I mean, I can --

THE COURT: Overruled. He can answer.

BY MR. WOLF:

Q. Go ahead.

A. I'm sorry. Can you reword the question?

Q. Was that a fair comparison?

A. Oh, no, no. I mean, the NovaSure has been around for 15 years and things have changed. Things have changed both in the device as I pointed out to you, in the generator, simplifying the way we do it, understanding the procedure [512] better and how physicians use the device, can insert it into the uterus, how they can deploy it and seat it.

Choosing the right patients. We've had so many articles, over 80 articles published on NovaSure, so we have an understanding of which patients might do better, which patients might not. It helps in our patient selection. All of these issues help contribute to success rates that we see are higher than we originally saw back in 2001.

Q. What's a peer-reviewed article?

A. So journals exist to published articles for physicians to read, and to find out new information, new data from studies that have been performed.

Some journals are call peer-reviewed journals. That means that they go through the process by which these articles submitted, the studies have been evaluated for both their significance, the credibility, their contributions, the way their methodologies are done, to determine if they are worthy enough of being published in these journals. And then they are, once edited, deemed acceptable for publication.

They come out in journals, many of which you've heard of, like New England Journal of Medicine, the Journal of the American Medical Association, or Lancet. In OB/GYN, we have what's called the Green Journal, the Gray Journal, Sterility. I will talk about these later. But a number of [513] journals that are peer-reviewed that provide the practicing OB/GYN with articles from studies that demonstrate what we call real-world data. How is this device being used by mainstream physicians? How is it being used by physicians doing clinical studies in the real world?

Q. Have there been peer-reviewed studies since 2001 that have been published that have talked about NovaSure's success rates?

A. Many.

Q. And have those peer-reviewed journals shown that NovaSure's success rates are comparable to Minerva, better than Minerva, or worse than Minerva?

A. Essentially comparable.

Q. Is there a reason why NovaSure's non-prejudice in the market from 2001 to 2014 might have helped Minerva get better numbers to its FDA study?

MR. BISH: Objection, Your Honor. It calls for speculation.

THE COURT: Yes. I would like to hear a little bit more foundation before he offers the opinion.

MR. WOLF: Understood.

THE COURT: Sustained.

* * * *

[531] Q. Let's just blow it back up altogether and look only at the bottom line, the grand total row. So we know from before that that fiscal years, up to 17,577. Let me ask you can you roughly add up how much you spent on R&D there?

A. Yes.

MR. BISH: Objection, Your Honor, on foundation. I'm not sure we have a basis for his knowledge for the number yet.

BY MR. WOLF:

Q. Are you familiar with the research and development programs at Hologic?

A. I'm familiar with the names, except for TOTO.

Q. And are you generally familiar with the budgetary process for research and development programs?

A. I am. Finance releases, yes.

Q. And you see it in your ordinary course of business?

A. I do.

Q. Okay. So then let me ask, roughly speaking, how much you have you spent on R&D from fiscal '08 to fiscal '17?

A. About 90 to 100 million.

Q. We can obviously add that up ourselves.

A. Okay.

Q. That's 90 to 100 hundred million. Does that include [532] money spent on physician training?

A. No.

Q. Does that include money spent on marketing?

A. No.

Q. Does that include money spent on education?

A. No.

Q. If we include physician training and marketing and education, how much more has been spent on NovaSure since the acquisition?

A. About 40 million.

Q. So if you include the 325 million you spent to purchase Novacept, 100-plus on R&D and the 40 million or so in total, how much have you spent to bring NovaSure to patients?

A. Roughly 450 million or so.

Q. Are you familiar with the term star product?

A. Yes.

Q. What does that mean in business lingo?

A. So that's a product that's in a market that's growing and the product is growing and you want to continue investing in it to make it even better, to continue to see its improvement so that you can continue to generate more revenue into the future.

Q. Is NovaSure a Star product?

A. It is.

* * * *

[537] BY MR. WOLF:

Q. And are you aware that during that window -- let me ask it differently. Has Minerva made public presentations about its technology at trade shows?

A. Yes.

Q. Can you look in your binder at PTX-270 -- oh . . .

(Pause while counsel conferred.)

MR. WOLF: May I approach, Your Honor?

THE COURT: Yes, you may.

THE WITNESS: Thank you.

BY MR. WOLF:

Q. Let's turn to the first page. Just look at it first.

Can you tell me what that document is?

THE COURT: Well, first, would you identify it

for the record as an exhibit number.

MR. WOLF: I'm sorry, Your Honor. PTX-0278.

Apologies.

THE WITNESS: Yes. So this is a program from the AAGL meeting. It stands for the American Association of Gynecologic Laparoscopy.

Q. And when is it dated?

A. It is November 6th through November 10th, 2011.

[538] MR. WOLF: Move the admission of PTX-0278.

THE COURT: Any objection?

MR. BISH: No objection, Your Honor.

THE COURT: 278 is received.

(PTX-0278 was admitted into evidence.)

BY MR. WOLF:

Q. If we can turn to the page ending 242313.

And let me ask you: I assume you've been to AAGL?

A. I go every year.

Q. The title of the page is technical exhibit description, and you see in the middle of the right-hand column Minerva Surgical?

A. I do.

MR. WOLF: Could you blow that up, please?

BY MR. WOLF:

Q. Could you please read allowed the description of Minerva's technical exhibit?

A. Minerva Surgical is clinically testing a new endometrial ablation system utilizing RF energy and argon plasma energy within a balloon. System attributes include: Total procedure time -- three minutes, small diameter device, large opened array, easy seating, cervical canal sealing balloon, easy removal, touchscreen plug-and-play controller. Visit their web page.

[539] Q. And how big is the conference that this is identified?

A. About 5,000 typically would attend.

Q. And physicians attend this?

A. They do.

Q. And competitors?

A. Yes, exactly. A lot of businesses attend.

Q. Does Hologic have its own booth?

A. Yes. Can I describe what booth it is?

Q. Yes?

A. There's this big conference where we have scientific exchange. People get up. They talk about abstracts or they give presentations that have been accepted. There's some educational and training programs and then there's this one area where all of the product, the medical device companies and some pharmaceutical companies have an opportunity to have booths where they show their product.

They showcase new products and it's an opportunity for them to engage and interact with physicians who can look at it and ask direct questions.

Q. Do you need to sign a nondisclosure agreement to attend this conference?

A. No, you don't need to have a nondisclosure agreement in place.

* * * *

[571] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

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CIVIL ACTION NO. 15-1031-JFB-SRF

---

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
*Plaintiffs and Counterdefendants*,

vs.

MINERVA SURGICAL, INC.,
*Defendant and Counterclaimant.*

---

Wilmington, Delaware
Wednesday, July 18, 2018
8:34 o'clock, a.m.

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VOLUME 3

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BEFORE: HONORABLE JOSEPH J. BATAILLON,
U.S.D.C.J., and a jury

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* * * *

[627] REDIRECT EXAMINATION

BY MR WOLF:

* * * *

DIRECT EXAMINATION

BY MR. WOLF:

* * * *

[632] Q. Is there any reason why Hologic might have been particularly uniquely concerned about Minerva as opposed to another competitor coming on the market?

MR. BISH: Same objection.

THE COURT: Overruled.

THE WITNESS: Yes.

BY MR. WOLF:

Q. And what is that?

A. It was frustrating. We're competing against our own product with a balloon. It's a -- we're competing against many of our own previous reps. We are competing against inventors of our own device, and we were hearing claims from our physician customers that, yes, they told me it's the new NovaSure, that this is the -- you know, that this is, you know, what -- it looks like NovaSure, maybe a little better. That's what we were hearing. We were competing against ourselves essentially, and, yes, that -- that was -- that made us rather emotional.

* * * *

[879] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

---

CIVIL ACTION NO. 15-1031-JFB-SRF

---

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
*Plaintiffs and Counterdefendants*,

vs.

MINERVA SURGICAL, INC.,
*Defendant and Counterclaimant.*

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Wilmington, Delaware
Thursday, July 19, 2018
8:32 o'clock, a.m.

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VOLUME 4

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BEFORE: HONORABLE JOSEPH J. BATAILLON,
U.S.D.C.J., and a jury

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* * * *

[1042] . . . CHRISTOPHER C. BARRY, having been duly sworn/affirmed as a witness, was examined and [1043] testified as follows . . .

* * * *

[1151] RECROSS EXAMINATION

BY MR POPLAWSKI:

Q. Cytyc bought Novacept in about 2004?

A. Yes.

Q. And Novacept is the company that put the NovaSure product on the market in 2001?

A. Yes.

Q. And then Hologic bought Cytyc in about 2007?

A. Yes.

Q. And Hologic, since by Cytyc, including the NovaSure product, has made about $3 billion on sales of NovaSure product?

A. On the top line, correct. Sales, right.

Q. And so in essence here, and that's basically for all technology. Right? It has been on the market since 2001?

A. Yes. It has been around and it's established and still popular.

Q. So Hologic believes it should get well over half of Minerva's sales going forward as lost profits?

A. It's not going forward. The damages that we'retalking about are historical, the past sales.

Q. Okay.

* * * *

[1156] THE COURT: Mr. Truckai, if you would stand right there. We're going to ask you a couple questions and then swear you in.

. . . CSABA TRUCKAI having been duly sworn as a witness, and was examined and testified as follows . . .

MS. ELSON: Thank you, Your Honor.

And just to introduce -- let's get you set up here.

THE COURT: You may proceed, counsel.

MS. ELSON: We have binders.

Thank you, Your Honor. We are very pleased now to finally begin the presentation of Minerva's case.

I would like to introduce you to Minerva's first witness, who is Mr. Csaba Truckai, and he is an inventor and founder of Minerva, and I will now ask -- well, Mr. Csaba is on the stand.

[1157] DIRECT EXAMINATION

BY MS. ELSON:

Q. Good afternoon, Mr. Truckai. We'll at least give a little bit of an introduction and then we'll have to pick up again tomorrow.

Have you ever testified in court before?

A. No. It is the first time.

Q. Would you please introduce yourself to the ladies and gentlemen of the jury.

A. Good afternoon. My name is Csaba Truckai.

Q. And feel free -- there should be a mike.

THE COURT: If you just move it a little closer, it might help.

THE WITNESS: Okay. Thank you.

BY MS. ELSON:

Q. It's right there and there's water if you need it?

A. Thank you.

Q. All right. So where do you live, Mr. Truckai?

A. Saratoga, California.

Q. Do you have a family?

A. Yes, I do. Wife and three boys.

Q. Three boys?

A. Yes.

Q. Are you a U.S. citizen?

A. Yes, I am.

[1158] Q. Were you always a U.S. citizen?

A. No, I was not.

Q. And where were you actually born?

A. I was born in Hungary.

Q. Can you just briefly describe your studies in Hungary.

A. I had three years of pre-med and the fourth year I transferred to mechanical engineering.

Q. How long did you study mechanical engineering?

A. A year.

Q. I'm sorry?

A. A year.

Q. Okay. Now, when did you move to the United States?

A. 1984.

Q. Okay. Now, today, how would you describe your main line of work?

A. I'm inventing new medical devices, new technologies, and evaluating them, their application in the medical device field.

Q. How long have you been an inventor of new medical devices?

A. Close to 30 years.

Q. Okay. Now, where do you spend most of your time nowadays?

A. I'm still spending up to 14 hours in the lab, checking prototypes, devices, what's wrong with them, how we can fix [1159] it, how we can apply to various procedures.

Q. Okay. Now, have you prepared a list of the different types of medical devices that you have invented and developed over those nearly 30 years?

A. Yes. Yes, I did.

Q. Can we see that, please?

So can you just briefly for the ladies and gentlemen of the jury describe the different kinds of medical devices you've invented over those nearly 30 years.

A. I started in cardiac device market and I have a very unique patent for cardiac catheters. Angioscopy, the way you can look inside the heart and evaluate various plaques in the arteries.

Q. If you could speak a little more into the microphone and just a little slower?

A. I'm sorry.

Q. Okay.

A. Pulmonology for intubation. Cardiac ablation for arrhythmia.

Q. Arrhythmia?

A. Arrhythmia. Irregular heartbeat. Endometrial ablation, vessel sealing to replace sutures. Spinal fraction fixation. Spinal tumor ablation. Arthroscopy and orthopedic products. Fibroid resection and an enlarged prostate resection, BPH.

[1160] Q. BPH?

A. It's a prostate resection.

Q. Okay. Now, how many of these products that you have developed over those 30 years that are listed here are still being sold? How many of these products that fall in these categories?

A. The only one that's not sold is the angioscopy product and the orthopedic and the prostate product will be on the market in the next couple of months or so.

Q. Okay. So out of all of these, the only one that's not being sold is angioscopy?

A. That's correct.

Q. And this one is soon to be sold?

A. In a month or so.

Q. Okay. Now, are you a named inventor on any U.S. patents?

A. Yes, I am.

Q. Okay. How many issued? Let's start with issued U.S. patents?

A. I have over 160 issued U.S. patents.

Q. All right. And how about any pending United States patent applications?

A. Over 150.

Q. Okay.

A. Pending applications.

[1161] Q. All right. So roughly altogether, over 300 issued United States patents and pending applications? Inches approximately.

Q. Okay. Now, when the Patent Office issues you a patent, do you consider it your property?

A. Every issued patent is a property. Very important intellectual property that I own.

Q. Okay. Now, do you respect the intellectual property of others?

A. Absolutely.

Q. Okay. And why is that?

A. I respect it because I hope others are going to respect mine, too.

Q. Fair enough.

Now, after you arrived in 1984 in the U.S., what was your first job in the United States?

A. I couldn't speak English, so the first job I got was a graveyard shift in a hosptial. I was a nurse assistant.

Q. A graveyard shift in a hospital?

A. That's right.

Q. And your position was?

A. Nurse assistant.

Q. Nurse assistant. Okay.

A. And during the day, I went to English school.

Q. All right.

[1162] A. And I had to learn English.

Q. You did a good job.

What was your first job with an actual company here in the United States?

A. Cordis Corporation.

Q. Okay. And what was your last position? And what do we sear here?

A. This is just one of the devices from Cordis.

Q. Okay.

A. But it's a very broad range of products. It's a very large company.

Q. And what was your last position -- when you left Cordis, what was your title or position?

A. I was a senior R&D engineer in custom products.

Q. Okay. Now, what kinds of products did you personally develop while at Cordis? And if it helps you, we have it here on the screen?

A. This is one of the products which I'm pretty proud of. We call it a Brite Tip Guiding Catheter. The catheter introduces the device into the coronary artery. Pressure. That's for evaluating heart valve function.

Q. Evaluating heart valve function?

A. That's right. But generally speaking, the braiding technology which I developed used today about 6 to 10 million catheters. So most of the products that Cordis has [1163] has my technology.

Q. Okay. You said braiding technology?

A. Braiding.

Q. Do we see that here?

A. That's right. The mesh you see on the device here, the wire structure is call the braided wire structure.

Q. Okay. So is the -- you said this product is still on the market?

A. That's right.

Q. All right. So what was your next job after leaving Cordis?

A. I joined a company in California called Advanced Cardiovascular Systems.

Q. Advanced Cardiovascular Systems?

A. That's correct.

Q. Okay. Was that also in Florida?

A. Unfortunately, not. I had to move to California.

Q. Okay. And is that where advanced cardiovascular was located?

A. Yes. In Santa Clara, California at the time.

Q. And what was your position at Advanced Cardiovascular Systems?

A. I was a senior R&D engineer and project lead engineer.

Q. All right. By the way, did you apply to them for a [1164] job?

A. Actually, no. End of 1989, they called me, that they would like me to join them and run this project for the company.

Q. Okay. So they sought you out?

A. They did.

Q. Okay. Now, as a lead engineer, what products did you develop while at Advanced Cardiovascular Systems?

A. It was two products, the an gee yo scope and guide wire.

Q. What?

A. It's called a guidewire.

Q. Guidewire?

A. Fine filament, which goes in the center lumen of this catheter.

Q. And is Advanced Cardiovascular Systems still around?

A. Yes, but they why bought by a large company called Abbott.

Q. They were purchased by Abbott?

A. That's right.

Q. Okay. Abbott Laboratories?

A. Yes.

Q. Is that a large company?

A. It's a very large company.

Q. And where did you go next?

[1165] A. After that, I joined a very small startup company called CardioRhythym.

Q. Can you spell that, please?

A. My spelling is not the the greatest.

Q. Okay. Oh, let me give it a try.

C-a-r-d-i-o-R-h-y-t-h-m.

A. That sounds right.

Q. Where was CardioRhythm located?

A. In California.

Q. And what did you do -- what did you develop at CardioRhythm?

A. Developing radiofrequency-based cardio devices. And actually, we request see it here on the picture.

Q. Yes.

A. One of the slides.

Q. And is CardioRhythm still around?

A. No. Medtronic bought at the very early stage.

Q. Okay. Medtronic?

A. Medtronic, which is again a very large, probably the second largest medical device company in the world.

Q. Are the products you developed while at CardioRhythm still on the market?

A. Yes. I'm not sure what you can see here is identical. The only thing they changed is the color.

Q. Of this?

[1166] A. That's right.

Q. Now, when you started at CardioRhythm, did you work there exclusively?

A. No. When I joined the company, I talked to the CEO and the founders and I told them that I would like to run my own company some day, and would they mind if I start on not interfering with the company business, starting my own company, and they agreed.

Q. So this is before you even started, you worked something out up front?

A. Absolutely right.

Q. All right?

A. I felt like it's the right thing to do because if they don't like it, I don't want to interfere with them. But I told them that it would not interfere with the business and I would do everything I need to do to make sure that the company is successful and acted actually it turned out very well because it was such a startup company, they had nothing, and I had more equipment in my garage, you know, from equipment and other

devices, that, you know, actually used to build their first devices.

Q. Now, so far, are any of these products you talked about so far, are any of these companies you talked about so far Minerva?

A. I'm sorry?

[1167] Q. Are any of these companies or products that you've talked about so far, are any of them Minerva or Minerva products?

A. No.

Q. Okay.

A. Absolutely not.

Q. So how did you manage to do both your own company on the side and work for CardioRhythm?

A. I work a lot, so I start usually around, at the time, around seven, and I was there until 11:00 or 11:00 o'clock at night.

Q. There, where?

A. At the company.

Q. All right.

A. And I went home and I started to do my own business like 3:00, 4:00 in the morning, and it started again the next day.

Q. And was that your lab in your garage?

A. That's correct.

Q. Now, what happened eventually to your own side startup?

A. So we called the company KST Medical and eventually over many name changes, it ended up Novacept.

Q. Okay. And when did you formally, can we see the slide -- are we seeing here the prior company up here?

[1168] A. That's correct.

Q. All right. And so when did you formally kick off Novacept?

A. 1993.

Q. Okay. And what inspired you to found Novacept?

A. Well, we were working on endoscope, and one of the products was a hysteroscope.

Q. Excuse me. A what?

A. Hysteroscope.

Q. Hysteroscope?

A. That's correct. That's a device, you can look inside uterus and I was talking to gynecologists in the bay area.

Q. Gynecologists?

A. Gynecologists. They talk about the problems they have and one of the problems, they mentioned that it's a big issue for them, was endometrial ablation. It was very technique dependent and the new devices, they didn't always address the issues --

Q. And I am sorry. The new devices didn't?

A. They didn't address some of the issues they considered to be important.

Q. All right.

A. On a personal note, you know, my mother had, you know, this problem, and in her mid-forties, you know, she went through a hysterectomy. So even then I thought, there has [1169] to be a better way to deal with this problem.

Q. Okay. And what was wrong? What did you find was wrong or deficient about the existing technology?

A. Partly.

A. The part I was interested in the radiofrequency devices, try to address this issue, and I found that the liquid buildup they have on the surface, preventing these devices to work normally, or function the way they should.

Q. Did you say the liquid buildup?

A. Liquid buildup on the surface of the device and the tissue.

Q. Okay. And so were there electrodes on the surface of the device?

A. So, yes. If you have a -- if you have radiofrequency electrodes on the surface, you have to make direct contact with the tissue, and when you apply energy to the tissue, radiofrequency energy, you know, the fluid from the tissue can come out.

So only way I can explain, if you grill a steak, you put it on the grill.

Q. First, would you explain, what causes biologically -- what causes the moisture to build up?

A. So if you heat up the tissue, all the collagen structure constructs in the tissue and the moisture oozes out from the tissue.

[1170] So just like I mentioned that, you know, if you put a steak on the grill, you can see the same process. You know, the liquid comes out, and that liquid is actually very conductive. It's filled with salt, very conductive, and current is bypassing the tissue, but rather goes through this liquid layer. Two things.

Q. Let's break this up a little bit. The liquid that you come out you said is saline?

A. It's almost like, it's very conductive.

Q. Okay.

A. It's high salt content.

Q. Okay.

A. So it's conductive.

Q. It conducts electricity?

A. That's right.

Q. Okay. And what is it that happens to the electricity? I apologize for interrupting. Go ahead.

A. So two things happen. The first thing is liquid buildup pushes it away from the tissue. You're losing the direct contact.

Secondly, between this liquid layer is channelled energy. It's almost like shorting. So you are no longer running the current through the tissue, but rather this liquid layer and that prevents the device to function normally.

[1171] Q. Is it fair to say current was getting diverted into this liquid layer?

A. Not just diverted. The current that's required is extremely high, which I considered unsafe.

Q. Okay.

Q. In your experience, what is wrong with using more current than necessary in the human body?

A. So, you know, you've got to look at the safety aspect, and I always thought, you know, if you can do something, a minimal amount of energy, do it with minimal amount of energy.

The reason why if something goes wrong, we are putting a large amount of current in the tissue, the side effect can be devastating. You always want to minimize the amount of current you put into the tissue.

MS. ELSON: Your Honor, we've actually reached a transition point. This might be a good time to take a break, break for the day.

THE COURT: That's fine.

So, ladies and gentlemen, I asked Ms. Elson to introduce you to this witness and she has done that. We will continue his testimony tomorrow morning at 9:00 o'clock.

I will again remind you, don't talk to anybody. Don't do any research. This is your decision, nobody [1172] else's. So keep an open mind until you've heard all the evidence and I will see you tomorrow morning at 9:00 o'clock.

(The jury was excused for the evening recess.)

THE COURT: The record should reflect we're outside the presence of the jury and everyone may be seated.

Mr. Truckai, you're welcome to step out of the courtroom if you would like to.

THE WITNESS: Okay. Thank you.

(Witness excused.)

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[1178] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

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CIVIL ACTION NO. 15-1031-JFB-SRF

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HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
*Plaintiffs and Counterdefendants*,

vs.

MINERVA SURGICAL, INC.,
*Defendant and Counterclaimant.*

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Wilmington, Delaware
Friday, July 20, 2018
8:32 o'clock, a.m.

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VOLUME 5

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BEFORE: HONORABLE JOSEPH J. BATAILLON, U.S.D.C.J., and a jury

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[1201] Welcome back. We are going to continue the examination of Mr. Truckai.

Ms. Elson, you may continue.

MS. ELSON: Thank you, Your Honor.

. . . CSABA TRUCKAI, having been duly sworn as a witness, and was examined and testified further as follows . . .

DIRECT EXAMINATION, Continued.

BY MS. ELSON:

Q. Good morning. So, Mr. Truckai, we're going to just recap a little bit to see where we left off. We were talking about the early days at Novacept.

Do you recall?

A. Yes.

Q. Okay. And we were talking about the problem with the existing technologies when we were first thinking of developing the NovaSure.

Do you recall?

A. That is fine.

Q. Okay. So can you just recap for us, what was the problem with those older devices in general?

A. All of them, you know --

Q. Can you lean just a little closer to the mike?

A. Is that better?

Q. Yes. Thank you.

[1202] A. Okay. So all of the devices were having the same issue that a liquid buildup on surface of the electrode, between the electrode and the tissue caused the ablation process, not to path 1. But they should -- but that liquid layer, the gap and also electrically conductive liquid channelled energy not into the tissue, but through the liquid layer, between the coat, and that was one of the fundamental issues, also causing current needed to run the process.

Q. All right. So a gap between the tissue and the electrode?

A. Developed, and the liquid started a buildup, and the liquid came from the tissue, which I explained, the process, squeezed the moisture out from the tissue.

Q. And why couldn't the older device, why couldn't the liquid come out?

A. Because they had like a solid surface, either ceramic backing, or they had a balloon like, you know, one of the devices.

Q. All right.

A. So the moisture has no way to escape from the location. It just keeps collecting.

Q. Okay. And so yesterday's we were discussing that was the problem. So can you tell us, what was your solution to that problem of liquid buildup in the uterus?

[1203] A. Our solution was moisture transport system and the moisture transport system does exactly as the name defines it. The moisture, which, you know, squeezes out from the tissue, you know, the suction, removed it from the ablation site, and that's a pristine, clear, dry condition for that conducting the tissue. So the liquid would not build up, the electrode is always making contact with the electrodes, and the current always was passing through the tissue.

Q. Okay. And when, roughly, when did you come up with your solution of moisture transport?

A. 1996, when we started ablation.

Q. Okay. So what do you now see here?

A. This is the NovaSure electrode head. You can see the gold color, the electrode. You know, this white color is the inner layer, so this is two opposing for any given

moment, point in time. And here on the magnification, we can see how porous this electrode is.

Q. How porous?

A. Yes. It's a metallized fabric. Actually, what we used was this Lycra that we sent out to be metallized, and that's the way we formed the electrode in the early days.

Q. All right. If we could go to the next slide, please.

So what do we see here on the left? Start with [1204] the left.

A. So, you know, if you would strip away this electrode mesh, this porous electrode mesh, you would see, you know, the interior. And the most important part of that is the suction. And the reason why that was a very important portion, because all the moisture, the gap, the seems generated during the ablation process was suctioned out here and outside, to the outside of the uterine cover.

Q. Thank you.

MS. ELSON: Your Honor, I'm thinking, would it be all right if we put something beneath Mr. Truckai's mike to lift it up a bit?

THE COURT: I think you can -- yes. Do whatever you want to do. It doesn't matter to me.

MS. ELSON: I'm going to scrounge up a binder somewhere. There you go.

THE COURT: We'll see how it goes along. The microphone might be overloading a little bit, too, and cutting out. If it doesn't work out very well, we'll take a break.

MS. ELSON: I think he's taller than the mike was.

THE COURT: All right.

MS. ELSON: Okay. Thank you.

BY MS. ELSON: [1205] Q. Now, have you prepared an animation, Mr. Truckai, to illustrate the problem and your solution?

A. Yes, I did.

Q. Okay. So what do we see here?

A. So this is the old technology. What you what you can see here is a balloon.

Q. This is the old technology?

A. This is the old technology which existed prior to I started experimentation with our device.

Q. You'll have to talk a little closer to the mike.

A. Okay. So this device, you can see is based on a bubble surface. So it's a known permeable, nonporous. So those electrodes are glued on or molded on the surface.

Q. Okay.

A. And it's positioned inside the uterine cavity. You can see this triangle shape, generally speaking, and the device is approximating the size and the shape of the uterine.

Q. This was one of the older-type devices?

A. This is one of the older-type devices.

Q. Next, please. So what do we see here?

A. So if you would magnify only this area here, you know, that's what you see. You can see the tissue, which is the endometrium, and you can see this is the balloon and this is the balloon interior. And you can inflate this balloon with [1206] either air or fluid.

The point I'm trying to make here, this electrode is coming in close contact with the tissue. The balloon is forcing the electrode to be pushed against the tissue.

Q. So you can place the balloon and push the electrodes against the tissue?

A. That's right.

Q. Okay.

A. And you can see hear the positive and the negative. It's just showing the two, and current starts to flow through the tissue, heats up. The liquid is driven out from the tissue and builds up. It's pushing the electrodes apart and the current goes from one electrode to the other versus going into the tissue and going back to the other electrode. That's a fundamental issue of the technology.

Q. All right. And was that basically shorting the electrodes?

A. Technically, a different type of short. I would say 90 percent of the current channelled through the liquid versus channelled through the tissue.

Q. Okay. Instead of going to the tissue, where it's supposed to go?

A. That's right. The goal is to get energy into the tissue, not the liquid layer.

[1207] Q. Next, what do we see here? Next, please. What is this?

A. So this is, as you can see, the same triangle shape. This is a NovaSure device with, again, the two opposing at any given point in time, and it opens up and it's approximating the uterine cavity size and shape.

Q. Okay. Next?

A. This is --

Q. So how does your NovaSure solve the problem of moisture buildup?

A. So, again, if I magnify this little area, you can now see how this metallized fabric, you know, was constructed. And you can see there are huge openings on it.

So the current passes from this electrode structure into the tissue, but then moisture is generated. That moisture was actually drawn through that porous mesh.

Q. Can you see the next slide? The next step? What's happening here?

A. So this is just showing that, you know, that the electrode heats up, that moisture is drawn through this mesh, like a filter, and that suction that I mentioned before, all of this moisture was channelled through this, the porous mesh.

Q. Can we go to the next set. So what's happening here?

A. This is the suction that I just talked about, and that [1208] moisture is being drawn everywhere, every direction. It's pulling the seems, the moisture, keep it dry at all times.

Q. Okay. And do you have a name for your solution, or did you back then?

A. We called it just like, you know, named here, moisture transport system.

Q. You can take that down.

Did there come a time when you filed an original application relating to your moisture transport system?

A. 1998, May 8th.

Q. And if you could turn, please, in your binder, that one, to DTX-16.

A. Yes.

Q. Okay. And what is, what do you see there, Mr. Truckai?

A. I see my original patent, moisture transport system.

Q. Are you a named inventor on that patent?

A. Yes. I'm the named inventor.

MS. ELSON: Move to admit, Your Honor.

THE COURT: Any objection?

MR. WOLF: No objection, Your Honor.

THE COURT: It is received.

(DTX-16 was admitted into evidence.)

MS. ELSON: We can show it on the screen, [1209] please. Just zoom in at the top.

BY MS. ELSON:

Q. Again, now that we can all see it, Mr. Truckai, what is this?

A. This is the original patent that was filed. You can see here, which is the '520 patent, which we're talking about. It says the title. It shows the title that is the moisture transport system, as you can see here, for coagulation. You can see the inventor, the person, me here, and the others, you can see it has been

assigned to Novacept, and you can see that, you know, it's filed -- actually, you can see the patent application. It's for that one. It's 1998, June when it was filed.

Q. Can you go to the abstract, please. What do we see here? What is this telling you?

A. Very short, describes what the invention is, and the invention was permeable to moisture.

Q. Permeable?

A. That's right. Permeable to moisture although to mount an electrode carrying member on it. And through this permeated electrode member, the moisture can leave the ablation site.

Q. Is there a simpler way of putting electrode carrying member?

A. It was a host metallic fabric.

[1210] Q. The fabric we saw earlier?

A. That's right.

Q. If we could go to DTX Figure 23, please. DTX-16, Figure 23.

What do we see here?

A. This is the -- in the patent, this is a drawing representation of our proposed property.

Q. The porous fabric?

A. That's right. Electrode mesh.

Q. Okay. If we could go to Figure 26(a). What do we see here at the top, this upper half?

MR. WOLF: Your Honor, briefly, just for presentation purposes about claim construction issues, we would object to this line of questioning.

THE COURT: All right. I'm overruling it, but you're asking a continuing objection?

MR. WOLF: Yes, Your Honor.

THE COURT: All right. I will give you a continuing objection, but I have to know when the continuing objection stops, so when it stops, would you please stand and let me know?

MR. WOLF: I will do my best, Your Honor. Thank you.

THE COURT: Thank you.

Ms. Elson, you may continue.

[1211] MR. WOLF: Thank you, Your Honor. If we could go to the upper half and zoom in.

BY MR. WOLF:

Q. What do we see here, Mr. Truckai?

A. This is a magnified representation of our porous metallized mesh.

Q. The porous metallized mesh?

A. That's right.

Q. All right. And this is in the patent?

A. This is in the patent.

Q. And Figure 28, please. And if we could zoom in on the center figure. Thank you.

And what is this illustrating, Mr. Truckai, in your '520 patent?

A. The very thing I was talking about, that all the moisture, which was transmitted through that mesh was suctioned out through the suction, too.

Q. And did any of the examples, sometimes called embodiments described in your '520 moisture transport patent, describe a head with a, an exterior that liquid could not flow through?

A. None of them, because it would defeat the purpose. It would not work, just like the prior device.

Q. I'm talking about examples of your invention.

A. That's right. None of them.

[1212] Q. Now, do any of your early patent applications in this moisture transport family say anything about using plasma?

A. No.

Q. Now, given what we've seen in your '520 patent, what was your belief about the nature of the property that Novacept sold to Cytyc?

A. Well, the most important part of this moisture transport system, which we've been talking about.

Q. Okay. Can you say that just one more time slowly?

A. So the most is that the very subject, the moisture transport system for electrocoagulation is metallic mesh that all the steam moisture go through and suction out from the ablation cite.

Q. So that was your understanding what was sold to Cytyc?

A. That was my understanding.

Q. Did you ever think that when that what Novacept sold to Cytyc covered in a handpiece a head that used plasma to ablate tissue?

A. No.

Q. Now, could you turn to, let's go to column 19, and in particular, claim 1 of that same '520 moisture transport patent. What do we see here?

A. It describes the same thing we've been talking about. This is a fluid permeable elastic member. This is the same [1213] porous metallic fabric which we've been talking about.

Q. Okay. This is in the claims of the '520?

A. That's right. This is claim number 1.

Q. Do all of the claims in the '520 patent require 'fluid permeable elastic member.'

A. They are.

Q. Now, when you -- let's go back a little early to when you filed the application for this '520 patent.

Was there one claim, and if we could pull it up and see what I'm talking about. Let's zoom in on claim 31.

Was there one particular claim that you submitted along with your application that did not require a fluid permeable exterior?

A. Yes. When we filed the patent, the broader application, broader description of the patent, but the patent examination, one of the --

THE COURT: All right. Let's stop. We're losing the microphone.

This is a technical issue that requires somebody way over my training, so let's take five minutes, ladies and gentlemen, and ask IT to come in and restore the original configuration.

All right. So let's take five minutes.

(The jury was excused for a short recess.)

[1214] THE COURT: I think when we changed out the microphone, this microphone is not set up, generally speaking, to hook into the system for this particular input, and so they put something to kind of translate the two, and then they turned up the gain on this microphone, and I think it's shorting, it's cutting out. So we're going to have to go back to the original system, which the system is designed for, and then we'll just have to put it close to the witness and hope that it works.

MS. ELSON: Because what I'm hearing is that it's perhaps because he's breathing into the mike?

THE COURT: I don't know.

MS. ELSON: Okay.

THE COURT: But we'll have the IT guy come and then we'll figure it out.

MS. ELSON: Thank you, Your Honor.

THE COURT: So we're on a short break.

MS. ELSON: We appreciate the accommodation.

(Short recess taken.)

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(Proceedings resumed after the short recess.)

THE COURT: Please be seated.

Let's get the jury.

(The jury entered the courtroom.)

MR. WOLF: Your Honor, may I suggest I get the [1215] last question and answer?

MS. ELSON: I will recap.

MR. WOLF: Thank you.

(The jury entered the courtroom.)

THE COURT: Please be seated, ladies and gentlemen.

I believe we have the problem solved, so you may continue, Ms. Elson.

MS. ELSON: Thank you, Your Honor. We resolved the technical issue.

BY MS. ELSON:

Q. So, Mr. Truckai, you were looking at JTX-15, and in particular, the application that you filed that ultimately led to your '520 patent.

Do you recall that?

A. Yes, I do.

Q. Okay. And just to recap, first I just want to know, was this the one claim in that application that didn't require a fluid permeable exterior?

A. That's right.

Q. Okay. Did claim 31 ever issue as an actual issued claim?

A. No. It was canceled.

Q. And why did you cancel it? Yes, perfect. Yes, go ahead.

[1216] A. Because during, submitted it after the examiner brought it to our attention that it's prior art. We reviewed it and we agreed that this is too broad, and our invention is actually the proposed metallized fabric moisture transport system.

Q. Now, let's go back to the timeline to after you completed how you filed your application for the NovaSure product, what was your next project?

A. My next project was SurgeRx. It's a company, radiofrequency tissue, which means we, using a very simple instrument, sealing vessels and veins.

Q. Like blood vessels?

A. Like blood vessels. You didn't have to use staples or sutures.

Q. No need for a staple or suture?

A. It speeds up the procedure. You didn't leave anything behind.

Q. This is for sealing blood vessels?

A. That's correct.

Q. What do we see next? What is this?

A. This is probably the most recent product for the EnSeal product.

Q. This is the product you were just talking about you developed?

A. That's right.

[1217] Q. Okay. Can you just describe it briefly?

A. You can see these are instruments. This is what a physician holds. At the end it's a structure that has clamps, hold the vessels between, compress it together, apply energies, melts vertically the wall in the vessel, fuse it together and in the middle, we could dissect it.

Q. Very good. If we could have the next slide, please.

And what do we see here?

A. That's a trade show. We went to it every year. AAGL.

Q. American Association of Gynecological Laparoscopists?

A. That's right.

Q. Thank you.

A. So this is the largest surgical show for Gynecologists since our device was used for hysterectomy to cut through the ligaments, both sides of the uterus. You know, we had a booth there. You can see SURGRx.

Q. This is your company, SURGRx?

A. That's right.

Q. Can we zoom in on the left there? Is that the product we were just looking at?

A. That's right.

Q. So is SURGRx still around as a company?

A. No. In 2008, Johnson & Johnson, they brought it.

Q. They bought it?

A. Yes.

[1218] Q. Is your EnSeal product still being sold by J&J today?

A. Yes.

Q. Okay. If we could go to PTX-278, please.

THE COURT: So, Mr. Wolf, I assume your continuing objection has ended?

MR. WOLF: Yes, Your Honor. I apologize. Yes. Thank you.

THE COURT: Thank you. You may continue, counsel.

MS. ELSON: Thank you. Thank you, Your Honor. If we could have that up again.

BY MS. ELSON:

Q. Okay. So what do we see here, Mr. Truckai?

A. This is an AAGL journal they publish before the AAGL meeting. So this is the cover page of it. Fortieth year of AAGL.

Q. Do you attend the AAGL?

A. Every year.

Q. Every year. If we could go to PTX-278 at 2306. What are we looking at here?

A. This is a trade show floor where you can see the various companies that demonstrate their products for the surgeon.

Q. Is this part of the same brochure?

A. Yes.

[1219] Q. All right. And what is shown here highlighted in yellow?

A. You know, these are the companies who are selling, or the companies my product being sold one way or the other.

Q. Okay. So these are all companies who are selling a product that you developed?

A. That's right.

Q. All right. Let's go on briefly. What was your next project after SURGRx?

A. The next project was DFINE.

Q. Okay. And just briefly, if you could tell us, what did the DFINE product do?

A. DFINE product was for vertical compression and also for vertebral tumor.

Q. Vertebral tumors?

A. That's right.

Q. Okay.

A. So the issue was that of a woman's age or man's age, the bone density loses. You can have a fracture. It's extremely painful.

Q. It's extremely painful?

A. Painful. That's right. And the technique they used in the past was a bone cement. Bone cement.

Q. So the old thing was the bone cement?

A. And it took about 30 minutes and it resolved the pain, [1220] so it was very effective. However, it did not resolve the compression. The patient stayed in a hunchback.

Q. The patient would stay hunchback?

A. That's right. We came up with a brand-new technique where we were able to increase the viscosity of the bone cement, that we elevated the height of the vertebral body. It's not just the pain, but the patient has a straight posture.

Q. So the old solution to carry the pain, that the patient was still hunchbacked?

A. That's correct.

Q. With your solution, you took care of the pain and the patient was able to straighten up?

A. Yes.

Q. And is DFINE somewhere else?

A. Yes.

Q. Okay. Were they acquired at some point?

A. Yes.

Q. Now, what was your next company?

A. Minerva.

Q. Okay. Now, when did you found Minerva?

A. 2008.

Q. Is Minerva a Delaware corporation?

A. It is.

Q. Okay. Now, so by the time you started Minerva, how [1221] many years had it been since you designed the older NovaSure product?

A. About ten years.

Q. Ten years?

A. Yes.

Q. And are you president -- at the time when you founded it, were you president and CEO of Minerva?

A. Yes, I was.

Q. Okay. Did there come a time when someone else assumed that position?

A. Yes. In 2011, Dave Clapper took over for me.

Q. Okay. And did you remain on the Board of Directors?

A. Yes, I am.

Q. Okay. At a high level, what's your role as the director?

A. I go to the board meetings. Management of the company, make the presentation at the company. R&D, sales, various corporate subjects.

Q. Okay. Including sales?

A. That's right.

Q. Now, were you a member of the board when Minerva began to actually sell its product?

A. Yes, I was.

Q. Okay. And so did the board have to approve the launch and sale of Minerva's product?

[1222] A. I'm not sure the board had to approve it.

Q. Well, collectively, did the board approve the launch and sale of Minerva's product?

A. Absolutely.

Q. Okay. And let's see. We'll move on.

So are you aware that Hologic has alleged that Minerva copied the old NovaSure product, the handpiece?

A. Yes, I am.

Q. Okay. And let's see. I guess we've seen it now several times. If you held up the two devices, the handpieces side by side from a distance, they appear to have a similar shape. So why do you believe that, nevertheless, Minerva did not copy the NovaSure product?

A. It can be very deceiving. You know, there are devices on the market prior to NovaSure that has very similar shape. You know, handle, controller, handpiece.

Q. Okay. Now, do you personally have knowledge of an older device that predated even the NovaSure with this same general shape?

A. Yes, I am.

Q. Okay. And what device was that?

A. That was the Vesta device.

Q. Now, when did you become aware of the Vesta device before you completed your design of the NovaSure?

A. In 1995, when I reviewed their patent.

[1223] Q. Was that before you completed your design of the NovaSure?

A. Way before.

Q. Way before?

A. Way before.

Q. Okay. Can we see the next slide, please?

And what are we looking at here?

A. This is the Vesta disposable device. You can see a slender shaft, a handle. What you don't see here, the connection that goes to an outside controller. On the shaft, you can see the tip.

This is enclosed within this, so the sheath was pulled back, exposing the triangular shape. You can see the electrodes on the surface of the balloon.

Q. So am I correct that this portion here is inside here?

A. That's correct.

Q. Okay.

A. It's easier at this point, the physician, when they put it into the uterus, they pull back the sheath and exposing this triangle shape, applicator.

Q. Is this the portion that would go inside the uterus?

A. That's right. I call it the business end. This is the most important part of the entire product. The rest of this is -- it's really just a shaft and a handle. Every [1224] device has a shaft and a handle.

Q. And was the Vesta system that you even be countered in '95, I think you said, was that an endometrial ablation device?

A. Very specifically designed for endometrial ablation. They called it at the time global endometrial ablation.

Q. Let's go to the next line. What do you see here?

A. The same thing. You can see the business end is enclosed within the shaft, the handle, and you can see the controller that they used, and that's it. So that is the entire system here.

Q. Okay. And if we could go to JTX-18, the cover, and zoom in on the upper half, please.

Okay. What do we see here?

A. So --

Q. If we could start with what's up in the upper right?

A. So just like with every patent, you can see this is the patent number. The last three digits, the '470 patent. You can see, you know, it was Vesta Medical who it was assigned to. That was the company, intellectual property. You can see it was filed in 1993.

You also can see it was issued in 1995, August 22nd, about a year earlier before we started the NovaSure project.

Q. And if we could also highlight the title. What does this tell us?

[1225] A. The title, it just says this is a device for endometrial ablation.

Q. Okay. Now, if we could go to Figure 12 of that same '470 patent, so that's the patent?

A. Yes.

Q. And what do we see here?

A. This is a drawing representation we just talked about.

Q. All right.

A. You know, the triangle shape, applicator head, the slender introducer, some sort of handle, and then the controller.

MS. ELSON: If I may, Your Honor, step over here.

THE COURT: Which exhibit are you handling?

MS. ELSON: Thank you, Your Honor. It doesn't have a label, but this is the -- oh, here we go. JTX-47.

THE COURT: Thank you.

MS. ELSON: It's the NovaSure Advance, I believe.

THE COURT: All right.

BY MS. ELSON:

Q. So, Mr. Truckai, did the -- what's shown there have the same general shape as the NovaSure?

A. It has to. You know, I cannot put a square device into a triangle shape.

[1226] Q. Okay. And your patent was filed in 1993?

A. That's correct.

Q. Okay. Can we go to the next slide, please.

So what do we see here? Let's start with the right.

A. Okay. So, again, just as I described, 190 is a triangle shape, applicator head. You can see a slender tube, which actually is slidable, so you can hide head to put in. You can see a handle. It's nothing specific, but the handle was described in the patent to objection date the sheath, you know, to move over enough from the energy applicator head, and a controller that controls the radiofrequency ablation process.

Q. Now, at the time you filed your '520 application for your moisture transport invention, did you disclose this earlier Vesta patent to the Patent Office?

MR. WOLF: Your Honor, we're back to the continuing objection.

THE COURT: Overruled, and you may continue.

MS. ELSON: Thank you, Your Honor.

BY MS. ELSON:

Q. So did you disclose this older Vesta patent to the Patent Office?

A. Yes, I did.

Q. And why was that?

[1227] A. For the very same reason you asked me at the very beginning yesterday. Do I value other intellectual property of others?

Q. Do you value?

A. I am. And I feel it's very important for me to provide the Patent Examiner all the intellectual

property which relates to the product I'm submitting for invention, to evaluate that subject, and in this case, it happened. You know, this is a very important disclosure to the Patent Office.

Q. All right. Could we go, please, to the background section of DTX-16, the '520 patent, the written part of the patent, of the background section, please.

All right. And with a do we see here, Mr. Truckai?

A. So the patent we filed, the '520 patent, we clearly described that there is a device out there, you know, prior to our invention.

Q. Prior art?

A. Moisture transport. Prior art. It describes that it has an expandable bladder with electrodes on its outer surface.

Q. Just so we're clear, that's the '470 patent you're disclosing to the Patent Office in your application?

A. That's right. That's right. That was one of the [1228] patents among many that we disclosed.

Q. Now, did you consider this general shape of the NovaSure handpiece to be your invention?

A. Not at all.

Q. Okay. And what did you consider your moisture transport invention to be?

A. Exactly what you just said. This is the business end, moisture transport that posed electrode mesh that holds the seem to go through and away from the ablation site.

Q. Now, I'd like to just now jump ten years into the future and talk about Minerva's device.

What did you consider to be the most critical component of Minerva's device?

A. Very much the same thing. You know, the very end, the end of the applicator, because that's what's doing the procedure.

Q. And what does Minerva call that business end of its device?

A. We named it PFA, plasma formation array.

Q. Plasma formation array?

A. That's right, because it really describes the energy source we're using the plasma energy to ablate the tissue.

Q. All right. Can you just tell us just briefly, what is plasma? Briefly, if you can?

A. It's ionized gas, so it doesn't tell us too much. But [1229] the best way I can describe it, if you look up in the sun, it's all plasma.

Q. Okay.

A. So plasma is the most common material, you know, in the universe.

Q. So could we put up slide DDX-7-36, please.

Okay. So what do we see on the left?

A. On the left, the device we've been talking about, the porous electrode mesh with a metallized fabric.

Q. And on the right, ten years later, what do we see?

A. So this is, you know, the Minerva energy applicator head. This is plasma energy. What you see here, you know, internally, circulated. Those little filaments, okay, they are scanning the silicone

material membrane surface and they're looking for on the other side tissue which hasn't been thermally treated yet.

Q. Ablated?

A. Ablated.

Q. Now, did you ever believe, or were you aware of anyone at Minerva believing that Minerva covered the NovaSure?

A. No, I didn't. I don't know how. So different.

Q. Okay. Now, what did you -- let's see. Is there anything else like Minerva's plasma formation array on the market as far as you know?

[1230] A. I'm not aware of anything remotely.

Q. As far as you know, do any of the NovaSure variations along the way use plasma in any way to ablate tissue?

A. No.

Q. All right. Have you prepared a summary of the, what you consider the advantages of the Minerva over the NovaSure?

A. Yes, I have.

MS. ELSON: Can we bring that up, please?

BY MS. ELSON:

Q. Okay. Just briefly, we've heard some of this, but can you just briefly touch on what some of the advantages are as far as you believe?

A. So, first of all, you have a very smooth slippery silicone membrane, non-stick. NovaSure has a rough metallized fabric. We are controlling the ablation steps. We call them plasma streamers. You can see the

little filaments kind of moving around. Those are the ones seeking out where there is un-ablated tissue. So this is a completely different mechanism. You know, the plasma streamers. We have a smaller diameter. That means, you know, that it's easier to insert.

We used a small portion of the power. You know, you say here one-fourth of the power. Very likely, that's one fourth of the power, which is great, because you want to [1231] put the minimal amount of current into the patient. Because of the silicone, you are able to retain the moisture.

My pointer died.

Q. I got it.

A. Sorry about that. So we weren't able to -- there's nothing moving the moisture. Keeping the tissue moist, it's very important, because it's very easy to remove the device. With NovaSure, many times what happened, it's almost like the tissue is seared.

Q. Seared?

A. That's right. Yes. So seared to the electrode. It was very hard to remove. Many times, it would pull, coagulate the tissue off.

So retaining the natural moisture is very important. And because of that, we had less tearing and bleeding, which is very important for the procedure, because you -- other issues are not favorable to the patient.

Q. Less tearing and bleeding?

A. That's right. It's always better. This membrane doesn't over heat, because it keeps the moisture to maintain the equilibrium of the surface.

Q. Okay. Now, did all of this factor into your belief that you did not copy the NovaSure?

A. At the time, I really believe and I still believe.

Q. Now, have you prepared -- I'm sorry. Can we show [1232] JTX-32 and JTX-24, just the two charts of the SSED, please.

Okay. What do we see here?

A. This is the safety and efficacy chart approved by the FDA.

Q. So what's the upper one?

A. So the upper one is the Minerva, as you can see, and the lower one is the NovaSure.

Q. Okay.

A. Effectiveness.

Q. And what is the difference in study success rates?

A. This one shows that the Minerva device was significantly higher. And if you are looking at amenorrhea, complete stop of bleeding.

Q. Complete stop of bleeding?

A. Complete stop of bleeding. It's virtually double.

Q. Okay. Now, did this factor into your understanding that you didn't copy the NovaSure at all?

A. I think -- I think this is the other proof that they are different, and it is factored in, because if we would have the same technology, we would have the same result.

Q. I'm sorry. Can you say that again?

A. So if we would have copied the NovaSure, we would have ended up with the same result. Same technology, same process.

Q. You would have expected the same result?

[1233] A. Same result. This is significantly different.

Q. Now, did Minerva's rates stay the same since 2015?

A. I believe they improved.

Q. Okay. Can we see the next slide, please.

Can you tell us what we're looking at here?

A. So after 2015, the last year the FDA agreed that Minerva success rate is 93 percent versus the 77.7 percent of NovaSure and the amenorrhea rate is 72 percent versus 36 percent. I think we additionally proved the point we were making before.

Q. Okay. Now, let's go back to our timeline. We left off where you started Minerva.

And did you at that time, as you were about to found Minerva, did you immediately think to use plasma for specifically endometrial ablation?

A. No.

Q. Okay. Can you look in your binder at DTX-1367, please.

A. One second. Oh, DTX. I'm sorry.

Q. DTX-1367. There are two volumes. Do you have it?

A. I see it.

Q. Okay. And it's probably best if you turn to the second page. There we go.

What is this document?

A. This is a patent for tissue ablation.

[1234] Q. Okay. Is that your patent?

A. This is my patent, yes.

Q. Okay.

MS. ELSON: Your Honor, move to admit.

MR. WOLF: Subject to --

THE COURT: Objection?

MR. WOLF: Subject to prior objection, no objection, Your Honor.

THE COURT: It's received.

(DTX-1367 was admitted into evidence.)

MS. ELSON: May we publish, Your Honor?

THE COURT: Yes, you may.

BY MS. ELSON:

Q. Okay. If we could see the cover of DTX-1367.

And what do we see here, Mr. Truckai?

A. So if we go in the same order before, you can see this is the patent number, which is the '068 patent, and it says it's a tissue ablation system. I'm the primary inventor, and it has been assigned to Hermes innovation, which is my intellectual property holding company. I put many patents into the corporation.

Q. Who owns this patent now?

A. Minerva.

Q. And you're a named inventor; is that correct?

A. Yes.

[1235] Q. Now, did you in your -- let me just ask you generally. So was this patent directed to use of plasma specifically for endometrial ablation yet?

A. No, because this technology is very valuable in many other procedures.

Q. So were you exploring?

A. Exploring, you know, other areas where we can use the technology.

Q. Okay. Now, did you disclose even in this patent the older moisture transport patent, the '520, we were looking at earlier?

A. Yes, I did.

Q. May we go to that, please? Page 2, I believe. All right.

This is -- at the top, this is page 2 of the patent?

A. That's right.

Q. Okay.

A. That's right.

Q. You have it in front of you, too?

A. Yes.

Q. What is all this listed?

A. This is all the patents I found I have to disclose to the Patent Office, to the examiner, to evaluate if this is a new novel technology or not. So I felt even though it's my [1236] own private patent, I felt compelled to disclose it, because they have to see what's out there and make a determination, is it patentable or not.

Q. All right. And what do we see here?

A. This just shows that it was disclosed to the Patent Office, the existence of the '520 patent.

Q. This is the old moisture transport patent?

A. Yes.

Q. Now, if we could go to the abstract. Go back, please. The page, the cover. What is this telling us?

A. It's pretty much describing the invention. It says that you have an enclosed chamber. You are creating plasma within the chamber, which is ionized plasma.

Q. If we could go to Figure 27 of your same '068 patent, please. What do we see here?

A. This technology easily can be used in a cardiac application, where you want to ablate some cardiac tissue responsible for arrhythmia.

Q. Just generally backing up, this is very early just before you founded Minerva?

A. Yes.

Q. And were you exploring different uses of plasma at this point?

A. Yes.

Q. Okay. Can we go to the next figure, 33, please.

[1237] Okay. What do we see here?

A. This is your -- this is the stomach and this is the area which needs to be ablated for eliminate cancerous cells.

Q. Okay. Did there come a point when you began to hone in on the use of plasma specifically for endometrial ablation?

A. I mean, realized the capability of the technology, and we found it's very applicable for ablation and would improve lots of shortcomings of the prior technology.

Q. So you began to focus on endometrial ablation?

A. Yes.

Q. Would you please look at your binder, and DTX -- yes, I'm sorry. So there's a series here. DTX-71. Look at that first.

A. DTX-71.

Q. Take a look. And we've seen, what is it?

A. This is a picture. I'm assuming it's a video.

Q. This is the same video of the plasma formation we've seen earlier?

A. Yes.

Q. Okay. Now, if you could look also, just quickly at DTX-103 to 118. Just flip through those and let me know generally what those are.

A. They are -- seem to be older experimental videos which [1238] were made.

Q. And were these videos you had created of your prototyping?

A. Yes, in our lab.

Q. Roughly, when was that?

A. 2008/2009.

Q. So are these video records of your work that you created in the ordinary course of your prototyping?

A. Yes.

Q. Okay.

MS. ELSON: Your Honor, move to admit, that would be DTX-71, DTX-103 to 118.

THE COURT: Any objection?

MR. WOLF: No objection, Your Honor.

MS. ELSON: All right.

THE COURT: The exhibits are received.

(DTX-71 and DTX-103 to DTX-118 were admitted into evidence.)

MS. ELSON: Thank you.

BY MS. ELSON:

Q. Let's play some of these videos for the ladies and gentlemen of the jury of your prototyping work. Let's show the earliest one, DTX-103.

Okay. First of all, before we roll it, what are we looking at here?

[1239] A. That was one of the early experts where we put a silicone membrane on a tissue. You can see this is under the device. Square box.

Q. This is a box?

A. That's right. So you can see through it with an injecting argon gas.

Q. You're injecting argon gas?

A. Into that chamber and we're looking at how the plasma formation took place, how it reacted, and studying, we have to exchange argon.

Q. Okay. Can we play it?

A. Sure.

MS. ELSON: Go ahead.

(Video played.)

THE WITNESS: You can see, once you started somewhere, that plasma formation, it spreads throughout the entire chamber.

You can see here, you know, you have long plasma. I want to point out, this is plastic, you know, and it

doesn't melt. So it's ablating the tissue. The plasma filaments are hitting the membrane and kinetic energy of the plasma is going to heat generally, heat within the silicone membrane.

BY MS. ELSON:

Q. So this is one of your early prototypes?

[1240] A. Yes. It was very exciting to see how that technology works.

Q. Okay. Could we see DTX-105, please.

What do we see here? And you can ask to zoom in on any part.

A. A squid.

Q. A squid? Okay. And what is it?

A. So this is all the inflow and outflow. You can see how slender is the shaft. And down here, that was the earliest prototype we were able to put together. You can see the silicon chambers. We put electrode inside. We flow argon gas in and out of the chamber.

Q. Did this early prototype have two chambers?

A. That's the separation. One chamber and another chamber.

Q. And can we play or bring up 106, please.

Okay. Before we roll it, what are we looking at?

A. So this is our squid. You can see nobody expended it. We put in this argon gas. I it expended. Vaguely, you can see the electrodes.

Q. Can we play it now?

A. We'll be putting the argon gas. You can see the same plasma formation happening, just like the other one. Not perfect. You can see it's expending and

contracting. There [1241] was no way for us to know how this technology based, because there was no prior art. So I couldn't learn from anybody that experiment. Just like this one, you can see it exploded. So it wasn't a very good day for us.

Q. Is this a setback?

A. I would say so.

Q. Okay. So can we go to DTX-107. And what do we see here?

A. Now, this is another experiment, you know.

Q. Can we just roll this one?

A. Where we lose the two chambers. This is a single chamber now.

Q. So now you're down to a single chamber?

A. That's right.

Q. Okay.

A. So then the expert is thinking, can we make this more uniform in nature. Can we control the plasma formation and ablation process more, especially that depth of coagulation of the tissue.

Q. Would plasma control an issue?

A. I can't even describe the number of issues.

Q. Okay.

A. Exchange rate, voltage, keeping the argon gas pure, you know, during the process. I mean, I can talk a whole day about it. It was a lot of bad days.

[1242] Q. Unfortunately, we don't have a whole day.

So DTX-108, please. And what do we see here?

A. You can see it's resembling a balloon.

Q. Can we zoom in on the tip there. Okay.

A. Again, it's still crude, but now you've got the triangle shape. Unfortunately, it's not transparent, but maybe it has the electrodes inside and the gas outflow for controlling the argon gas.

Q. Okay. Now, if we could go to DTX-109. Okay. Now, before we roll it, what do we see here?

A. That was very exciting. That was one of our better prototypes. You can see now it's a nice triangle shape and the internal electrodes, because the internal electrode is not touching the shape.

Q. So far are we seeing these videos in chronological order?

A. Pretty much.

Q. Yes? Okay. And if we could go to DTX-111, please.

A. Yes.

Q. Okay.

A. This is, again, just showing that you see much finer this solution of plasma, more controlled. This is just a configuration, very close to what we have today.

Q. If we could go to 113.

A. And this is, again, very, very close, but it's still [1243] not the current product. But you can see here, now we have the length, improve the flexure. Everything was worked out.

What you can see here, you put the external electrode on it. Aluminum foil.

Q. Aluminum foil?

A. Yes.

Q. At this time?

A. At this time we used whatever was in the kitchen. We just glued it on and we had a beautiful plasma formation.

Q. What does the final device use in place of the aluminum?

A. We have gold.

Q. Gold. Now, if we go to DTX-115, please.

And what are we seeing here?

A. This is again an experiment with the same device. Actually, you can see here.

Q. And what is the device sitting on?

A. It's liver tissue.

Q. Liver tissue?

A. Yes.

Q. What kind of liver tissue?

A. We use pork or cow liver.

Q. Pork or cow liver?

A. That's right. Porcine or bovine.

[1244] Q. All right.

A. Because it has the closest consistency to endometrial tissue.

Q. Okay. If we could go to 117, please. And were you still having issues at this time?

A. Yes. As you can see, this didn't control very well the process. So move forward, a setback. I mean, years of development.

Q. Right. Let's look at again the final product, the final result of all of your research and development. What do we see here?

A. Now you have the gold electrode on the outside. Inner electrode, all the proportions for plasma formation has been finished.

Q. So this is the commercial device?

A. This is the commercial device.

Q. And did there come a time when you decided to file patents on your own plasma based solution for endometrial ablation?

A. Yes, I did.

Q. All right. If you could turn back to your binder, please.

A. Okay.

Q. And it's specifically DTX-1368 to start with.

A. 13?

[1245] Q. 1368.

A. DTX?

Q. DTX-1368, and just tell me what you see there.

A. I do not have DTX-1368. Oh, I'm sorry. 1368.

Q. Eight.

A. I'm sorry.

Q. And what is it?

A. This is tissue ablation patent.

Q. Okay. And just to deal with them together, if you go to the next one, DTX-1369, what is there?

A. Again, this is our endometrial ablation patent.

Q. Okay. And roughly, when did you file these two patents?

A. In 2009/2010.

MS. ELSON: Okay. Move to admit, Your Honor.

MR. WOLF: Same objection as before.

THE COURT: Overruled. 1368 and 69 are received.

MS. ELSON: Thank you, Your Honor.

(DTX-1368 and DTX-1369 were admitted into evidence.)

BY MS. ELSON:

Q. So if we could just bring up one of the two for now.

So this is DTX-1369. And before we start that.

MS. ELSON: So may I approach the witness, Your [1246] Honor, just to show him something?

THE COURT: Yes, you may.

BY MS. ELSON:

Q. I'm going to bring you, Mr. Truckai, these two documents. What are these? What are the two items I've just handed you?

A. This is the two issued patents describing our technology.

Q. Are these the originals?

A. These are the originals.

Q. From the Patent Office?

A. From the Patent Office. This is like a piece of deed or property.

Q. Thank you.

Now, let's take a look at one of your two plasma formation patents. DTX-1369. And if you could just briefly again walk us through what we see here as far as the number, title, and your name, et cetera.

A. The patent issued. The last digit is 732. The patent was issued in 2013, August 6th. It's describing an endometrial ablation device and system, such as devising the system. It's naming me the primary inventor and one more person. It's assigned to Hermes Innovation.

Q. Who owns these patents now?

A. Minerva Surgical.

[1247] Q. Okay.

A. And you can see that it was filed in 2009, October 26th.

Q. Okay. Go to the abstract, please. And what does this tell you?

A. Pretty much it's describing just like a prior patent. Specifically, an endometrial ablation device.

Q. Now it's specifically endometrial ablation?

A. Yes. It's still having flute-like interior chamber.

Q. If we could go to page 2 of this same patent. Again, what are all of these columns?

A. These are the referenced patents.

Q. That you disclosed?

A. We disclosed to the patented office.

Q. If we could zoom in on that one at the bottom. Once again, did you disclose your old moisture transport technology to the Patent Office?

A. Absolutely.

Q. Okay. Now, let me ask you, why you didn't you disclose the '348 patent that's in this case?

A. I couldn't. At that time, it wasn't in existence.

Q. It didn't exist?

A. No, it did not.

Q. Okay.

A. Years later.

[1248] Q. Okay. Very good.

Now, I'm going to change gears now and ask you just a few questions about Minerva's red/green indicator, so this little red/green item here on the handle.

THE COURT: So why don't we take our morning break before you do that, counsel.

MS. ELSON: Yes.

THE COURT: So let's take ten minutes, ladies and gentlemen.

(The jury was excused for a short recess.)

(Short recess taken.)

- - -

(Proceedings resumed after the short recess.)

THE COURT: Please be seated. If we can get the jury.

MR. WOLF: Your Honor, when do you want to break for lunch today?

THE COURT: I don't know. Sometime around noon. Before, but not after. The jury doesn't listen to you after noon when the clock strikes, so sometime around noon. If at a quarter till, we'll break at a quarter till.

MR. WOLF: We'll still be on cross-examination.

THE COURT: So if your cross-examination is going, then we'll go until noon, but if we're finished with him, we might stop.

[1249] MR. WOLF: I was just trying to figure out if I get to a module at five of, should I flag Your Honor?

THE COURT: That's fine.

(The jury entered the courtroom.)

THE COURT: Please be seated, ladies and gentlemen.

You may continue your examination.

MS. ELSON: Thank you, Your Honor.

BY MS. ELSON:

Q. So, Mr. Truckai, just to wrap up on the three patents we just walked through collectively, that was DTX-1367, 1368 and 1369.

Are those three collectively, do you mind if I call them your plasma formation patents?

A. You may.

Q. Okay. And does Minerva actually practice its own plasma formation patents in its system?

A. Yes, they do.

Q. Okay. Very good. And these plasma formation patents, do they have anything to do with the older NovaSure technology?

A. I don't believe so.

Q. Okay. But you disclosed the older NovaSure technology in the form of that '520 patent?

A. Absolutely.

[1250] Q. Okay. And, you know, I just want to ask you: You've been accused of copying NovaSure in this case. How do you feel about that?

MR. WOLF: Objection, Your Honor. Mr. Truckai has not been accused of anything.

THE COURT: Please?

BY MS. ELSON:

Q. Excuse me. Minerva, your company, has been accused of copying the NovaSure. How do you feel about that?

A. Speechless.

Q. Does it trouble you?

A. Yes.

* * * *

[1256] BY MS. ELSON:

Q. Okay. I'm going to change topics, Mr. Truckai, and ask you just a couple questions.

[1257] Let's go back to 2004, when the board sold Novacept to Cytyc. Okay?

Now, at the time of the sale of Novacept to Cytyc, what percentage of Novacept did you own personally?

A. Two or two-and-a-half percent.

Q. Two or two-and-a-half percent?

A. Somewhere around there.

Q. Now, how much did Cytyc pay for Novacept?

A. $325 million.

Q. Okay. So if I had my math right, you -- if you owned, let's go with the upper bound, two-and-a-half percent.

You made about 8 million from that sale personally; is that right?

A. That sounds about right.

Q. Okay. So can you tell us, what happened to the other $317 million from the proceeds of that sale?

A. A large portion went to the investors and a large portion went to the people who developed it and worked within the company.

Q. Employees?

A. Technology. The employees, yes.

Q. All right. So was that the remaining 97.5 percent of the sale went to others?

A. Yes, it did.

Q. Okay. Now, one last topic here. Would you please [1258] turn in your binder to tabs PTX-22 and 23.

A. Okay.

Q. Now, what do you understand these to be?

A. If I recall right, it's the video which I shot back in 1996 or around.

Q. So these are screen shots of videos you took in, when did you say?

A. 1996.

Q. Okay. And did you create these videos?

A. I did.

MS. ELSON: I move to admit, Your Honor.

MR. WOLF: No objection.

THE COURT: 22 and 23 are received.

(PTX-22 and PTX-23 were admitted into evidence.)

BY MS. ELSON:

Q. So let's start with PTX-22. And if we could just start, not play it. Just bring it up.

Okay. What is this? This is before you completed your design of NovaSure?

A. Yes. We had nothing. That was just a very rough fabric. We created insulated layers. We had no triangle shape, no handle. We didn't even have a generator.

Q. This is very early?

A. Very, very early.

Q. Okay. So give us some context. What is this? Why [1259] did you create this video?

A. I'm sorry?

Q. Just some context. Why did you create this video? What is it?

A. I had to go to Johnson & Johnson and ask for an investment and they asked me to create a description of the technology.

Q. Okay.

MS. ELSON: Can we play it now?

(Video played.)

BY MS. ELSON:

Q. So --

A. So --

Q. So just very briefly, what are we seeing here?

A. We can see the -- you can see the coagulation in the tissue, so the tissue. Anywhere where the tissue turns white is being killed or ablated. An area, you can see that the depth is being controlled by the center, the center distance of the electrodes.

You can see -- you can have a coagulation where the depth of coagulation goes, and then stops.

Q. Okay. I really only have two questions with respect to this video. Are we watching an ablation using Minerva's device?

A. No.

[1260] Q. Okay.

A. This is -- you can see different, probably different everything.

Q. How many years was it until Minerva's device even existed?

A. Twelve, 13, something like that.

Q. Sorry?

A. 12 or 13, or something like that.

Q. So this is about 12 or 13 years before Minerva's commercial device even existed?

A. Something like this, yes.

Q. And so if I was showing this to someone and telling them or suggesting to them that this is what they would get as a consequence of using Minerva's device, would that be true?

A. No, not at all.

Q. Now, is this using even the NovaSure?

A. No, it's not. It's a concept, a technology concept.

Q. Okay. If we could now play PTX-23.

Actually, can we go back on the years for a moment. You said you did this in '96?

A. That's right.

Q. And you formed Minerva in 2008?

A. Yes.

Q. So how many years was that?

[1261] A. That's about 12 years, but, you know --

Q. You're right, you're right.

A. In 2008, I just did the math.

Q. All right. So PTX-23, please. And if we can just ROLL it.

Okay. I have basically the same question: Are we seeing proof of concept, whatever you call it, using Minerva's device?

A. No.

Q. Okay. And did Minerva's device even exist?

A. No.

Q. This was also '96?

A. Yes, same time.

Q. Was this even using the NovaSure?

A. No.

Q. Did this predate the NovaSure?

A. Way before.

Q. Okay. So if I showed this to somebody and said or suggested, implied this was somehow reflecting a

consequence of what would happen if you used Minerva's device, would that be accurate?

A. Not at all.

Q. Okay.

MS. ELSON: That is the end of my direct examination, Your Honor. Pass the witness.

[1262] THE COURT: Cross-examination, counsel.

MR. WOLF: It will take us a moment to set up.

THE COURT: Yes, that's fine.

MR. WOLF: I promise we will not use all of these documents.

(Pause.)

THE COURT: Whenever you are ready, Mr. Wolf, tell me, and I will turn the microphones on.

MR. WOLF: Yes, Your Honor. Thank you. I'm ready. Thank you.

THE COURT: All right. You may proceed.

CROSS-EXAMINATION

BY MR. WOLF:

Q. Good morning, Mr. Truckai.

A. Good morning.

Q. It is an honor to speak with you, and I speak for everyone in the room when we say we were truly impressed with the history of your development and your contribution to medical science.

I want to talk to you first about the board that you talked about, the board of directors. If I recall correctly, you said board made important decisions with regard to the Minerva product; is that right?

A. The board advises the CEO how to proceed, but the CEO makes the decision.

[1263] Q. The board advises on significant decisions?

A. The board approves significant decisions.

Q. Okay. So let's find out who the board is and who makes those decisions.

And just so we're clear, you are a member of the board?

A. I am.

Q. And you have been the whole time Minerva has existed?

A. Yes.

Q. You've never actually been an employee of Minerva though; right?

A. No.

Q. I asked my question badly because it was a double negative. Have you ever been an employee of Minerva?

A. No. I was always a CEO or board member.

Q. Now, given your other business interests, you don't spend much time on Minerva; is that correct?

A. I spend whatever I have to.

Q. But you don't spend time on Minerva; right?

A. Not anymore. Not on a daily basis.

Q. Yes. And Mr. Clapper is fully capable to run the company in your opinion; is that right?

A. Absolutely.

Q. All right. So you don't need to?

A. I don't.

[1264] Q. All right. Now, from 2008 to the present, Minerva has raised about $125 million of debt and equity; is that right?

A. It sounds about right.

Q. And I want to get a sense of who has been investing and what the role is.

Let's start with a company called Novo Holdings. Are you familiar with that?

A. Yes, I am.

Q. They are a global venture company?

A. They are a very large venture firm.

Q. Could you explain to the jury what a venture firm is?

A. Venture firms, these are inventors who put money into a company for -- in exchange for a certain percentage of ownership in the company.

Q. Okay. So Novo, do they have a board seat?

A. Yes, they do.

Q. Okay. Could you explain how venture companies come to have a seat on a board of directors?

A. They, they come on the board as part of the investment. Very simply, you know, you want X amount of money? Okay. I want X percent of the company, and I also want to be on the board of the company. And it depends on the situation where the company is. You can take the offer [1265] or not.

Q. Right.

A. So most of the time, you know, companies do take those offers, and they bring them on the board.

Q. And sitting here today, roughly, what percentage of Minerva does Novo hold?

A. I have no idea.

Q. Would Mr. Clapper be in a position to know that, do you think?

A. Probably, he could give you a more accurate number.

Q. Okay. Let me ask the question a couple more times then. If you don't know, that's just fine.

Vivo Capital, is that another venture capital company that has invested in Minerva?

A. Yes.

Q. And they're headquartered in Beijing, Shanghai, Taipei and Palo Alto; right?

A. know only the Palo Alto people.

Q. And they have a seat on the board; is that right?

A. They do.

Q. Do you happen to know what percentage of Minerva Vivo Capital owns?

A. I can't give you a very accurate answer.

Q. Okay. New Enterprise Associates is another global venture capital company; is that right?

[1266] A. That's right. One of the largest.

Q. And they have a seat on your board as well?

A. That's correct.

Q. And I will ask the same question, but don't worry. Do you know what percentage they own?

A. Double digit.

Q. Double digit?

A. Yes.

Q. Okay. Versa, another San Francisco venture capital company that has invested in Minerva; is that right?

A. That's correct.

Q. Do you have a sense collectively what these venture capital companies and similar companies own in Minerva altogether?

A. Most of it.

Q. And you and your family personally own about five percent of Minerva; is that right?

A. 4.9.

Q. Now, the goal of the venture capital companies that own Minerva is to sell Minerva as a company to some other big company; right?

A. Not necessarily.

Q. Well, are you familiar with the term liquidity event?

A. Oh, yes.

Q. What is a liquidity event? Could you tell the jury?

[1267] A. A startup has technically two exits, successful exits. One is to go for an IPO, which you go on the stock market. Another way to go is if a larger company can purchase the company, and they pay you

money for the company. So either you go IPO or you go into a merger and acquisition.

Q. These venture companies that own a fair majority of Minerva, they're looking to do one of two things. Either get bought by someone big like Johnson & Johnson or Medtronic, some of the companies that bought your previous startup company, or alternatively go into the stock market and do an initial public offering; is that right?

A. I can't speak for that the venture partners.

Q. But you've had board meetings where they've talked about strategies and what you are trying to do with the company; is that right?

A. We are at the stage where we want to run the business, so we want to be involved with the business, and we want to be -- that's the stage we're at the company.

Q. You would agree it's important to the venture companies that Minerva reaches a liquidity event?

A. I think it's very important for all of us.

Q. Now, this case is about the '183 and the '348 patents. You understand that?

A. I do.

Q. All right. Can we call up on the screen JTX-001, and [1268] that's the '183 patent, what we sometimes call the procedure patent. And you are one of the named inventors; is that right?

A. That's right.

Q. And you would agree that you had a significant role in developing the technology in the '183 patent?

A. Yes, and I'm proud of it.

Q. And in this case you understand that it has been determined that Minerva infringes this patent; is that right?

A. I understand that the decision has been made. The decision has been made.

Q. Understood. Let's call up JTX-002. And this is the '348 patent. And this is what we've been calling the product patent.

You're the lead inventor on that; is that right?

MS. ELSON: Objection, Your Honor. We talked about this.

THE COURT: This is what Hologic has been calling the project patent. That's better.

MS. ELSON: He's calling it the '348.

THE COURT: This is what he's calling it. The witness can agree or disagree. Your objection is overruled.

BY MR. WOLF:

Q. And you're the named lead inventor on this as well?

[1269] A. Hologic put my name on it even though I declared that I'm not an inventor.

Q. We'll get to that, but you are the lead inventor; right?

A. I am not.

Q. Isn't your name the first?

A. I didn't put my name there.

Q. This is a continuation of the application you sold to Hologic in 2004; is that right?

A. Correct.

Q. Okay. Now, you're also aware that it has already been determined that Minerva infringes this patent; is that right?

A. That's my understanding.

Q. Okay. Now, you held up in your direct the pretty -- the PTO issue, what we call ribbon copies of your, your patents with Minerva; is that right?

A. Correct.

Q. All right. And these are the pretty versions of the '183 and the '348 patent.

You characterized these as like a deed in property on direct; is that right?

A. That's correct.

Q. And you would agree that the '183 and the '348 patents are just as much a deed or just as much property as the [1270] patents you held up; is that right?

A. Absolutely.

Q. And you don't mean to suggest that the '183 or the '348 patent are entitled to less respect as deed or property than the patents you held up during your direct examination, do you?

A. No, I'm not.

Q. Okay. You understand it's important for a company to respect the intellectual property of other companies; is that right?

A. Yes, I do.

Q. So I want to spend some time focusing on Minerva's decision-making regarding the '348 patent, the patent we have on the screen.

If we could go to PTX-0114, please. Now, let me tell you.

If at any time -- it's probably going to be much easier if we used the screens for documents, but if at any time you want to see a whole document, they're in the binders next to you, it's entirely up to you, but it probably will go smoother to use, if we're all focused. But, again, whatever you prefer.

A. I'm fine with that.

Q. Okay. Now, this is a letter to you from Mandy Callahan at Hologic in 2014; is that correct?

[1271] A. That's correct.

Q. This "Re" line is request for signature, Hologic inventor declaration; is that right?

A. That's right.

Q. And the last sentence of the first paragraph sat, as a reference, I have also attached a copy of the application as published in February 2014.

Do you see that?

A. Yes.

Q. Let's turn to that application, 42877.

Okay. Now, this is the application that became the '438 patent; right?

A. Yes.

Q. Okay. Now, there were some things -- we can take that down for the moment.

A couple things that have been said earlier in this case that I think might be helpful for you to offer some insight.

When you file a patent application the first time, not maybe later on in continuations, but when you file a patent the first time, that's not public; right?

A. No. Usually, it's six months to a year. I can't determine how the PTO publishes.

Q. Sure. When you first submit a patent, it's quote in secret end quote; right?

[1272] A. I don't know if you call it secret, but I have no access to it.

Q. Right.

A. Not public.

Q. Not public.

MS. ELSON: I'm sorry. I just want a clarification. Do you mean application?

MR. WOLF: The witness answered the question. He understood it.

MS. ELSON: Okay. Confusing.

BY MR. WOLF:

Q. Not public. When you file your application, your first applications, there's nothing wrong about it not being public when you file it; right?

A. I have no control. I can't say it's a problem or not. It's -- you know, the PTO published them on their own timetable.

Q. So you submit an application that's not public, and then at some point later on, it becomes public. The

Patent Office tells the world, hey, here's an application that has been filed. That's your experience?

A. Normal.

Q. Yes. And once an application is published, you can go to the Patent Office's website and look at it. The whole public can; right?

[1273] A. That's correct.

Q. Now, the date -- can we pull that back up, the date of the document? And we see up there publication date, February 13, 2014.

Do you see that?

A. Yes, I see it.

Q. Okay. So on that date, anyone in the world can see that Hologic has filed this application; is that right?

A. Yes.

Q. Now, as of that date, Minerva had not yet even applied for FDA approval for its device; is that correct?

A. They were in the process of completing their FDA filing.

Q. So they hadn't yet filed for FDA approval; is that right?

A. That was about the time. But you can talk to Mr. Clapper.

Q. Fair enough.

Now, on that date, on or about -- let's just round up a little bit, March 2014, in the face of this application, Minerva had at least three choices. It could, in light of the application, it could redesign its product. It could go to Hologic and say, we'd like a license if this ever

becomes a patent, or it can say, we're just going to go ahead and keep doing what doing; is that right? Are those [1274] your three basic choices?

A. I have no idea if anybody besides me was aware. The only time I was aware of that patent, then the letter was sent to me.

Q. Let's talk about that. At the time you get the letter as a member of the Board of Directors, Minerva could have done one of three things and maybe more, but at least these three things.

It could have said, we're going to design around to avoid this problem with the patent issues. We're going to change the way our product is built.

They could say, we're going to go to Hologic and get a license, or they could say, we're just going to take our chances.

What did Minerva do at that point?

A. Personally, I was advised -- I don't recall the discussion we had at the time, but I can tell you my advice would be just move forward because our technology is completely different. And it's very clearly in this patent, it's getting twisted in some way, that you turn a moisture transport system into a no moisture transport system.

Q. I understand your opinion about the patent, but did you communicate that opinion to anyone, or was that what was in your head at the time?

[1275] MS. ELSON: Objection, Your Honor. I just want to make sure we're not treading into privileged communication. Otherwise, it's fine.

THE COURT: So your question is: Did he communicate that with anyone on the board?

MR. WOLF: Right.

THE COURT: And management?

MR. WOLF: That's right. Thank you, Your Honor.

THE COURT: You're welcome.

THE WITNESS: So when I got this letter, it was on my mind.

BY MR. WOLF:

Q. Okay.

A. Because I looked at this, it doesn't make sense.

Q. All right. So now let's go to JTX-005.

And this is what we call a notice of allowance; right?

If we go to 145901, do you see that, notice of allowance? Do you see that document?

A. Yes, I can.

Q. And the date mailed in the right-hand side is 4/27/2015.

A. Yes.

Q. And we see that this was mailed to Hologic, but it is a notice.

[1276] So on this date, on or about April 27th, 2015, the whole world was put on notice that the '348 patent was going to come out; right? That it had been approved by the Patent Office?

A. I was not aware of it.

Q. Well --

A. The only thing I know, when it was published.

Q. You're aware that the notice of allowance is a public document put on the website; is that right?

A. I wasn't aware personally.

Q. Well, are you generally aware with all of your patents that a notice of allowance is the kind of thing that's publicly available?

A. No, I'm not.

Q. All right.

A. I'm not a patent attorney.

Q. I understand. There are certainly people at Minerva whose job it is to make sure you don't infringe other people's patents; right?

A. I assume it.

Q. Yes. So let me ask you, as a board member, in around the time frame of 4/27/2015, when this notice of allowance came out, was there any discussion along the lines of, hey, Hologic is about to get a patent that we might infringe. We need to do something about it, and excluding lawyers at the [1277] board or at management?

A. I don't recall discussion.

Q. The same three choices; right? You could have at this point, now that you know a patent is coming out, you could redesign. You could go to Hologic and ask for a license, or you could just push ahead.

Minerva chose to push ahead after April 27, 2015; is that right?

A. Again, I just can speak for myself. I was not personally aware of it.

Q. And let's go ahead then to August 4, 2015. If we could bring up JTX-2 again, please.

So the way this works is, the Patent Office issues a notice of allowance. There are some formalities. It takes a couple months to get this printed out. Apparently, it takes three months to get this printed. And on August 4th, the patent issues; is that right?

A. That's right.

Q. Okay. And now again, this is -- this is the same month that you launched the commercial launch of your product; is that right?

A. That's right.

Q. And you had three choices again, at least three choices. In the face of this patent, it now exists. You could launch the product and risk infringement. You could [1278] change the design of the product to avoid infringement, or you could ask Hologic for a license.

What did you do at Minerva?

A. So first choice, changing the product, it's virtually impossible. This is a PMA trial. Even the smallest detail, change in the PMA application, it would be a month if not a year delay, which I'm sure you're aware of. So I don't think that we can talk about that, the company was in the position to change the design of the product.

Q. Did you ask Hologic for a license to the '348 patent?

A. I'm not aware.

Q. At or around the time of the issuance of the '348 patent, are you aware of any discussions within the board or within senior management of what to do about the '348 patent?

A. I believe all of a sudden, big challenges.

Q. So you decided at that point that you roll the dice rather than ask for a license and challenge the patent?

A. I don't feel that, you know, we are rolling dice. We felt that we had a very good argument that this patent should have been issued, but, again, it was our opinion or my opinion at the time.

Q. Okay. Now, let's go to claim 1 of the '348 patent. And we've been through this a number of times.

You understood at the time you made that [1279] decision to challenge the patent that if you infringed each of these steps, if your device had each of these things in it, it didn't get you off the hook for infringement if you added other things; right? You understood that, didn't you?

A. Repeat it one more time.

Q. Sure. Okay. Let's break it down. I was trying to get through it. That's my fault.

So we see that there's a device for treating the uterus comprising, an elongate member, an applicator head, a handle, a deflecting mechanism, and indicating mechanism. Those are the bake features of the device; right?

A. Yes.

Q. And you will agree with me that there's nothing in there about whether you do or do not use, for example, argon gas; right?

A. Okay.

Q. Do you agree?

A. I agree.

Q. All right. And you showed those interesting experiments of the balloon and the water and first it

failed, then it succeeded. There's no mention of whether you should or shouldn't have that feature in these claims; right?

A. I don't know how that relates to that.

[1280] Q. All right. Let me go back to my original question, see if this is a better question.

Did you understand as a board that if you did everything in claim 1, it didn't matter if you also had other things in the device. You would still be infringing?

A. I have not done any analysis or formal analysis of the claims of this patent, so I can speak only on my own belief, and my own belief was that, you know, you know, that claim should be challenged.

Q. Sitting here today, do you understand that if you practice all of the claims, all of the elements of the claim, but also do other things, that you still infringe?

Do you understand that?

A. Yes, I do.

Q. When did you come to that understanding?

A. Sometime ago.

Q. So before you made the decision to launch the Minerva product?

A. Yes.

Q. So you understood when you launched that, it didn't matter if you did other things, even if they were really important, good, useful things, that it didn't matter for deciding whether or not you infringed as long as you did what's on the screen right now; right? You understood that when you chose to launch the product?

[1281] A. I still feel that, you know, the right thing to do at the time. Again, just my opinion. It's a challenge because it doesn't make it right.

Q. You didn't agree with the law?

A. I do agree with the law, but the law also allowed you to challenge.

Q. So you decided as a board you would roll the dice?

A. Me, I'm not the board. I'm just a member of the board.

Q. Yes. Mr. Truckai, as I said, none of this is personal. It's company versus company. All of my questions are about Minerva.

You as a board decided that you were going to take a chance and challenge the patent rather than get a license from Hologic or change the design of the product; right?

A. I didn't feel that this is a valid patent, personally.

Q. Now, one more question about your understanding at the time.

There were a lot of questions in your direct about copying. You understood at the time that if you copied what was on the screen or copied that part of the NovaSure device that's reflected on the screen, even if you added new stuff, you're still copying; right?

A. So, you know, let's talk about specifically, what did [1282] we copy?

Q. I'm just asking as a general matter, did you understand that?

A. You know, generally speaking, yes, I understand, but what is it directed and how does it relate to, you know, the Minerva technology? And I'm not trying to be argumentative.

Q. No, no.

A. I'm just trying to understand the points you're trying to make.

Q. If I invent this notebook, and you copy the notebook but then add a great feature so that these things don't pop open as they always do on me, you understand you still copied what I invented; right?

A. I understand.

Q. Even if you come up with a great idea later that may improve the notebook.

A. As long as it's not in the prior art, that's the invention.

Q. Now, you talked about, at some length about the moisture transport system in your direct; right?

A. Yes.

Q. All right. And you said you thought that was essential to your invention, part of your invention, something to that effect?

[1283] A. It's not part and essential. It didn't work without it.

Q. Okay. Now, you, Minerva -- and, again, I apologize. When I say "you," I mean Minerva. I really don't want to make this personal.

Minerva made that very argument to a Court, and that argument was rejected in April 2017; right?

MS. ELSON: Your Honor, this is opening a big door here.

MR. WOLF: Your Honor --

THE COURT: I don't know how else to do this, counsel, so I'm going to overrule the objection. And you may have a continuing objection.

MS. ELSON: Yes, Your Honor.

THE WITNESS: Sir, if you could repeat it?

BY MR. WOLF:

Q. Yes. Let me back up a little bit.

You understand that Minerva made an argument, not to this Court, but to a Court that this claim needed to have moisture transport in it. You understand that; right?

A. Yes.

Q. That was your challenge that you talked about before; right?

A. That's correct.

[1284] Q. Now, in April 2017, that challenge was rejected by a Court; right?

A. Some portion. I believe not everything, but some portion of it.

Q. Well, that particular thing. All of that discussion of moisture transport, that argument, that's not part of claim 1; right?

A. I understand.

Q. Okay. So now as a board, you had this idea that, well, we're going to go ahead and sell the product even though the '348 patent exists, because we think it should include moisture transport, and since we don't

do moisture transport, we can't infringe. Now that's rejected, so what do you do as a board in light of that?

A. There are other ways, you know, to look at the validity of the patent. You can look for patent re-examination or IPR, and I think that's the sensible thing to do, because, you know, the Patent Office is especially focused on this and they're very knowledgeable, more knowledgeable than -- you know, about how to deal with this.

Q. Were there any discussions at the board that you're aware of about the importance of the Court saying, this doesn't include moisture transport, claim 1? Did anybody say, we need to revisit our decision to launch the product [1285] because of what the Court said?

A. The product was already launched.

Q. Fair enough. To continue selling the product as is?

A. We definitely had a discussion regarding the core decision. I felt, you know, personally as a board member, you know, to challenge it to the Patent Office.

Q. So despite what the Court said, you said, we're going to just keep selling?

A. I found out the Patent Office, the people who are very knowledgeable to the case, should be better, whether this claim is valid or not.

Q. Yesterday you weren't here, but we saw a discussion of a design-around with a different measure of, method of attachment of the handle. There was discussion of a pivot point.

Do you remember discussion of a design-around within Minerva?

A. Yes.

Q. Do you know what a design-around is?

A. I do.

Q. Could you explain to the jury what a design-around is?

A. If you can't do it that way, can I change something to make it still work, but it's a little bit different. I would say it's a little bit different.

[1286] Q. So the idea is that there's a patent that I don't want to infringe, but I think I can still make a product without infringing, so I'm going to change the design. I'm going to design around the patent; is that right?

A. That's fair.

Q. It's like if I own this piece of the floor, rather than walk through my piece of the floor, you're going to walk around it; is that right?

A. That's my understanding.

Q. And Minerva looked at a design-around to '348, claim 1; right?

A. Again, I'm not aware of the design-around.

Q. Were you aware that there was a lawyer that was called in to analyze whether the design around infringes the '348 patent?

A. No, I'm not.

Q. Do you know why you were not part of that discussion?

A. I ran two companies at the same time. I'm fairly busy.

Q. So there are some parts of Minerva's activities regarding '348, claim 1, that you are a part of, and others that you are not?

A. I was part of this. Hologic sent me that disclosure, the disclosure statement. I was aware of that. But other effects, I may or may not be aware.

[1287] Q. Now, one more question or series of questions on claim 1.

You understood at the time that Minerva decided to launch its product, that if you infringed claim 1, this language, it didn't matter whether you also had your own patents on your device. You still infringe; right?

A. My personal belief that that patent should have been issued, but, again, it's just my personal belief, and I think the company should challenge it to the USPTO and the PTO should make a determination at the time. That's, again, just my belief, so . . .

Q. I asked a slightly different question.

A. Okay.

Q. Just so I understand what the decision-making was at the board.

You understood it was no defense to patent infringement to say, well, we also have patents on it; right?

A. I don't believe that the board looked at it, that we have a patent. I think the board was in good faith told that, you know, our technology is completely different, and I still believe personally that our technology is completely different.

Q. Okay.

A. And I do understand that, the it written words of this [1288] patent, the claim, and the Patent Office makes mistakes, and, you know, we've got to go and challenge it.

Q. Please try to answer my question. I understand your position.

A. Okay.

Q. But try to answer my question. You understood that it was not a defense to patent infringe. To say, well, we got our own patents on the product, too; right?

A. At that time.

Q. And you understood that the whole time; right?

A. I do understand.

Q. Right. So when you were showing the jury your patents, you weren't trying to tell them, but you got patents, well, you knew you didn't infringe '348, claim 1; right? Wasn't what you were trying to suggest?

A. No, it does not.

Q. Okay.

MR. WOLF: Can we call up DTX-1367, please.

BY MR. WOLF:

Q. You showed us this patent before, do you remember, in your direct?

A. Yes, I recall.

Q. Okay. Can we blow up the first half?

You are the inventor. The assignee is Hermes Innovations, LLC.

[1289] A. Yes.

Q. What is Hermes Innovations?

A. It's my company, and I have my health insurance through Hermes Innovations, and I put intellectual property into the company. And I license it all.

Q. I didn't mean to interrupt. I'm sorry.

A. And I license technologies all from the company.

Q. Right. So you own Hermes; right?

A. Yes.

Q. And Hermes owns the '068 patent?

A. Yes.

Q. And Minerva pays a royalty fee to Hermes to use the '068 patent; right?

A. No, they do not.

Q. They have a license to it?

A. No. In exchange of ownership.

Q. Oh. So you're paid, but in the form of ownership as opposed to a royalty?

A. That's right.

Q. Okay. So let me start over. The '068 patent is owned by Hermes. Yes?

A. Correct.

Q. And Minerva licenses it so that they can, in order to sell their product, they can use the technology in the '068 patent?

[1290] A. That's correct.

Q. And the form of payment you get for that is a part of the ownership of Minerva?

A. That's correct.

Q. Right. So Minerva regularly, in fact, licenses other people's technology to practice and sell its product; is that right?

A. I'm sorry?

Q. I will put some more up there. Let me ask you this: Let me ask it. Minerva licenses other people's technologies in addition to their own patents to sell their product; right?

A. I don't know.

Q. Okay.

A. I know they license mine.

Q. You don't know whether they license others or not?

A. I don't believe so, but I think Mr. Clapper can answer that.

Q. Okay. That's fair.

Now, you would agree that at the time of the launch, you were not qualified, the launch of the Minerva product, you would agree you were not qualified to analyze the claims of the patent and form an opinion about it, because that's not your job; right?

A. That's not my job and I'm not a patent lawyer.

[1291] Q. And you would agree that personally, you're not qualified to go into a patent and analyze the claims and form opinions about it; right?

A. That's correct.

MR. WOLF: Your Honor, may we approach?

THE COURT: Yes.

MR. WOLF: He just answered the $64,000 question. What I normally want to ask next is, so who was it at

Minerva that was competent to decide, that said it was okay to launch the product.

MS. ELSON: It is a foundation issue.

MR. WOLF: No.

THE COURT: No. His next question is, so who at Minerva has said it was okay to launch?

MS. ELSON: Okay.

THE COURT: And then you're going to ask -- so say it again how you're going to do this.

MR. WOLF: So who was it at Minerva that was qualified.

THE COURT: Oh. And then gave the advice to launch?

MR. WOLF: Yes. That said it was okay to launch. I won't say advise.

MS. ELSON: You are saying it's one individual.

THE COURT: Well, that's the who. It could be [1292] five people, four people, three people.

MS. ELSON: Okay.

THE COURT: And if he says a lawyer, then you've got problems. That's the bottom line.

MS. ELSON: Okay.

THE COURT: But he has to answer it truthfully.

MS. ELSON: Yes. But as long as it's not asked. There may have been lawyers involved, but there were also businesspeople. Is there a way to ask it to just exclude any conversations with lawyers?

THE COURT: I think he just names the people, and if he names them and one of them turns out to be a lawyer, we'll take it up then.

MS. ELSON: Your Honor, I would like to have a continuing objection, because we'd like to talk about excluding the two UIT patents. The Exmark decision has a pass knowledge we'd like to show Your Honor.

THE COURT: Excluding what?

MS. ELSON: Those two perforation test patents that we talked about earlier on direct.

THE COURT: Oh.

MS. ELSON: Exmark said expressly, and they should know, you have to show for purposes of the damages that your system is covered by your own patents and that's relevant to damages. If we could just address this later [1293] because they've agreed, we have a stipulation, they've agreed if these patents come in, they've stipulated that we practice our own IT patents already.

THE COURT: We'll take that up later.

MS. ELSON: Okay.

MR. WOLF: I will look at the case. If I'm wrong about the objection, we'll withdraw it. They can deal with it on redirect.

THE COURT: Okay.

MS. ELSON: Or we can just enter the stipulation.

THE COURT: Okay.

(End of sidebar conference.)

BY MR. WOLF:

Q. So I had just asked you, and you would agree that you were not qualified to go into a patent and analyze the claims and form opinions about it; is that correct?

A. No, I'm not.

Q. Who at Minerva, who is qualified to go into a patent and analyze the claims and form opinions about it made the decision or was involved in the decision to release the Minerva product?

MS. ELSON: And, Your Honor. I'm sorry. Objection.

THE COURT: Oh, as previously stated.

[1294] MS. ELSON: That's a different question from what we discussed.

MR. WOLF: I don't think so.

THE COURT: So I just want to be sure. Who at Minerva made the decision to go forward with the product after the patent was published.

Is that the question?

MS. ELSON: That wasn't the question. The question was, who at Minerva who actually did basically an infringement analysis. Perhaps we could just have the question read back.

MR. WOLF: I will break it up into two questions.

MS. ELSON: The first part is objectionable.

THE COURT: Okay.

BY MR. WOLF:

Q. Who at Minerva made the decision to launch the product despite the '348 patent?

A. The board and the management.

Q. Who among the board and management, if any, was qualified to go into a patent and analyze the claims and form opinions about it?

A. None of them. Nobody. None of us are patent attorneys.

Q. So there was not a single person that was qualified to [1295] go into a patent and analyze the claims and form opinions about it who told you it was okay despite the '348 patent to sell your product; is that right?

MS. ELSON: Objection, Your Honor.

THE COURT: Overruled.

MS. ELSON: Can I have a running objection based on Section 289?

THE COURT: Yes.

MS. ELSON: Thank you.

THE WITNESS: Sorry. Can you repeat it?

(The court reporter read back the testimony as follows:

"Question: So there was no one on the board or in management who was qualified to tell you whether or not you infringed '348 patent, yet you went ahead and sold it anyway; is that right?

"Answer: The only thing I can say, I'm sure that management of the company talked to the lawyers who can evaluate.")

THE COURT: All right. I thought it was who on the board or who in management. So I'm going to ask you to rephrase your question.

MR. WOLF: Well, so, Your Honor, just to be clear, the previous question was, who had those qualifications and the answer was no one.

[1296] THE COURT: On the board or in management?

MR. WOLF: In management.

THE COURT: Okay.

BY MR. WOLF:

Q. So there was no one on the board or in management who was qualified to tell you whether or not you infringed '348 patent, yet you went ahead and sold it anyway; is that right?

A. The only thing I can say, I'm sure that management of the company talked to the lawyers who can evaluate.

MR. WOLF: Your Honor, shall we take a break?

THE COURT: This is a good time.

Ladies and gentlemen, I'm going to give you an early lunch. Okay? It's Friday. I feel good about an early lunch. So let's come back at 1:00. Okay? So we're in recess until 1:00.

(The jury was excused for a luncheon recess.)

THE COURT: All right. So if the witness would step down, and you have to go back outside because we're going to talk about your testimony. Okay?

THE WITNESS: Okay.

THE COURT: So I think you're on lunch break.

THE WITNESS: Okay. Thank you.

THE COURT: The rest of us aren't. You are.

MR. WOLF: Enjoy your launch.

* * * *

[1342] BY MR. WOLF:

Q. Just a few followup questions on what we were talking about when we broke and then we will move on to a new topic.

If someone at Minerva had identified what they thought was a serious concern about infringement of the '348 patent, whose decision, one or more people, would it have been to hit the red button, to pull the plug, to stop the press? Who was making that decision?

A. You mean, when you say pulling the plug?

Q. Fair. Let me ask it more formally. It's important to Minerva not to infringe someone's patents; right?

A. That's correct.

Q. Yes. And so if at any point there had been a determination that there was a risk of patent infringement, who, which one or more people would have been the ones that decided, we've got to do something about it, whether it's get a license or not release the product or change the product, whatever it was? Who were the people that would actually decide that?

A. Yes. The board, but they use legal counsel to make that determination.

Q. Let's shift topics now to your role in the early days of the company and the jury was instructed on what a [1343] 30(b)(6) witness is. I assume you don't remember that you were a 30(b)(6) witness for Minerva?

Do you remember you were asked to be the designee on the topic of conception, design, development and testing of the Minerva endometrial ablation system?

A. Yes, I do remember.

Q. So you were speaking on behalf of the company?

A. That's right.

Q. Okay. We call that legal nonsense jargon 30(b)(6). And you were that guy; right?

A. That's right. Yes, I was.

Q. All right. Let's go back to JTX-20, or let's go to JTX-20, which the jury has seen before, but you haven't. And this was a slide deck that you were involved in preparing for a meeting with Hologic; is that right?

A. That's right.

Q. And this was your standard template; right? You presented a similar presentation to J&J and others?

A. As I recall.

Q. Let's go to the next page. That was this mission statement on the next page of the document. That was Minerva's, that's what they were trying to do; right?

A. As I recall.

Q. Next slide.

And that was the attributes you were seeking, [1344] the third slide, the project goal?

A. Sounds reasonable.

Q. Okay. Let's go to the next page. I just want to -- I talked to the jury about this in opening, but I want to now get this officially in the record. This is

Novacept, at least the core team at Novacept in 2009; is that right?

A. Novacept?

Q. Not Novacept. I'm sorry. Minerva.

A. Okay.

Q. I was going to talk about the Novacept. Let me start over. This was the core team of Minerva in 2009; is that right?

A. Yes. And others, and others.

Q. And others? Okay. So we see the board of directors up there, the top, the five people?

A. Yes.

Q. And all five of the board of directors were at one time or another part of Novacept; right?

A. That's right.

Q. All right. Now we see medical advisory board and we see 1, 2, 3, 4, 5, 6 names. What is a medical advisory board?

A. These are physicians who are evaluating your product and they tell you that, you know, this is what they think is needed in the marketplace.

[1345] Q. And how do you decide as Minerva who you want on your medical advisory board?

A. I like knowledgeable people who don't sugar coat it for you and they tell you that, look, you know, this is great, but. So I'm looking for the but. What do we need to fix?

Q. And so these are physicians that you respect to give it to you straight?

A. Yes.

Q. And I want to focus on a couple names. Ted Anderson first. Dr. Anderson has now a relatively prominent role in the community, doesn't he?

A. I believe, I have not kept in touch with him. He was already a very respected physician.

Q. Do you know whether he has a current president title with an organization?

A. I'm not sure. I heard about it. Maybe AGL was going to be one, but I'm not sure, you know, that this is true or not.

Q. Right. In any event, Dr. Anderson is a well

respected --

A. Who's very well respected.

Q. Let's go to the last one. Adolf Gallinat. Another very well respected physician?

A. He passed away, but, yes.

[1346] Q. Fair. But he was a very well respected physician?

A. Yes.

Q. And then Dr. Garcia is actually one of the expert witnesses Minerva will be calling in its case; right?

A. Right.

Q. And she's a member of your medical advisory board?

A. Was part at the time.

Q. Yes.

A. I don't know, I don't know who is the medical board.

Q. But at the time --

A. At the time, she was.

Q. Yes. And then we have Corpora. What does that refer to? I assume that's a typo?

A. Yes. Should be Corporate.

Q. And then we have IP, Jim Heslin, Townsend, Townsend & Crew.

Do you see that?

A. Yes.

Q. Who was Mr. Heslin?

A. Patent attorney.

Q. Is he still Minerva's patent attorney?

A. Yes.

Q. And he was actually Nova's past patent attorney; right?

A. At some point. At the very beginning, no.

[1347] Q. He prosecuted -- he took to the Patent Office a number of the patents we've seen in this case; right?

A. Yes.

Q. He was at Novacept and -- he represented Novacept. Then he represented Minerva; is that right?

A. At the very beginning, you know, I couldn't use Jim at all, also when we started Novacept.

Q. And at some point he became your attorney?

A. At some point.

Q. Okay. Then we have management. I think that's probably self-explanatory, but we see that you and Ms.

Williams and Ms. Morgan were former Novacept folks; is that right?

A. Yes.

Q. Consultants, Mary Edwards. Who was Mary Edwards?

A. Regulatory person.

Q. What do you mean by a regulatory person?

A. Regulatory means dealing with FDA matters.

Q. So you used her as an FDA person at Novacept. Then you chose to bring her to Minerva; is that right?

A. Yes.

Q. We know who Mr. Clapper is. At the time he was a consultant. At some point he became the CEO of Minerva?

A. Yes.

Q. Okay. The Medical Advisory Board, are they [1348] compensated for their services?

A. I think we at the time -- I don't recall precisely, but I think we had formal compensation for them.

Q. You did have formal?

A. Yes.

Q. All right. Let's go to PTX-63. Rather than have them flip in the binder, do you have any objection to what's on the screen?

(Pause while counsel conferred.)

MS. ELSON: What was the question?

MR. WOLF: Just do you have any objection?

MS. ELSON: To 63?

MR. WOLF: Yes.

(Pause.)

MS. ELSON: No objection.

MR. WOLF: All right, Your Honor. Move the admission PTX-63.

THE COURT: Received.

(PTX-63 was admitted into evidence.)

MR. WOLF: Will you publish, sir? Thank you

BY MR. WOLF:

Q. So we see here an e-mail from Michael Regan. Who is Michael Regan?

A. He was the COO of the company.

Q. The chief operating officer?

[1349] A. Yes.

Q. Does that make him number two or number three?

A. He was really doing that day to day, running the company.

Q. So he was running the company on a day-to-day basis. And it's to you, among others.

A. That's correct.

Q. And we talked about Mary Edwards already. Could you remind us who Dominic Filloux is?

A. Vice president of research and development.

Q. And the subject is MAB notes; right?

A. Yes.

Q. All right. Let's look briefly at the notes. Next page. Actually, the third page of the document.

Let's just look at the top two boxes. We say, a topic and a response and action.

Do you see that?

A. Yes.

Q. This is input that your doctors gave you that said this is important for your device. Is that fair?

A. Many times, you know, they said that these are issues. You have to explain to them.

Q. And one of your MAB members said, number scale for cornu measurement is important. If it is under three centimeters, it is almost guaranteed that the device is not [1350] opened enough or is impaled in the wall; right?

A. Yes, I see it.

Q. And that was the advice that physicians were giving you as you were designing the product; right?

A. Yes, but you have to take into consideration, the first time you're talking to these guys, you know, they pretty much tell you what they know. So the physicians are using, as is most of them, are using NovaSure. So once you go into the technology and I explain to them you no longer need this. You don't know what you are going to need to measure regardless of the size of the cornu, and you don't have to, you no longer have to input the cornu. I think they got, you know, pretty much the idea. But that was more like an action that, you know, physicians in the marketplace, you know, they've been conditioned to take a measurement and enter it into equipment.

Q. Respectfully, the answer to my question was: Yes, this is what a doctor would.

A. Yes, but you can't take it out of context. You noted it that, you know, they broke up. Look, you have to enter this in the marketplace. This is important to us right now.

Q. Mr. Truckai, you've attended and participated in FDA meetings regarding the Minerva product; is that correct?

A. Yes, I did.

[1351] Q. And you've been involved in pre-IDE activities as well; is that correct?

A. Yes.

Q. Can you explain to the jury what pre-IDE means?

A. So you go to the FDA, and physicians and other FDA persons who understand the type of product and procedure. They sit down with you and you explain to them how your device is working. You know, they understand, you know, what you're trying to do, and you are trying to give them the information.

You are trying to bring them up with technology, what we're trying to do, how the device is working and what we want to achieve. And this is very important because based on that, you establish later on the protocols, the clinical protocols, how you're going to conduct your clinical trial.

So that's the purpose of that meeting. How are you going to conduct your clinical trial.

Q. Very good.

So let's go to Exhibit 41, PTX-41, please. And this is an e-mail chain at the bottom from Mary Edwards to Colin Pollard, and then from Colin Pollard to Mary Edwards. Keep it blown up.

At the top, it's back to Regan. We'll break this up. Start at the very top of page 2, very top of [1352] page 2, the signature block.

And we see it's from Mary Edwards, and she's identified as the VP of regulatory and clinical affairs; is that right?

A. She was at that time, yes.

Q. Right. What does the VP of regulatory and clinical affairs do?

A. She was responsible to establish the regulatory framework, how we're going to work with the FDA constructing the regulatory file for submission, and she was managing the clinical, overall, the clinical.

Q. And she was good at her job, I assume?

A. She was pretty good.

Q. You brought her from Novacept to Minerva; right?

A. Yes.

Q. Okay. So let's go to the top of this e-mail. It's from Mary Edwards to Colin Pollard. Now, Colin Pollard was at the Food and Drug Administration at the time?

A. That's right.

Q. This is an official communication, or at least one communication between Minerva on the one hand and the United States Food and Drug Administration on the other; right?

A. Mm-hmm.

Q. Yes?

[1353] A. Yes.

Q. I'm sorry. I do this all the time, so it's my fault, but the mm-hmms and the nods, unfortunately, the court reporter can't get?

A. Yes.

Q. This goes without saying. I assume you try to be accurate and honest in all communications with the Food and Drug Administration?

A. You have to be.

Q. Have to be. So she writes, "Colin: I'm under huge fire because I was not able to get answers after almost six weeks. I know it's crazy for you; but not getting any internal sympathy. We have a board meeting on the 20th and fundraising will be dependent on the regulatory plan."

Do you have any idea of what she meant by we have a board meeting on the 20th and fundraising will dependent on the regulatory plan?

A. I can't really can't comment. This is the first time I'm seeing it. I don't know what context she's referring to.

Q. Is it generally true that in order to get fundraising from those large venture capital companies we heard about before, they want to see progress with the Food and Drug Administration towards approval of the product?

A. They want to know what the plan is.

[1354] Q. Right. I'm really hoping that we could touch base for just a couple minutes on the Monday when you return?

MS. ELSON: Your Honor, objection.

THE COURT: Yes?

MS. ELSON: I think he needs to lay some foundation. He just said he hasn't seen this e-mail before, not familiar with it.

THE COURT: Foundation for what?

MS. ELSON: For testifying about this document. It may be appropriate for other witnesses, but Mr. Truckai just testified that he's not familiar with the document.

THE COURT: All right. Mr. Wolf?

MR. WOLF: Among other things, Your Honor, Mr. Truckai was asked the following question:

Was anyone at Minerva -- did you or anyone at Minerva ever believe Minerva copied the NovaSure?"

And he said, No.

THE COURT: Overruled.

BY MR. WOLF:

Q. I'm really hoping that we could touch base for just a couple minutes on the Monday when you return. I fully understand that some of the below might sound new -- but they really are not new questions.

And then number three. The Minerva device is almost dead identical to NovaSure except using plasma energy [1355] (RF).

Now, plasma energy RF, that refers to that balloon you talked all about in your direct; right?

A. Yes. That's assuming that that is what she meant.

Q. And this says that the Minerva device is almost dead identical except for that feature; right?

A. Yes, but, you know, I don't know what before that. You've got to look at it in the context. The clinical trial is pretty much the same, you know, regardless, you know, it's an HTA trial, it's a Minerva trial, it's a NovaSure trial. She was referring from the FDA standpoint, I'm assuming again, but I don't know, that the device trial, which should be engaging, trying to get information out of them, how do you get to run the trial? This is pretty much the same trial, you know, you run many times before. And at the time I remember we were talking about this, this is a PMA. That was like the eighth of the kind at the time. It was eight devices went through the same process.

Q. You would agree that your answer to Ms. Elson might have to be changed in light of this e-mail; right? Ms. Edwards at least thought that the Minerva device was almost dead identical to NovaSure.

A. I -- I don't think so. I'm not sure that she's talking about the way the trial is from the FDA standpoint. You have to look at it from FDA standpoint. It doesn't [1356] matter I'm using -- what do I use. This is from FDA standpoint, conducted go the same trial. You know, you're going to use, you know, the same diary method, evaluation. I mean, I didn't see anything new here from the FDA. I think that's what she's referring to, but, again, I can't comment.

Q. All right. Let's go up one more e-mail in the chain. Keep the whole thing blown up.

Now, you can just keep the whole blown up. I think everybody can read it.

From Colin Pollard. Then we see the official FDA address. Food and Drug Administration at Human Services.Gov.

Do you see that?

A. Yes.

Q. He's writing to Mary Edwards. He says, I'm sorry. I was away last week on vacation. I hoped my last e-mail to you would help, but I will find some time to talk to you tomorrow even if it's late any day. So the FDA is trying to be cooperate you've with you; right?

A. I can't comment. I don't know what the discussion was. If that was the only conversation they had at the time, I can refer to the written words.

Q. All right. Now, next at the top, Ms. Edwards forwards this to Michael Regan; right? Do you see it to Michael [1357] Regan, she forwards this e-mail exchange?

A. Okay. I see it.

Q. Yes. And she writes: Mike, interesting. We're getting better response from FDA than from our own advisory board. Talk to you tomorrow.

Do you see that?

A. Yes.

Q. To your knowledge, did Mr. Regan or anybody else ever say to the FDA at any time, you know what we talked you it was dead identical? We were wrong. It's not dead identical.

A. I don't know. Even in the response, the prior e-mail, there's no response. You can see a short answer,

and then the next thing, we had a better response, so I'm confused, you know. I mean, I don't know what she's referring to. I don't know we got a great response, you know. After weeks, there's no response, then a little blurb and she called it a great response. I just want comment.

Q. You understand that to infringe a patent, you don't need to copy it. You can infringe a the patent even if you didn't even know about an old product; right?

A. Of course. If you don't know anything about it, you are looking. This is a prior art.

Q. I'm sorry. That was a bad question. Patents are like deeds. I think you used that before; right?

[1358] A. Yes.

Q. If I infringe someone's patent and I didn't even know about it, I'm still liable for infringing; right? It's not something I have copy or anything to be an infringer; right?

A. I understand.

Q. But copying is a big deal for whether you're a willful infringer; right?

A. I understand.

Q. And what you thought about your similarity to a product that's patented, that's a big deal; right?

A. We didn't feel that we have any similarity beyond the point, which was public knowledge. Those devices, you know, had existed before. So that was our belief.

Q. Let's move on to PTX-601. Is that objected to?

MS. ELSON: It's okay.

MR. WOLF: Thank you. If we could put 601 up on the screen.

THE COURT: Has 601 been received?

MR. WOLF: It has, Your Honor. Well, it hasn't.

It's no objection from Minerva.

THE COURT: Okay. Can you move?

MR. WOLF: I move to admit 601, Your Honor.

THE COURT: 601 is received. Okay.

(PTX-601 was admitted into evidence.)

[1359] BY MR. WOLF:

Q. We see in this e-mail, it's from Michael Reagan, the person we were just talking about, your COO; is that correct?

A. Correct.

Q. And it's to a number of members of your advisory board, including Dr. Ted Anderson; is that right?

A. Yes.

Q. And these were folks on your Medical Advisory Board; is that right?

A. That's right.

Q. And you're on this as well. Is that right?

A. That's right.

Q. You look under the first full paragraph, last sentence. We were fortunate to have Dr. Gallinat proctor these cases which helped tremendously with the new user learning curves.

Do you see that?

A. Yes, I do.

Q. You would agree as we were talking about before, doctor Gallinat's opinion is well respected?

A. Yes. I think his is pretty good, what he used to do.

Q. Yes. And then we have procedural observations, and just a few examples. The second bullet: We are investigating methods to minimize tip profile, that [1360] referring to the handpiece of the device; right?

A. The tip of the device.

Q. Of the handpiece, the tip of the handpiece?

A. This is the plug formation.

Q. Just so we understand what we're talking about, whichever product we're talking about, this is the handpiece; right?

A. Yes, but this is talking about the very tip, this one.

Q. Understood. It's a piece of the handpiece? It's a part of the handpiece?

A. There's a big difference between a handle and a tip. This is specifically stating the tip profile, which is that was the important thing, because I'm not taking the handle and put it into the uterus. The only portion that goes into the uterus --

Q. I am delighted to hear that that is not the case. But just so we're getting our words and our nomenclature straight, when I say handpiece, do we all understand that that is what I'm referring to?

Does that make sense?

A. That's a handpiece.

Q. Yes. And so he's talking there about a part of the handpiece?

A. He's talking about the most important part of the device, which is the tip. He's not talking about the entire [1361] device. He's talking about a portion of the device.

Q. All right. If we look three bullets down, a suggestion was made to use dot scale for feedback on cornu-to-cornu measurement. Additionally, it might be helpful to increase the resolution of the reading scale.

Again, talking about a part of the handpiece; right?

A. Yes.

Q. And there we're talking about this measurement right here; is that correct?

A. It's not a measurement. It's an indicator. But that's what we're talking about.

MR. WOLF: Your Honor, may I approach?

THE COURT: The witness?

MR. WOLF: No. You, Your Honor.

THE COURT: Yes, you may.

(Sidebar conference held out of the hearing of the jury as follows.)

MR. WOLF: So, Your Honor, you will recall we had a discussion I guess on Friday about this. I envision major patent infringement disputes.

THE COURT: This is from Anderson.

MS. ELSON: This is the one I think Your Honor excluded.

MR. WOLF: With invitation to revisit, lay a [1362] foundation. And I just went through this document and established who Mr. Anderson was, what his relevance to the company was and some of the bullets refer to the handpiece, so I think I've laid the foundation now to get his response.

THE COURT: Just let me look at it again.

MS. ELSON: Okay.

THE COURT: This is from Anderson. Your objection is?

MS. ELSON: My objection is that this is now -- it's four-and-a-half years before the patent ever existed, so how can it be relevant to a recklessness or state of mind with respect to what is covered by the patent. Copying in the instructions was covered by the patent. It wasn't filed. It wasn't published, nothing.

This is going to overlap into the '183, which one could, you know -- that one is out. Willfulness is out on the '183.

THE COURT: But you're saying that this covers both.

MR. WOLF: Yes. We just saw on direct, she went through claim 31 of the original patent that talked about moisture transport.

MS. ELSON: Let me be clear. These bullets are separate from that statement. Just because he's commenting [1363] about things about the handpiece doesn't mean -- it's ambiguous. We don't know because they never deposed Dr. Anderson. It's unclear.

THE COURT: All right. He was never deposed by either side.

MS. ELSON: Correct.

MR. WOLF: Correct.

THE COURT: All right.

MS. ELSON: There's no foundation linking this to.

THE COURT: I'm sorry. I think it goes in.

(End of sidebar conference.)

THE COURT: So, Ms. Elson, when we get to the appropriate time, if you would lodge your objection.

MS. ELSON: Yes. Yes, Your Honor.

THE COURT: Okay.

MS. ELSON: For the record, I object now.

THE COURT: Now? Let's wait for a question first.

MR. WOLF: Your Honor, we would ask to admit and publish Exhibit 58.

THE COURT: Okay. And your objection?

MS. ELSON: We object, Your Honor, for all the grounds we just discussed.

THE COURT: All right. This is Exhibit --

[1364] MR. WOLF: PTX-58.

THE COURT: PTX-58 is received.

MR. WOLF: Thank you.

(PTX-58 was admitted into evidence.)

MR. WOLF: Could we go to PTX-58 and start with the section we were just on. The second page, please.

BY MR. WOLF:

Q. Mr. Truckai, just to be clear, this is the e-mail we were just looking at from Mr. Reagan to, among others, seconds line, Dr. Anderson; is that right?

A. Yes.

Q. And if we scroll up to the response, please. And this is from Mr. Anderson to Mr. Reagan; is that right?

A. Yes.

Q. It says, looks good. How long after treatment is the hysterectomy done? Have you looked at hysterectomy about two to four weeks after treatment? There is going to be further tissue devitalization after the initial burn and it would be good to examine at what that looks like.

He says, I have one sort of global question. I envision major patent infringement disputes for this device versus NovaSure. How is this being dealt with or how do you plan you will be able to deal with it?

Do you see that?

A. Yes.

[1365] Q. You were on an e-mail that responded to the list. Scroll up. And this is from Mr. Reagan to Dr. Anderson, and cc'd on that was Mary Edwards, who we talked about before, and then Dr. Skalnyi.

So now Mr. Reagan, your COO, writes, thanks for your comments on our peri-hysterectomy series. The hysterectomy is typically done just following the ablation treatment. The uterus is sent to pathology within the hour. We have not done any two to four-week post treatment hysterectomy. Discussions to date with FDA indicate that we won't be required to do delayed hysterectomy cases. Then he said, regarding the patent position, we have been closely working with counsel on this matter since the inception of the company and will continue this approach on our design choices.

Do you see that?

A. Yes.

Q. So Mr. Reagan told Dr. Anderson at that time that you were aware of the risk of patent infringement, right?

A. That was Dr. Anderson's opinion, not our opinion. Dr. Anderson didn't know all the details, so, for example, he didn't understand using know meter versus pressure sensor. So, you know, his general comments here is not understanding, you know, what we were doing at the time.

Q. You weren't surprised when Hologic sues you in 2015, [1366] were you?

A. I was somewhat surprised.

Q. Even though members of your Medical Advisory Board were telling you there were global patent problems?

A. But they have no information about that, how we're doing.

Q. Let's go to Exhibit JTX-15 and specifically let's start with page 146893. It's about 15 pages before that. 146893.

All right. Focus on claim 31. Do you recall talking about this?

A. Yes, I do.

Q. So this was a claim in your original application all the way back in 1998; is that right?

A. Yes. They filed the patent application with that claim.

Q. And you agreed that there's nothing in this claim, in claim 31, that says anything about mesh or moisture transport; right?

A. At the time, it was our belief that we can get a broader claim.

Q. All right. So in 1998, when you filed this application, all that discussion you had about how moisture transport was what you invented, you thought you invented more than that as represented in claim 31; right?

[1367] A. We thought we can have a broader claim.

Q. So you thought just like Hologic thought with claim 1 of the '348, that you could get a claim without moisture transport; right?

A. Correct.

Q. Okay. Let's go to 146906. We see -- actually, can we see, go down, please. One more page.

That is your signature?

A. That's correct.

Q. And you, although the printing is not great, you're agreeing that you hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true letter further, that these statements were made with the knowledge that willful false statements and the like are so made and are punishable by fine or imprisonment or both.

A. Yes.

Q. And you understood at the time that the Court signed the declaration, you were attesting that you

believed you were the original first inventor on the subject matter of claim 31; right?

A. The entire patent.

Q. Including claim 31?

A. Yes.

[1368] Q. This was all before Hologic bought Novacept; is that correct?

A. Yes.

Q. So Hologic bought Novacept at a time when you had written a sworn statement that you believe that a patent could issue on a claim that didn't require moisture transport; right?

A. Based on the information I had at the time.

Q. I understand that. But Hologic bought the patent, bought -- spent a lot of money on it. $325 million. We agree that's a lot of money; right?

A. Yes.

Q. And a big part of the deal was the intellectual property; right?

A. Yes.

Q. And if the patents weren't useful, they never would have made the deal; right? No one is going to buy a company with a cool product if other companies can come in and just knock it off because there's no patent protection; right?

A. That's correct.

Q. A big part that makes your company potentially attractive to others is that you have your own patents; right?

A. That's correct.

[1369] Q. If you didn't have patents, if someone could come in and knock off Minerva, your company wouldn't be worth anything, or be worth very little; right?

A. Correct.

Q. And so when Hologic bought this patent, they had your sworn statement that you didn't believe that moisture transport was an essential part of your invention; is that right?

A. Again, I believed, but later on I mentioned the Patent Examiner brought it up, this is not going to go because there is prior art. So that's why we canceled the claim.

Q. Understood. You came to change your mind, I guess, but at the time, it wasn't like you told Hologic, look, these patents only apply to moisture transport and you are not going to get protection against someone that uses something different like an argon balloon, did you?

A. Well, no, because the technology is so different anyway.

Q. Now, we've heard in this case about supposed confidential information shared with Hologic.

As far as you know, all the conversations with Hologic and Minerva, Minerva didn't share any confidential information; right?

A. Shared a ton of confidential information with Hologic.

Q. You remember that Minerva's talks with Hologic at [1370] board meetings around 2009 or 2010 involved nonconfidential discussions; is that correct?

A. In 2009. I can't recall 2010, but 2009, yes, it was not confidential.

Q. To the extent there were any board meetings in 2010, they also involved nonconfidential information; right?

A. I can't recall. Honestly, I can't just tell you what information I had in 2010 with the board.

Q. I believe not to go to the deposition. Let me just ask you. You are not aware of any confidential information shared with Hologic in 2010 board meetings?

A. 2009 and 2010, I don't really know.

Q. All right. So let's shift our attention to 2011. Mr. Truckai, by 2011, Minerva's EAS design, and by EAS, referring to this product?

A. That's right.

Q. Minerva's EAS design is completed in all material respects; is that correct?

A. Pretty much.

Q. Well, I want to be clear. It was completed in all material respects; right?

A. I don't know what changes they have done after. But from my standpoint, it was pretty complete.

Q. Now, you showed the will map of the AAGL 4. Do you remember that in your direct?

[1371] A. Yes.

Q. All right. And you showed -- I don't think you talked about it, but you showed that Minerva had a booth there; right?

A. That's correct.

Q. Let's call up PTX-602. This will be used as a demonstrative, Your Honor.

If we go to the top of the screen, this is from Mr. Clapper to a series of folks, including you. You're on the last "to" lines.

A. Yes.

Q. The subject is Minerva at the 2011 AAGL meeting in Florida.

Do you see that?

A. Yes.

Q. It says, attached is a brief recap of this week's AAGL meeting, and a short slide show so you can see the team in action. Dave?

Do you see that?

A. Yes.

Q. I think the jury probably knows it. Just in case, the AAGL, that's the Super Bowl of your industry?

A. Yes.

Q. I probably just committed a trademark violation by using that term.

[1372] Let's go to the next slide. So you showed -- that's the cover of the slide presentation.

Next slide. I think that's the slide that you had showed with Ms. Elson with the various booths colored in; is that right?

A. I believe so.

Q. Right. The next slide. That's your booth; right?

A. That's the Minerva booth.

Q. Right. And we see in that booth -- is there a laser pointer? We see in that booth, we see the device; right? The handpiece device?

A. Yes.

Q. And then there's the controller?

A. Yes.

Q. And just so we're clear, by this time, the handpiece, everything was completed, so this is the final design; right?

A. Or very close to the final.

Q. Okay. And then we have this board. So let's go to the next slide. This shows us what the board said. It gives us the procedure time; right?

A. Yes.

Q. It tells us, no pre-treatment?

A. Yes.

Q. Tells us about the sealing balloon.

[1373] A. Yes.

Q. Tells us about the silicon array?

A. Yes.

Q. The plasma energy design?

A. Yes.

Q. The diameter?

A. Yes.

Q. And there's a note basically say, you're not yet approved to sell; right?

A. That's correct.

Q. Right. And just to get back to this in a second, but just so we're clear, as a medical device developer, you are allowed to develop a device without any fear of patent infringement; right? It's when you start selling that you get at risk. Isn't that your understanding?

A. That's not completely accurate, because I wouldn't have been able to find the company, patent infringement. I cannot go with a clear conscience. When investors give money to me, I'm not looking, they give it to the company. They I've it to me. So I have to do a better job if there's any chance for patent infringement.

Q. I asked a very bad question. What I was trying to say is, legally speaking, you're allowed to, for example, do your clinical trials, and that's not patent infringement, right, because patent infringement is only if you are [1374] selling the product commercially?

MS. ELSON: Objection, Your Honor.

MR. WOLF: I'm just trying to explain what the bottom of that is. I can move on.

MS. ELSON: Trying to elicit a legal opinion.

MR. WOLF: I can move on.

THE COURT: Well, you're going to withdraw the question?

MR. WOLF: Yes.

THE COURT: Okay.

MR. WOLF: You understood that you are allowed to do clinical research with your product, and even if the product would infringe when you start to sell it, it's not infringing doing clinical research; right? That's your understanding?

THE COURT: Overruled.

THE WITNESS: It's not very practical, because end of the day, you know, if you have patent infringement or not, you know, you've got to go in front of the investors and tell them that, you know, I think we have a problem or not. You're not going to be able to raise any money. It's not very practical to do -- spend the money on a clinical trial and you know you are infringing. It makes no sense.

BY MR. WOLF:

Q. I don't want to dig too deep in, I don't think it [1375] matters that much, but sometimes companies will develop a product to launch after a patent expires; right?

A. Maybe. I don't know.

Q. So when the '348 patent expires, anybody can do anything they want. That's the whole point of the patent deal; right?

A. Yes.

Q. So you can develop prior to the expiration of a patent and wait to sell until the patent expires. Then you can do whatever you want; right?

A. Yes, but in this case, when they launch the product, that wasn't an issue. I mean, you know, it hit us out of the blue.

So if you are looking, I believe this started in August, everything was prepared by us. They got the FDA approval prior to that. You know, everybody felt very good about it, the boards, me. You know, said go ahead, launch the product, you know, and, you know, here you go a few weeks later, you know. A, the patent comes out. That's the first time that we're way, you

know, that it's potentially an issue. And, you know, Hologic should have let us know. Not until November of that year in November of 2015 that you have an issue with it.

Q. Are you aware of the fact that your CEO told folks right at the time of the launch, or excuse me, right at the [1376] time of the lawsuit that they had been anticipating a lawsuit for at least six months?

A. You know, I have to tell you, when I did SurgRx, I anticipated the lawsuit at any point in time. If you are not anticipating, you know, you're not doing your job as a CEO.

Every single company I started, I always believed, even at Novacept, I anticipated that somebody is going to sue us. Johnson & Johnson or somebody for reason or no reason, they're going to sue you.

Q. When did you personally first come to think that Hologic might sue you if you launched Minerva's product?

A. When the patent got issued and we were aware of it, so that's one. And really, I was hoping it's not going to happen, but Hologic, you know, filed the lawsuit.

Q. So you weren't aware of other activities or other information in the company prior to then anticipating Hologic's lawsuit?

A. No.

Q. Okay. That wasn't shared with you?

A. I mean, we knew that you filed the patent, but, you know, I didn't know that the patent is, you know, until it issued, I wasn't aware that it was an issue.

Q. Okay.

A. So by the time we launched the product.

[1377] Q. Were you monitoring Hologic's patent portfolio?

A. So my practice, you know, every, you know, six months or so, I go and I check, you know, what's going on. Otherwise, you know, if -- the person I'm looking at my patent is getting issued, I'm getting the notice of follow on or rejection. So I partly don't have to do that.

Q. I just asked another bad question because I used a pronoun that wasn't clear.

Does Minerva check on or keep track of Hologic's patent portfolio?

A. I have no idea.

Q. Shifting gears and we're wrapping up, Mr. Truckai, and I appreciate your patience very much.

You would agree that the cavity integrity test was one of the reasons for NovaSure's success; right?

A. That's one of the reasons, yes. But actually, if you -- believe it or not, we did the clinical trial without it.

Q. The cavity integrity assessment was very important to the commercialization of NovaSure; right?

A. It was very important.

Q. It was very important; right?

A. I would say it's important. Important, yes.

Q. Is there a reason today you're saying important and at your deposition, you said very important?

[1378] A. You know, the applicator had as important a task. You know -- what is the ethical, what is the safety? How do you want to split it?

Q. The cavity integrity assessment is a safety feature that you have to have; right?

A. Many products doesn't have it on the market right now.

Q. It was your view that you have to have it. Otherwise, the physician doesn't have feedback if the device is correctly positioned; right?

A. Correctly positioned and having a perforation is two different things.

Q. Well, let me just ask the question. You would agree that it's a safety feature, you have to have it. Otherwise, the physician doesn't have feedback that the device is correctly positioned; right?

A. I will agree with you only if you are talking about perforation, because the purpose of the it is did you perforate it or not? So it's nothing that has to do with the position. It's not fully opened and it's still passing the perforation detection and it's okay. It's not a safety concern. It's an ethical concern. I mean, it doesn't make -- I don't know if it makes sense. I'm not trying to avoid the question. I'm just trying to tell you, the positioning of the device is ethical. Perforation, it's a safety.

[1379] Q. Can we just agree that, for however you want to slice that apple, it's a safety feature that you have to have?

A. It's an important safety feature.

Q. And you would agree that Minerva's UIT, its uterine integrity test, is an important feature?

A. It is an important feature.

Q. And it's an important safety feature?

A. It's an important safety feature.

Q. And you would agree that without the UIT, the Minerva EAS really isn't the system; is that correct?

A. I'm sorry?

Q. You would agree that without the UIT, the Minerva EAS really isn't a system; is that correct?

A. I would not agree with that. I think it would be a significant and a safer system, but it still could be as effective as it is today. Again, it's a safety issue, not ethical issue.

Q. It's a must-have feature?

A. It's a good-to-have feature.

Q. It's a reason why in your deposition you called it a must-have feature and you're calling it a good feature today?

A. No. The way you slice it. One is safety, another one is ethical.

Q. I think just one more document. You would agree, I [1380] think, already that Minerva always strives to give truthful and accurate information to the FDA; is that correct?

A. Absolutely.

* * * *

[1385] REDIRECT EXAMINATION

BY MS. ELSON:

Q. So in the meantime, just for context, Mr. Truckai, now, Mr. Wolf raised the Hologic and, in

particular, Cytyc [1386] had filed an application that eventually issued as the '348 patent.

Are you aware of that?

A. Yes.

Q. Okay. And when was the first --

MS. ELSON: Can we pull up in the meantime, Jim, I'm sorry, PTX-0114, just while you're looking for that other one.

Oh, I missed it. So if we go to the back of the application that was attached to this cover letter. Okay. There's some claims.

You were sent these claims. And the first time, however, that you saw this application was when you received it. And if we could go back to the cover letter.

MR. WOLF: Your Honor, I just ask counsel be reminded, this is redirect, not cross.

THE COURT: Overruled.

BY MS. ELSON:

Q. So you --

MR. WOLF: I meant in terms of leading questions.

THE COURT: Okay. I understand.

BY MS. ELSON:

Q. Did you receive this on November 21st, 2014?

A. Yes, I did.

[1387] Q. Okay. So when was the first time you became aware that Cytyc Hologic had filed an application that later we learned issued as the '348?

A. I think about that time.

Q. Okay. And were you traveling at this time?

A. Yes. I was in Europe.

Q. What, to the best of your recollection, when did you actually sit down and read this and respond to Hologic?

A. I think in December sometime.

Q. Would that be December 2014?

A. I don't remember. I mean, I don't remember. Around that time.

Q. Around December 2014?

A. I remember that, you know.

Q. Okay. And this was the first time that you became aware of this application; is that right?

A. That's correct.

Q. Now, when patent -- counsel went on and on about how the world was given notice that the '348 application had been filed.

Does the world receive notice the minute an application is filed or do you have to go to the website to actually proactively look what's filed?

A. You have to look.

Q. Okay. So the Patent Office posts when something is [1388] filed and published; is that correct?

A. It's very random. You never know when they're going to publish.

Q. But when they do, they publish it on their website; right?

A. That's right.

MR. WOLF: Your Honor, same objection.

BY MS. ELSON:

Q. But you would have to go to the website to find it?

A. Absolutely.

THE COURT: I understand your objection. It's leading.

MR. WOLF: Yes, Your Honor. And these questions don't matter, but when we get to more significant ones, I want to note my non-waiver foundation.

THE COURT: Okay. So noted.

MR. WOLF: Thank you, Your Honor.

THE COURT: You may continue, counsel.

MS. ELSON: Thank you, Your Honor.

BY MS. ELSON:

Q. So, again, as far as you were ever personally aware of this application in the files is when Hologic actually sent it to you?

A. I had no way to know that they filed. I didn't, I didn't even go and look.

[1389] Q. Right. But when they sent it to you, you became aware; is that correct?

A. Oh, yes.

Q. All right. And when they sent it to you, and here's the cover letter, did they say a word about, hey, Mr. Truckai, we're concerned about infringement? Anything about that?

A. This is the letter.

Q. That's the letter. It doesn't say anything about infringement, does it?

A. No.

Q. In fact, what it says in the Re line, it's a request for signature.

Do you see that?

A. Yes.

Q. So where they were just saying, hey, Mr. Truckai, we'd like your signature on this.

MR. WOLF: Your Honor --

THE COURT: Now at this point. Leading.

BY MS. ELSON:

Q. What were they asking for, Mr. Truckai?

A. They wanted me to sign this document.

Q. What was it?

A. That I'm the inventor on this patent.

Q. Okay.

[1390] A. When I reviewed the patent, you know, I realized that I'm not the inventor of this patent.

Q. Okay. And anything in here indicate to you that they had even the slightest concern about infringement?

A. No.

Q. Okay. Any time before Hologic filed its lawsuit, to your knowledge, did they ever come to Minerva and say, hey, and this is for the course since Minerva was founded and they learned about you. In the course of the seven years, did they ever say a word about any concern?

MR. WOLF: Objection, Your Honor.

THE COURT: I'm asking if there was any concern about infringement expressed to Minerva.

THE WITNESS: Not I'm -- I'm sorry.

THE COURT: You can argue your case in closing argument. Okay? This is a direct examination, so you have to be -- I don't have to tell you. The objection is sustained.

MS. ELSON: Thank you, Your Honor.

BY MS. ELSON:

Q. All right. So you received this request for signature, and did you respond?

A. Yes, I did.

Q. Okay.

MS. ELSON: Can we bring up PTX-06. Okay.

[1391] BY MS. ELSON:

Q. And let me see here. And I apologize. Can we go back to the prior exhibit? The letter? I forgot to point out, do you have it there, Hologic's PTX-114? If you could look at that and go to the claims at the very back.

A. This is the --

Q. PTX-114. Hologic's PTX-114. This was attached to the cover letter.

A. PTX-114.

Q. Correct.

A. 0114.

Q. 0?

A. Oh, 0114.

Q. And if you could just go back to the claims at the very back of the attached patent application, the Hologic test. Flip to the last page.

Are you there?

A. Yes.

Q. Do you see the claims at the end of the patent? Excuse me. The application?

A. That are canceled?

Q. Claim 8, for example?

A. Claim 8?

Q. Yes. Do you see that?

A. Yes.

[1392] Q. Okay. Do you see the element, an indicator mechanism? Do you see that element?

A. Yes, I have.

Q. Okay. That's easier on the screen?

A. Yes. I didn't bring my glasses.

Q. So was this the first time you had ever seen an indicator mechanism as one of the claims in this family of patents?

A. Yes. That is the first time I've seen it.

Q. Okay. And then you responded, and if we could bring up, again, sorry, PTX-106.

So if you could go to the top and zoom in there. It's a little hard to read.

Okay. And this is -- what is this? What are we looking at?

A. This is a letter that I wrote to Mandy.

Q. And who is Mandy?

A. That person that sent me that request.

Q. Was she with Hologic?

A. Yes.

Q. And so you're responding to this letter that they sent in November attaching the application?

A. That's right.

Q. Okay. And what's the date on there?

A. 12/19/2014.

[1393] Q. In substance, what were you saying to her? Let's start with the upper part, starting with following will all the way down to the use of -- before the use of mechanical spreaders?

A. I stated --

Q. What are you saying here?

A. That I reviewed what they requested. I reviewed the document and that I, in good faith, I can't claim that I'm, you know, the inventor, you know, on this application. And it's not my invention. I mean, I don't want to put my name on an invention if I'm not an inventor.

Q. And why didn't you think this was your invention?

A. First thing, I knew in the past, they have -- oh, I'm sorry. I was aware that, you know, other devices like this on the market. So, you know, I didn't file a patent application because it was already there.

Q. Now let's just highlight starting with the use of mechanical spreaders. Go down the through the rest.

Okay. And can you just read that first sentence highlighted there, Mr. Truckai?

A. The use of mechanical spreaders for indicating the width of a uterus was well-known at the time that we filed the application describing uterine measurement.

Q. Go ahead and read the rest?

A. I would love it and such devices and I incorporated [1394] such features into the device that I described in the application. At no time have I ever considered the use of the mechanism indicator mechanism disclosed and for the first time now claimed in the application to be an invention.

Q. Did Hologic follow up and ask you to send them some prior art on the mechanical spreaders?

A. No, they did not.

Q. If we could go to now -- if we can pull up the one where the pat even office -- I'm sorry, the applicant amended the claims, rejected the claim. Maybe we can remember from yesterday.

So after this, did the Patent Office reject all the claims in this application?

A. I think so.

Q. Okay. If we can find that rejection. Perhaps, ladies and gentleman of the jury, remember this. All the claims were rejected, and were they rejected based on one of your earlier patents?

A. That was the prior art.

Q. All right. And then you provided prior art to Hologic for the indicator mechanism?

A. That's right.

Q. Okay. And there we go. So all of these claims -- can we go to the examiner's response, paragraph 15 to 16, just [1395] to remind the ladies and gentlemen of the jury.

So after you responded to Hologic, there we go, the Patent Office rejected the claims of this patent as unpatentable. Is that your patent, the '880?

A. That's right.

Q. Okay. In view of King.

Do you see that.

A. Yes.

Q. All right. So after you told them this wasn't in your invention and you thought mechanical spreaders were old, are you aware that the Patent Office rejected all of these claims?

MR. WOLF: Your Honor --

THE COURT: Your objection is?

MR. WOLF: Leading.

MS. ELSON: I'm asking if he's aware that the examiner rejected all of these claims.

THE COURT: I'm afraid we're never going to get finished with the testimony unless it's more or less leading.

MR. WOLF: All right, Your Honor.

THE COURT: Okay. But I don't want to discourage you from objecting when you believe that it's appropriate, but under the circumstances, and given the subject matter, I don't think that it's improperly leading [1396] the witness.

MR. WOLF: Understood, Your Honor. Thank you.

BY MS. ELSON:

Q. So did you become aware later that the Patent Office had rejected all of these claims?

A. Yes.

Q. Okay. And is that based on, is that your '880 patent?

A. That's correct.

Q. And is that based on the King reference?

A. That's right.

Q. Okay. If we go to paragraph 16.

And do you see hear the Patent Office said King discloses a uterine device, including an indicator mechanism.

A. That's right.

Q. So do you believe the Patent Office agreed with you, that King was right about this is all old and unpatentable?

A. I believe so.

Q. As far as what Hologic sent you?

A. Absolutely.

Q. I won't go into what happened after that, but we can talk about that later. So let me move on.

And let's see. Now, did you consider Minerva's red/green indicator to be again an improvement on the old gauge?

[1397] A. It wasn't that important to us.

Q. Okay. Now, if we could pull up PTX-41. Okay.

Do you remember this one, which is the one Mr. Wolf showed you from Ms. Mary Edwards, who at the time was Minerva's VP of regulatory with the FDA.

A. Yes.

Q. Okay. Now, this was sent, if we could go to the top, in July 2010; is that correct?

A. Yes.

Q. Okay. Now, do you recall when the '348 patent, which is the only one at issue for willfulness, did this exist yet?

A. No.

Q. Okay. And when did it issue?

Do you recall?

A. 2015, August something.

Q. Okay. And as far as -- just look at the subject line, because -- did you say something earlier about this had to do with clinical trials?

A. Clinical testing.

Q. And what did we see here in the subject line? Could you highlight please regarding endometrial ablation, just the word regarding endometrial ablation trials?

A. Yes, because the budget and the way you conduct in the cloud is very much related.

[1398] Q. Now, was Ms. Edwards, did she as far as you know have any technical degree?

A. No.

Q. What was her specialty?

A. Regulatory.

Q. Does the FDA have, just at a high level in general, its own regulatory scheme what they are talking about whether things are similar or not?

A. Also, they have their own language.

Q. And does that -- does the similarity have to do that you go to the same test, test the device in the same way?

A. I assume, but, again, I wasn't on this e-mail, but that's the assumption, you know.

Q. Okay. And if we could go down to the part that Mr. Wolf pointed to towards the bottom, item three, specifically. Let's highlight that. There we go.

Now, here she's saying the Minerva device is almost dead identical to NovaSure and she's talking about the trials; is that correct?

A. It is, because it's a global -- meaning you insert it blindly. You don't see where it is. You have to position it, and how do you test it?

How are you going to conduct --

Q. How do you test it?

A. Yes.

[1399] Q. Did she tag on, except using plasma energy RF?

A. You have to disclose to the FDA that, you know, the energy type is different.

Q. And is that, have you that that is what makes it different from the NovaSure?

A. Yes. And the agency's view about it. We did a demonstration for them. We showed them how different we are.

Q. Okay. So she's saying identical, but it says accept using plasma energy; is that correct?

A. Correct.

Q. Is that your plasma formation array?

A. Yes.

Q. If we go further down, one last thing here?

A. Just one thing I would like to point out.

Q. Sure?

A. We did show the working unit to the FDA. It's not just, you know, Colin Pollard, but others, so it wasn't like we tried to hide. We showed them, this is the device.

Q. Absolutely. And then if you go down to page 3691, let's go town to, this is the bottom of the e-mail chain, so this is the context for the conversation. So let's just take a look at that at the subject line.

MR. WOLF: Your Honor --

BY MS. ELSON:

[1400] Q. Again, it says regarding endometrial ablation trials; is that correct?

MR. WOLF: I understand the interest of moving this along, but this is pure testimony --

THE COURT: No. I understand. Some of it is and some of it isn't, Mr. Wolf.

MS. ELSON: I will just point out two more things, Your Honor. I won't comment.

THE COURT: Okay.

MS. ELSON: Okay. Go ahead. I'm sorry.

THE COURT: Well, I will talk to you about it later, but I'm going to overrule your objection right now, Mr. Wolf, and we'll go from there. But I can't make your objection for you either when she crosses the line, so I'm expecting you to make your objection. But I understand that it's not fair to Ms. Elson for you to be jumping up and interrupting the testimony all the time. So we'll just have to play it by ear.

Go ahead, Ms. Elson.

MS. ELSON: Thank you.

BY MS. ELSON:

Q. Do you see where it says, the first line, could you answer a couple of quick questions? Do you see that sentence?

A. Yes.

[1401] Q. Again, it says, we don't have to highlight that, but can you highlight regarding endometrial ablation trials?

A. That's right.

Q. Okay. And then just regarding endometrial ablation trials.

A. Yes, I see it.

Q. And then a little further down, the next paragraph, can you highlight pivotal trial? What is a pivotal trial? If you know?

A. Yes, I see it.

Q. Okay.

THE COURT: The question is, do you know what it is?

THE WITNESS: Yes, yes, I do know the pivotal. This is the final PMA clinical trial which you are going to submit to the agency if you are involved.

BY MS. ELSON:

Q. Okay. Is this in the context, this whole conversation? Does it appear to you to be in the context of how do you test the device?

A. Yes. I'm painfully aware what was the subject at the time. I can explain if you want.

Q. So I just want to make sure that her comment to Mr. Colin Pollard was regarding testing?

A. That's right.

[1402] Q. You don't need to elaborate?

A. Okay.

MR. WOLF: Your Honor, I don't know whether to laugh or object.

THE COURT: I think laughing is plenty fine. Okay?

So you may continue, Ms. Elson.

MS. ELSON: I'm only trying to move this along.

THE COURT: No, I know that.

MS. ELSON: Okay.

THE COURT: It's a precarious dance. Friday afternoon. I understand that.

MS. ELSON: Thank you.

THE COURT: So continue.

BY MS. ELSON:

Q. Okay. PTX. Let's move on from this one. PTX-0058. Okay.

This is that e-mail that Mr. Wolf showed you from a Dr. Ted Anderson.

If we could go down to where it says, I have one sort of global question.

THE COURT: So excuse me, counsel.

MS. ELSON: Yes.

THE COURT: What exhibit number is this.

MS. ELSON: PTX-0058.

[1403] THE COURT: Thank you.

MS. ELSON: Okay.

BY MS. ELSON:

Q. Do you recall talking about this earlier with Mr. Wolf?

A. Yes.

Q. Okay. Now, at the time, if you look at the date, at the time, did the '348 exist?

A. No.

Q. Okay. So do you think Dr. Ted Anderson was talking about the '348?

A. No. It was almost four years later.

Q. Okay. And as far as the patents we're talking about in this case, was it only the '183 that existed?

A. That's correct.

Q. Correct?

A. That's correct.

Q. Yes. And there's no allegation that Minerva willfully infringed the '183 patent in this case; is that correct?

A. Not at all.

Q. Okay. So just globally, if we could bring up, just JTX-42.

Okay. Now, if we could zoom in on the top, please.

So before I ask about this specifically, [1404] Mr. Wolf showed you some old power points and things from 2009; is that correct?

A. Yes.

Q. All right. Now, you do recognize what this is?

A. Nondisclosure agreement.

Q. And can we highlight this? This is between Minerva and Hologic.

A. Yes.

Q. Okay.

A. I'm sorry.

Q. And it's dated January 6th, 2010; right?

A. Yes.

Q. So when he was showing you and asking you about information conveyed prior to this, the NDA was not yet in place; is that correct?

A. Because I remember in November of 2009, it was a harmless, you know, nonconfidential, but that had been eight years.

Q. Okay. It was after that that Minerva revealed a lot more information to Hologic?

A. Yes, that would be correct.

MS. ELSON: All right. Thank you very much. No further questions.

* * * *

[1414] THE COURT: Please be seated, ladies and gentlemen.

You may continue your examination of the witness, Mr. Wolf.

MR. WOLF: Thank you, Your Honor.

If we could call up PTX-114, please.

BY MR. WOLF:

Q. This was the request for you to sign the patent application?

A. Yes.

Q. And to be clear, this is an application that tied all the way back to your work in 1998?

A. Yes.

Q. And at the time, November 21st, 2014, you had finalized your design for the Minerva product; is that right?

A. Yes.

Q. So you knew that if you signed this application, you would be signing onto a claim that your product that you had been working on for five years infringed; right?

A. It wasn't my thought, sir.

Q. You knew that you would infringe the claims that were in this application; right?

A. I felt, I wanted to see, you know, I've never been in the situation and I thought we had prior art, but I asked, [1415] you know, to sign something, which I knew that it shouldn't be valid.

Q. So the claim was rejected, but then it was amended. It issued and the product infringes; right?

A. The patent was issued.

Q. So let's go to. PTX-481. I just want to be clear. This is the document where Ms. Edwards says, the Minerva device is almost dead identical.

Two questions. You would agree with me that dead identical is not language in talking about clinical studies or -- that's talking about the product; right?

A. I cannot tell you what she meant by dead identical, but, you know, the two devices are not dead either.

Q. The second question is: You said, and I just want to be clear, that you had showed the FDA, at the time you were describing dead identical, I think you said, the whole final device; isn't that right?

A. Whatever stage the device was, which I cannot tell you besides this. Minor modifications.

Q. PTX-58, please. This is a document where it says, one of the members of your Medical Advisory Board, Dr. Ted Anderson said, I have one sort of global question. I envision major patent infringement disputes.

Do you see that?

A. Yes.

[1416] Q. Counsel asked you about dates.

A. Yes.

Q. Do you remember?

A. Yes.

Q. Just to be clear, the application, original application was filed in 1998, and by this time, it was public; right?

A. Yes, but nothing to do with claims. It was issued later. At the time I didn't know when it was going to issue.

Q. It's important for Minerva to make sure they don't infringe other people's patents; right?

A. If I know about it.

Q. Right. And you're aware that almost every medical device company on earth has a group that specifically is tasked with tracking the patents of their competitor; is that right?

A. I don't know. The company, I'm not sure. We do have a team. I don't think that we have the resources. But Mr. Clapper can answer that.

Q. Last question. JTX-42. You were asked about the date of this document.

Do you remember that?

A. Yes.

Q. Just so we're clear, you would agree with me that the [1417] 2011 AAGL conference occurred after the date of this document?

A. Yes.

MR. WOLF: No further questions.

MS. ELSON: No further questions, Your Honor.

THE COURT: All right. Ladies and gentlemen of the jury, do you have any questions of this witness?

You may step down, sir.

(Witness excused.)

* * * *

[1418] . . . EUGENE SKALNYI, having been duly sworn as/affirmed as a witness, was examined and testified as follows . . .

MR. BISH: Your Honor, may I approach?

[1419] THE COURT: Yes, you may.

DIRECT EXAMINATION

BY MR. BISH:

Q. Good afternoon, Dr. Skalnyi.

A. Good afternoon.

Q. Are you employed at Minerva Surgical?

A. Yes, I am.

Q. What's your title?

A. I'm serving as vice president of medical affairs.

Q. Can you tell the jury a little bit about yourself, starting with your education?

A. I was born and raised in Eastern Europe in the country of Maldova. I went to medical school. I graduated with a degree in medicine. Went through my specialty training in obstetrics and gynecology, subsequent to which I went through additional training in Germany in advanced endoscopy, followed by Stanford and some additional training in Sacramento.

Q. Stanford University, is that in California?

A. It's in California.

Q. So, sir, are you a medical doctor?

A. Yes, I am.

Q. Are there other medical doctors in your family?

A. Yes. Exactly. A family of physicians. My wife is an OB/GYN. My sister is an OB/GYN. Her husband. It's a [1420] number of gynecologists in the family.

Q. Now, sir, when you first moved to the United States, can you tell the jury what you did professionally?

A. Well, we moved to the U.S. in about 1998. Came in as refugees. I couldn't work as a physician right away. And we had to support our family, so I had actually two jobs. I was delivering pizzas initially and selling cars. But then subsequently, I obtained a position at Stanford teaching advanced endoscopy.

Q. Advanced endoscopy, what is that?

A. It's basically conduct of minimally invasive procedures and we were teaching basically technique, or how to con duck those procedures to gynecologists and surgeons that exhibited interest in this type of procedures.

Q. We've been talking a lot about endometrial ablations in these proceedings. Can you explain how what you were doing at Stanford relates to ablation?

A. Ablation back then and still is, the only one available was the rollerball ablation, which is a minimally invasive procedure. So that was a part of the curriculum that was taught at the course. So the rollerball procedure was taught to the doctors.

Q. You say rollerball?

A. Yes. It's rollerball.

* * * *

[1425] Q. How do you know that?

A. Any time you make a change to a medical device that has a material impact on the outcome of the procedure, certain documentation has to be filed with the FDA, where FDA has to be advised that this device is actually different than the device that was originally approved, and even though this is the case, most likely additional clinical resources are required.

And everything that was filed so far indicated that the generation to generation of this device is really equivalent to the one that was there before.

Q. Okay. Now, let's fast-forward. And now you're at Minerva Surgical; right?

A. Yes.

Q. And how many Minerva procedures have you observed?

A. Hundreds.

Q. And have you trained doctors on the use of Minerva?

A. Yes, I did.

Q. Now, so you're very familiar with the Minerva product; is that right?

A. I am.

* * * *

[1428] Q. That's from the doctor's perspective. Now, what about from the patient's perspective? In your experience, what is better about the Minerva device than anything else, any other ablation device?

A. Well, I will tell you this. That we see that -- we get a lot of reports that the amount of both intra and post-operative discomfort or pain is somewhat less. But I think the important ones are those that we

actually can actually touch, and basically say, okay, we know that for a fact, and success. Basically, the objective of the procedure, to make sure that you're successful.

This particular technology allows for the highest success among all when comparing to any device that was developed in history of ablation. Rate of amenorrhea. This is by far the most desirable outcome as indicated by the recent research of over 1200 women, that indicated that the ultimate outcome for them is to have amenorrhea, meaning no bleeding whatsoever.

So Minerva produces by far the highest rate of amenorrhea. Patient satisfaction is extremely important. [1429] Patients in our study show one of the highest, if not the highest rates of patient satisfaction. But I think the most important one often not looked into and not recognized is understanding why these procedures are performed in the first place and the true objective of end ablation is actually avoidance of hysterectomy. That's why these procedures are done.

So the question should be: In the long term, are his's avoided or not? And when you look at the outcome, at the clinical data coming from the FDA, outcome of Minerva procedure produces seven times outcomes when comparing to NovaSure when it comes to rate of hysterectomy at three years post procedure.

Q. And how does that compare to the other devices, like Thermachoice or HTA?

A. It's even better.

Q. Or Her Option. I'm sorry. What was that?

A. It's even better.

MR. BISH: Your Honor, I don't know how long you want to go this afternoon before we break. I'm at a transition point. I'm happy to keep going.

THE COURT: I think you should.

MR. BISH: Okay. Great.

THE COURT: I'd like to go for a bit longer.

So we've tipped our hand. We're going to let [1430] you out a little early. Mr. Bish let the cat out of the bag, but I'm the one that's going to let you out early.

MR. BISH: I'm not taking credit for Your Honor.

THE COURT: Mr. Bish, keep going.

MR. BISH: Can we get DDX-10, slide 5. Slide 5. Yes.

BY MR. BISH:

Q. Now, again, we've talked a lot about the success rate already. I know we've beaten the 77.7 number to Beth. Sir, what are the SSED rates for the Minerva?

A. Well, we've conducted two FDA clinical trials, and when you look at the success rate in the first clinical study, it was 91.8, so basically almost 92 percent, and 93 percent in the second study. When you look at the rate of amenorrhea, meaning complete cessation of bleeding, it was 66.4 percent in the Minerva treated patients in the first study, and 72 percent in the second.

Q. And if we can pull up JTX-24 at page 21 just very quickly.

What do you see here, Doctor?

A. Basically, these are the numbers. In the SSE document, which is the summary of safety and

effectiveness document, and this is a document that's published by the FDA.

* * * *

[1482] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

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CIVIL ACTION NO. 15-1031-JFB-SRF

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HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
*Plaintiffs and Counterdefendants*,

vs.

MINERVA SURGICAL, INC.,
*Defendant and Counterclaimant.*

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Wilmington, Delaware
Monday, July 23, 2018
8:30 o'clock, a.m.

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VOLUME 6

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BEFORE: HONORABLE JOSEPH J. BATAILLON, U.S.D.C.J., and a jury

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* * * *

[1654] . . . DAVID M. CLAPPER, having been duly sworn/affirmed as a witness and testified as follows . . .

* * * *

[1655] DIRECT EXAMINATION

BY MR. POPLAWSKI:

Q. Please introduce yourself to the jury and tell us where you work.

A. My name is Dave Clapper. I am the president and CEO of Minerva Surgical.

Q. A name we've heard from time to time. When did you start work at Minerva?

A. In May of 2011.

Q. What are your responsibilities as the president and CEO of Minerva?

A. I'm responsible for a variety of things, including setting the strategy for the company, filling out the organizational chart, particularly at the top level of the senior management team.

I'm responsible for finalizing the product line, financing the company, et cetera, et cetera.

Q. How many years did you work specifically with endometrial ablation devices?

A. I started in 1990s.

Q. How many years have you worked in the field of medical devices?

A. Over 40.

* * * *

[1682] Q. All right, Mr. Clapper. We're going to switch to another topic, and that is Minerva's communications with Hologic.

Did Minerva have any communications with Hologic when it was developing Minerva's product?

A. Yes.

Q. And when did that first happen to your knowledge?

A. I believe the first communications were in the fall of 2009.

[1683] Q. And how did that happen, sir?

A. Well, this is a, one of my unemployment periods, and I met with Csaba. He described to me what his plans were and his vision for Minerva Surgical. And we talked about the project and its financing requirements and getting to clinical trials and what his vision, again, of what -- how the product could potentially improve patients with AUB.

And we left and a couple days later, I thought about the project, and I suggested that since we had had such a good, you know, collaboration with Cytyc, it was then, of course, part of Hologic, but many of the people still worked there, that I suggested, you know, it just seems like the right thing to do to contact them and tell them right from the start exactly what you're up to, the project you're working on, your vision of why it could be an improvement over all the other ablation product that are out in the marketplace with your hope, because you're going to need money down the road, that they could get excited about this and say, hey, this looks great. We'd like to work on this with you.

Q. When did you first reach out to Hologic?

A. In the fall of 2009.

Q. And did you understand Hologic to be interested in talking further to Minerva?

[1684] A. Yes. Right away. Yes. Immediately.

Q. And what happened next?

A. So we had a short meeting at a surgical conference that took place, I believe the third week in November, and after that, they went away and thought about it, and we had gotten back in contact with each other and decided that we wanted to then

kind of formalize the effort of talking to each other, and we signed a nondisclosure agreement so that we could from that point on disclose everything about the product.

* * * *

[1693] Q. Now, let's move forward from January 6th, 2010. Did you share any confidential information of Minerva with Hologic under this confidential nondisclosure agreement?

A. Of course.

Q. What did you share, sir?

A. Everything that was on the list that we talked about earlier. We shared with them not just, here's the device and here's the controller. We took the cover off the controller in our laboratory, showed them the inner workings of the controller and how it worked. We had the engineers discuss and lecture their engineers on, at least a person from R&D, on how the system worked. We answered all of their questions about everything from plasma formation array, which takes a little while to understand, as everybody in this room can attest to now, through all the steps of the procedure and how they were different from the Minerva device because at the outset, it looks like this is a very similar device, but when you go through the steps, it's very different. But, yes, everything that they asked [1694] questions about, we gave them the answers.

Q. Did you share any financial and business information of Minerva's with Hologic?

A. Yes. We shared with them information that we don't even share with our own employees.

Q. All right. Would you go to, and I have to ask you about this first before we get a publication request.

A. Okay.

Q. So would you go to DTX-0642. And I will wait until you're there, Mr. Clapper.

A. I'm there.

Q. What is this document, sir?

A. This is a presentation, one of a series of presentations that were made to Hologic over the course of our discussions with them. This was -- it looks like this was made in September of 2012.

MR. POPLAWSKI: Your Honor, move to admit it into evidence.

MR. WOLF: No objection.

THE COURT: 642 is received.

(PTX-221 was admitted into evidence.)

MR. POPLAWSKI: Thank you, Your Honor.

BY MR. POPLAWSKI:

Q. Mr. Clapper, we've now published. What is the date of this presentation by Minerva to Hologic?

[1695] A. September 24, 2012.

Q. Okay. And was this a presentation of confidential Minerva information?

A. Some of it was confidential. Some of it was not.

MS. ELSON: But, yes, it included confidential information.

Q. And who gave this presentation to Hologic on September 24, 2012?

A. I did.

Q. Was that in person between you and Hologic?

A. I believe so, yes.

Q. All right. Let's talk about who those persons were at Hologic. Who at Hologic did you share this presentation with in person?

A. As I recall, it was Russell Layton and Shacey Petrovic.

Q. And at the time, what was Mr. Russell Layton's position with Hologic?

A. I believe he had just come out of a research and development position and was at this time working as a director of business development.

Q. At Hologic?

A. At Hologic. Mm-hmm.

Q. Shacey Petrovic. At the time of this September 24th, 2012, presentation, what was her position with Hologic?

[1696] A. She was the general manager of the surgical division, which included endometrial, the endometrial ablation product, NovaSure.

Q. All right. Now --

A. And vice president.

Q. Thank you.

Can you describe the circumstances under which you shared this September 24th, 2012, presentation with Ms. Petrovic and Mr. Layton?

A. Well, this was in one of the ongoing series of meetings and presentations. As you recall, we met with them in 2009, in 2011, in 2012, so here we are

again, and we're giving them a presentation that's formatted similar to the earlier presentations we gave, but as we're going through this, we're giving them a detailed update on where we're at.

Secondly, I point out, this presentation is a guide. Okay. So throughout this presentation, for example, when we would talk about the technology, we would break, go into the laboratory with them, and actually demonstrate the controller and the device. In fact, on this particular day, we actually went in and had them do a simulated endometrial ablation in a large piece of beef liver, where they actually walked through all the steps of the procedure.

Q. Was Minerva's intellectual property shared with [1697] Hologic?

A. Yes.

* * * *

[1702] Q. Now, what happened after Ms. Petrovic and Mr. Layton visited Minerva and received all of this information back in September of 2012?

A. They were very pleased with the meeting and told us that they were excited to go back to Boston, where the Hologic's headquarters are, and they were going to meet with Rob Casella, who set was the president of Hologic, and try to put together a creative deal whereby they would acquire Minerva.

Q. The --

A. This was a pretty exciting day at little Minerva Surgical.

Q. Did Minerva, in fact, receive any offer from Hologic to acquire the company?

A. No. We didn't hear anything. We thought -- when they left, said they'll get back to us in a week or ten days. It was two weeks, three weeks, four weeks. Finally, we prodded them. Hello, are you going to get back to us? And they [1703] did, finally.

* * * *

[1705] A. I tried to lay out the series of major events, not all of the communications and events that took place between our first contact in the fall of 2009 and, you know, the November 2015. So on this blue line, it shows we met 2009, 2010. We signed the nondisclosure agreement so we could really go to work collaboratively, sharing all kinds of information.

We met again in 2011. It's not on here, but we met in 2012, where we went through the presentation that we just looked at.

In 2013, five Minerva patents issued, so things are humming along. We're, you know, conducting clinical trials. Life is good. And then August 13th, we had other, you know, teleconference calls/meetings.

So this is the way that I and the senior management teams in Minerva looked at the relationship. We had everything going along great here.

What we didn't know is on the redline above it.

[1706] Q. All right. Would you talk about this redline that you prepared which starts with the word Hologic?

A. Okay. So this is the disappointing part. While we are sharing with them everything about our technology, our financial status, everything about the company, our view of the market, clinical investigators, detailed information on how our clinical trial was going after we treated 30 patients, 60, 90,

and so on, what we didn't know that was in August of 2013, secret to us -- remember, this nondisclosure agreement we signed was mutual, where we could both share confidential information, but secret to us, in August of 2013, Hologic filed for the '348 patent.

Q. All right. And that '348 patent issued in August of 2015?

A. Yes, I believe it was the first week of August 2015.

Q. And then we're here with a lawsuit in November of 2015?

A. Right.

* * * *

[1729] CROSS-EXAMINATION

BY MR. WOLF:

* * * *

[1736] Q. I'm talking as a general concept. What did you understand --

A. Putting this aside.

Q. Did you know --

A. A company is representing certain things and warranting certain things -- the company, an individual, et cetera.

Q. And you understand that -- you understood in the context of this document that Hologic was entitled to rely on your reps and warranties and that they did so in signing the document; is that right?

A. That's a good assumption.

Q. Let's go to 3.9(e), so just to be clear, before we go on, this is Article 3. These are horribly paginated documents, but this is Article 3.

A. Yes.

Q. Okay. So let's go to 3.9(e). And this is a rep and warranty that Novacept made to Hologic in 2004; is that right?

A. I have to read it.

(Pause while witness reviewed exhibit.)

THE WITNESS: Okay.

BY MR. WOLF:

Q. So you made the representation in 2004 to Hologic that Novacept has no present knowledge from which it could [1737] reasonably conclude that Novacept's own intellectual property and any intellectual property licensed to the company under the company licensed intellectual property, are invalid or unenforceable; right?

A. At the moment this was signed, yes.

Q. Yes. In 2004?

A. Yes.

Q. Now, there has been some testimony in this case about Novacept's awareness of a product called Vesta in 1995.

You would agree with me that to the extent that Novacept knew of something before 2004, it was telling Hologic, we don't think this invalidates any patents you might have or get; right?

A. Yes. I didn't know anything about the Vesta product whether we sold them. I had heard of it. I had

never seen it. I had never held it in my hands. I had never seen a picture of it. I don't know anything about it. I saw it last week though.

Q. Right. Certainly, Hologic was entitled as a matter of signing this agreement with you to understand that it was not Novacept's position that Vesta invalidated any IP; right?

MR. POPLAWSKI: Objection, Your Honor. Calls for speculation and what was not in the minds of what was set.

* * * *

[1778] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

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CIVIL ACTION NO. 15-1031-JFB-SRF

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HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
*Plaintiffs and Counterdefendants*,

vs.

MINERVA SURGICAL, INC.,
*Defendant and Counterclaimant.*

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Wilmington, Delaware
Tuesday, July 24, 2018
8:48 o'clock, a.m.

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VOLUME 7

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BEFORE: HONORABLE JOSEPH J. BATAILLON, U.S.D.C.J., and a jury

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* * * *

[1858] (The jury entered the courtroom.)

THE COURT: Please be seated, ladies and gentlemen.

You may proceed, Mr. Bish.

MR. BISH: Thank you, Your Honor. Minerva offers the deposition testimony from Ms. Whitney Parachek, which, as a reminder, as you've heard, Ms. Parachek

was the head of sales for Hologic's surgical division in 2015 and 2016.

We're going to start with Ms. Parachek's February 23rd, 2016 deposition.

THE COURT: You may proceed, counsel.

(The videotaped deposition of Whitney Parachek was played as follows.)

* * * *

[1862] "Question: You had conversations at Hologic that Minerva is a startup company; right?

"Answer: Yes.

"Question: That they have limited funds; right?

"Answer: Sure.

"Question: And if -- if Hologic is successful in preventing sales in the near term after launch, Minerva won't be bought and won't be a competitor; right?

"Answer: Those discussions have been had.

"Question: And so that is the strategy at Hologic, right?

"Answer: What is the strategy?

"MR. BISH:

"Question: To prevent Minerva from having any traction in the market in the very near term so that it can't be bought and will go under, right?

"THE WITNESS: Our strategy is -- our strategy is to focus on selling our products and continuing to partner with our customers that we have for the past 14, almost 15 years.

"Question: And you've had conversations that Hologic's strategy should be depriving Minerva of sales in the near term so they can't go bought and they go under; right?

"Yes or no? Have you had those conversations?

[1863] "Answer: We've had those conversations.

"Question: And I asked you earlier what were the factors that caused you in 2014 to perceive Minerva as a formidable competitor?

"Do you recall what factors you had in mind?

"Answer: I believe I answered that that was -- they were going to be a new competitor, as a new competitor coming to market.

"Question: And did it impact your opinion that several of the individuals at Minerva had -- were amongst the inventors of NovaSure?

"Answer: Did it impact my opinion?

"Question: That they were going to be a formidable competitor?

"Answer: Yes. I mean, I knew that Eugene and Dave Clapper had had success in startups:

"Question: Including Novacept; right?

"Answer: Including Novacept.

"Question: And they were amongst the inventors of NovaSure; right?

THE WITNESS: Eugene and Dave were part of that team.

"Question: Which gives them credibility in the market; right?

"Answer: Yeah, I think that -- yes, they had

* * * *

[1871] "Question: Can you give me a rough approximation as to the number of customers who were exposed to the videos after Minerva's launch?

"Answer: No.

"Question: Fair to say in the hundreds?

"Answer: I would have no estimate, I don't know."

(End of videotaped deposition.)

MR. BISH: Thank you.

Minerva now offers the video deposition testimony of Tom O'Neill.

As a reminder, Mr. O'Neill was the president of the surgical division in the 2015 time period, and the deposition is dated April 25th, 2017.

(The videotaped deposition of Tom O'Neill was played as follows.)

"Question: Do you recall anything about how the circumstances by which Minerva was first introduced to you?

"Answer: As near as I can recall -- and my memory is not always perfect at my age. But as near as I can recall, it's just that there was a competitor coming into the space. And it was -- the GEA space hadn't had a new competitor in quite some time.

"Question: But from the outset, you conveyed to [1872] your team that the goal was to not let them sell even one product. Right?

"Answer: No, I don't recall that at all.

"Question: Because you knew that putting financial pressure on Minerva at an early stage could put them out of business. Right?

"Answer: No, I don't recall that at all.

"Question: Sir, Exhibit 1 is an e-mail from you; right?

"Answer: Yes.

"Question: And you began, 'While you don't know me yet, I have past experience in a startup company.'

"Do you see that?

"Answer: Yes.

"Question: And then you write, 'The best thing we can do is not let them get a footing in any market.'

"Do you see that?

"Answer: I do.

"Question: 'This will put tremendous financial pressure on their entire organization and we will step them in their tracks.'

"Do you see that?

"Answer: Yes.

"Question: And so this is what we were talking about before, that your goal was to put financial pressure [1873] on Minerva. Right?

"Answer: Sure.

"Question: To stop them in their tracks?

"Answer: Right.

"Question: And put them out of business?

"Answer: That's what I said here, right. It's in an e-mail.

"Question: And that was your goal. Right?

"Answer: No. Actually, I don't think it was what the goal was. I don't think there's any reasonable person would think that we were going to keep them from having any cases. I think what I was trying to do is motivate and really get the team focused and energized and excited about selling our story. Because if you look at the rest of the e-mail from all of the folks involved from the beginning, whether it was Dan or Brian, up to Whit, it was really about this message, which was the Hologic story and our NovaSure message.

"So I wouldn't characterize my comments after having been there for a week as clear direction that they shouldn't let a case happen.

"Question: Now, you also had discussions with Ms. Parachek about implementing a 'scorched earth,' strategy to beat Minerva. Right?

"Answer: Yeah. I don't recall that.

[1874] "Question: I'm handing you what I've marked as Exhibit 2, which is an October 2nd, 2015, e-mail from you to Ms. Parachek, Bill Fruhan and Edward Evantash.

"Answer: Okay. What's the question?

"Question: Do you see Exhibit 2 starts with an e-mail from yourself --

"Answer: Right.

"Question: -- where you write, where are we with the Minerva defense program we discussed last week at dinner?

"Answer: Yes.

"Question: And Ms. Parachek responds, Tom, sorry for the delay. I planned to respond to this during our one-on-one, but we did not get to it. We have an outline of aggressive ideas for a scorched earth strategy that I will forward.

"Do you see that?

"Answer: Yes.

"Question: And do you recall what that scorched earth strategy was?

"Answer: So the way I read it here with what Whitney outlines is it has to do with leveraging our Med Affairs Group and making sure that we were putting together a co-op marketing program to drive partnership and growth. That's the way I read this.

* * * *

[1877] (End of videotaped deposition.)

* * * *

[1948] MR. BISH: Your Honor, Minerva offers the video deposition testimony from Ms. Shacey Petrovic, who is the former vice president and general manager for Hologic's gynecological surgical division in the 2013 time frame.

(The videotaped deposition of Shacey Petrovic was played as follows.)

* * * *

[1951] "Question: I've handed you what's been marked now Exhibit 16, HOL-MIN_10 -- excuse me, 016205 on its face. And can you confirm this is the attachment to the e-mail from Mr. Williamson of Exhibit 15?

"Answer: Yes.

"Question: And it's titled strategy planning meeting key themes and takeaways. Correct?

"Answer: Yes.

"Question: And at this point in time, which his e-mail again is dated June 17, 2011, Minerva has not appeared on the market. Correct?

"Answer: Correct.

"Question: You don't recall any concern at all about IP expiring with respect to the NovaSure?

"Answer: I really don't.

"Question: And here Mr. Williamson is exhorting the team to accelerate our time to market of that smaller diameter NovaSure device?

"Answer: Yes.

"Question: When -- at the very bottom bullet point, it says, 'Our Gen 4 team must focus their efforts on laying minefields around our product to: A, prevent more entrants into this field; B, protect our current portfolio.'

[1952] "Do you see that?

"Answer: Yes.

"Question: What did Mr. Williamson mean by laying minefields around our product?

"Answer: I understand that to mean additional patent protection.

"Question: Okay. So was there any discussion of filing for additional patents, for example?

"Answer: I don't recall that specifically.

"Question: Okay. What is it -- as specific as you can recall, what is he referring to exactly with respect to 'laying minefields around our product?'

"Answer: My understanding is he's asking the R&D team to continue to create valuable IP in order to protect new entrants from entering the market.

"Question: What you recall. But there was a concern to prevent more entrants into this field, being global endometrial ablation. Correct?

"Answer: Yes.

"Question: Okay.

"Answer: I don't believe that was the only feature associated with the next generation NovaSure device.

"Question: Okay. But it was a feature?

"Answer: Yes.

* * * *

[2319] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

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CIVIL ACTION NO. 15-1031-JFB-SRF

---

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
*Plaintiffs and Counterdefendants*,

vs.

MINERVA SURGICAL, INC.,
*Defendant and Counterclaimant.*

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Wilmington, Delaware
Thursday, July 26, 2018
9:00 o'clock, a.m.

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VOLUME 9

---

BEFORE: HONORABLE JOSEPH J. BATAILLON, U.S.D.C.J., and a jury

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* * * *

[2419] MR. WOLF:

* * * *

[2425] Remember Mr. Truckai said, nothing in 2009 to 2010 was confidential. And nothing that becomes generally public. We saw the AAGL. All the product stuff was already out in the public. That's the AAGL.

* * * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

---

C.A. No. 15-1031-JFB-SRF

---

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
*Plaintiffs*,

v.

MINERVA SURGICAL, INC.,
*Defendant.*

---

JUDGMENT FOLLOWING JURY VERDICT

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This action came before the Court for a trial by jury beginning on July 16, 2018. The jury rendered its verdict on July 27, 2018. The verdict was accompanied by the verdict form (D.I. 498 and 499), a copy of which is attached hereto.

On June 28, 2018, the Court issued an Order, *inter alia*, granting Plaintiffs' motion for a summary judgment of no invalidity, Plaintiff's motion for a summary judgment of infringement, and Plaintiffs motion for a summary judgment with respect to assignor estoppel. D.I. 408.

IT IS HEREBY ORDERED AND ADJUDGED that judgment be and is hereby entered on the July 27, 2018 verdict as set forth in the attached verdict form and on the June 28, 2018 Order (D.I. 408).

IT IS FURTHER NOTED that this Judgment Following Jury Verdict is subject to revision pursuant to any rulings on post-trial motions.

IT IS SO ORDERED AND ADJUDGED.

August 13, 2018

/s/ Joseph F. Bataillon
SENIOR UNITED STATES
DISTRICT JUDGE

Trials@uspto.gov Paper 8

Tel: 571-272-7822 Entered: September 12, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MINERVA SURGICAL, INC.,
*Petitioner*,

v.

HOLOGIC, INC.,
*Patent Owner.*

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Case IPR2016-00680
Patent 9,095,348 B2

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Before WILLIAM V. SAINDON, RICHARD E. RICE, and NEIL T. POWELL, *Administrative Patent Judges*.

RICE, *Administrative Patent Judge*.

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DECISION
Denying Institution of *Inter Partes* Review
*37 C.F.R. § 42.108*

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## I. INTRODUCTION

### *A. Background*

Minerva Surgical, Inc. ("Petitioner") filed a Petition (Paper 3, "Pet.") requesting an *inter partes* review of claims 1–15 ("the challenged claims") of U.S. Patent

No. 9,095,348 B2 (Ex. 1001, "the '348 Patent"). Petitioner supported the Petition with a Declaration from John Anthony Pearce, Ph.D. (Ex. 1002). Hologic, Inc. ("Patent Owner") filed a Preliminary Response (Paper 7, "Prelim. Resp.").

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the Petition and the Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Accordingly, we do not institute *inter partes* review.

### *B. Related Proceedings*

We are informed that Petitioner is named as a defendant in a federal district court case involving the '348 Patent (Case No. 1:15-cv-01031-SLR pending in the U.S. District Court for the District of Delaware). Pet. 14. We also are informed that Petitioner has filed a second Petition for *inter partes* review of the '348 Patent (IPR2016-00685). *Id.*

### *C. The '348 Patent*

The '348 Patent, titled "Moisture Transport System for Contact Electrocoagulation," issued from an application filed August 8, 2013, and claims priority to May 8, 1998. Ex. 1001, at (54), (21), (22), (60), 1:6–13. The '348 Patent relates to an apparatus for ablating the interior linings of body organs such as the uterus. *Id.* at 1:19–21. Ablation of the interior lining of a body organ, the '348 Patent explains, "involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins for hemostasis."

*Id.* at 1:26–28. Ablation may be performed, for example, to treat chronic bleeding of the endometrial layer of the uterus. *Id.* at 1:28–30. The '348 Patent states that conventional methods of effecting ablation include "application of RF energy [i.e., radio frequency energy] to the tissue to be ablated." *Id.* at 1:31–35. Problems addressed by the '348 Patent include the need for a device that eliminates steam and liquid buildup at the ablation site and that allows control of the depth of ablation in the treated tissue. *Id.* at 1:48–2:30.

Figure 21 of the '348 Patent, which is reproduced below, illustrates ablation device 100:

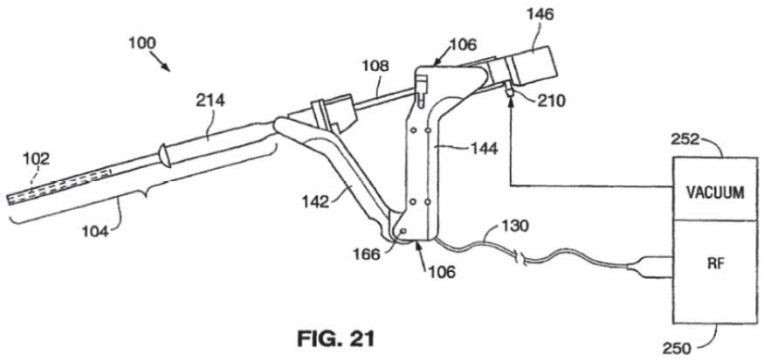



FIG. 21

Figure 21 is a side elevation view of ablation device 100 showing sheath 104, tubing 108, handle 106, and RF applicator head 102 slidably disposed within sheath 104. *Id.* at 11:59–62, 12:2–5. After insertion of the device into the uterine cavity, manipulation of handle 106 causes the applicator head to extend from the distal end of the sheath and to expand into contact with body tissue. *Id.* at 11:63–12:5. The ablation device can be used to measure the width of the uterus, and gauge 146 displays the measured width. *Id.* at 14:33–36. The measured width is entered into RF

generator system 250 and used to calculate the ablation power. *Id.* at 18:37–39. Vacuum source 252 is connected to inner hypotube 122 (discussed below) via suction port 210. *Id.* at 18:40–41.

As illustrated in Figure 23 of the '348 Patent, which is reproduced below, applicator head 102 extends from the distal end of tubing 108. *Id.* at 12:2–5.

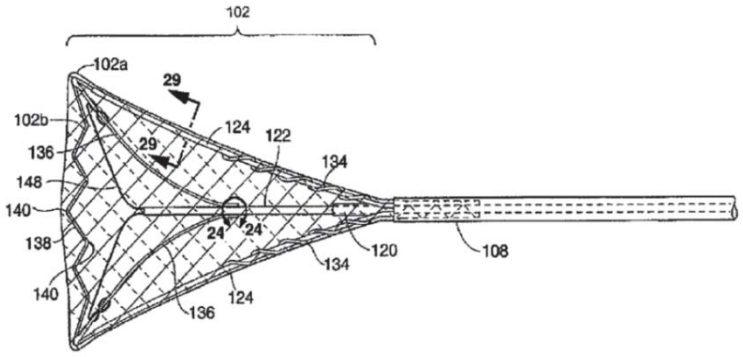



Figure 23 illustrates applicator head 102 in the expanded or deployed state.[1] *See id.* at Fig. 23. Applicator head 102 includes: external electrode array 102a, which is formed of a stretchable metallized fabric mesh; an internal deflecting mechanism 102b, which is used to expand and tension the electrode array for positioning into contact with uterine tissue; and non-conductive suturing threads 148, which extend from hypotube 122 for use in measuring the width of the uterus. *Id.* at 12:5–12, 14:33–39.

The deployment structure for deflecting mechanism 102b includes external hypotube 120, which extends from tubing 108, and internal hypotube 122, which is slidably and co-axially disposed within hypotube 120.

---

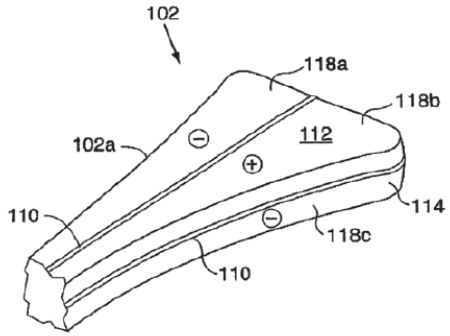
[1] The '348 Patent states that, for clarity, sheath 104 is not shown in Figure 23. *Id.* at 12:2–3.

*Id.* at 13:8–12. Outer flexures 124 extend laterally and longitudinally from tubing 108 on opposite sides of external hypotube 120. *Id.* at 13:12–13. Internal flexures 136 extend laterally and longitudinally from the exterior surface of internal hypotube 122. *Id.* at 13:56–58. Each internal flexure 136 is connected at its distal end to one of the outer flexures 124, and a transverse ribbon 138 extends between the distal portions of the internal flexures 136. *Id.* at 13:58–61. As described in the '348 Patent,

> during use distal and proximal grips 142, 144 forming handle 106 are squeezed towards one another to withdraw the sheath and deploy the applicator head. This action results in relative rearward motion of the hypotube 120 and relative forward motion of the hypotube 122. The relative motion between the hypotubes causes deflection in flexures 124, 136 which deploys and tensions the electrode array 102a.

*Id.* at 14:25–31.

Deflecting mechanism 102b and its deployment structure are enclosed within electrode array 102a. *Id.* at 13:8–9. Figure 25A of the '348 Patent is a perspective view of electrode array 102a in the deployed or expanded state. *Id.* at 3:52–53, 12:53–55. Figure 25A is reproduced below.




As shown in Figure 25A, insulating regions 110 are formed on the applicator head to divide the mesh into electrodes 118a–118d. *Id.* at 12:59–13:7. As power is supplied to the electrodes, the tissue is heated, releasing moisture. *Id.* at 18:44–47. Moisture is withdrawn from the uterine cavity through internal hypotube 122, which is connected to vacuum source 252. *Id.* at 18:47–49. Apertures formed in outer flexures 124 facilitate moisture withdrawal by preventing trapping of moisture between the flexures and the lateral walls of the uterus. *Id.* at 18:49–52.

Handle 106 comprises distal and proximal grip sections 142, 144, which are pivotally attached to one another at a pivot pin. *Id.* at 16:13–16, Figs. 21– 22. Proximal grip section 144 is coupled to hypotube 122 via yoke 168, overload spring 170, and spring stop 172. *Id.* at 16:17–19, 17:38–40, Figs. 34, 37A, 37B. Distal grip section 142 is coupled to external hypotube 120 via male and female couplers 174, 176. *Id.* at 16:20–22, Figs. 32A, 32B, 34. Figure 34 of the '348 Patent is reproduced below.

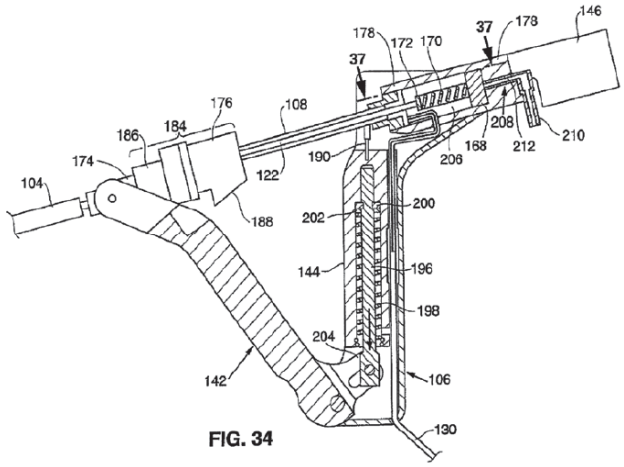


FIG. 34

Figure 34 is a side elevation view of handle 106 as depicted in Figure 21 (reproduced above). *Id.* at 4:19–21.

As the distal and proximal grips are moved towards one another, sheath 104 is withdrawn from array 102a until female coupler 176 contacts and bears against frame member 178. *Id.* at 17:54–59, Fig. 37A, 37B. "Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube 120." *Id.* at 17:59–61. "An opposing force is developed in yoke 168, which causes a relative forward motion in hypotube 122." *Id.* at 17:61–63, Figs. 37A, 37B. "The relative motion between the hypotubes causes deflection in flexures 124, 136 which deflect in a manner that deploys and tensions the electrode array." *Id.* at 17:63–66.

### *D. Illustrative Claims*

Claims 1 and 11 are independent. Claims 2–10 and 12 depend, directly or indirectly, from claim 1; claims 13–15 depend directly from claim 11. Claims 1 and 11

are illustrative of the claimed subject matter, and are reproduced below:

> 1. A device for treating a uterus comprising:
>
> an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;
>
> an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;
>
> a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;
>
> a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured

so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

*Id.* at 19:9–42.

11. A device for treating a uterus comprising:

an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;

a handle coupled to the proximal portion;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating one of the inner and outer

sleeves relative to the other causes the applicator head to transition from the contracted state to the expanded state;

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus; and

wherein when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.

*Id.* at 20:17–47.

*E. The Asserted References*

Petitioner relies upon the following references (Pet. 14–15):

| **Reference** | **Patent No./ Pub. No.** | **Date** | **Exhibit No.** |
|---|---|---|---|
| Yoon | US 5,514,091 | May 7, 1996 | Ex. 1007 |
| Nady-Mohamed | US 5,353,784 | Oct. 11, 1994 | Ex. 1009 |
| Ortiz | US 5,358,496 | Oct. 25, 1994 | Ex. 1006 |
| Jing | CN 1060594A | Published Apr. 29, 1992 | Exs. 1010, 1011 (translation) |
| Lichtman | US 5,620,459 | Apr. 15, 1997 | Ex. 1008 |

*F. The Asserted Grounds*

Petitioner challenges claims 1–15 of the '348 Patent on the following grounds (Pet. 14–15):

| References | Basis | Claim(s) Challenged |
|---|---|---|
| Yoon, Nady-Mohamed, Ortiz, and Jing | § 103(a) | 1–7, 10–13, and 15 |
| Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman | § 103(a) | 8, 9, and 14 |

## II. ANALYSIS

We turn now to Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a) for instituting review.

### *A. Level of Skill in the Art*

Dr. Pearce testifies that a person of ordinary skill in the art

> would include someone who had, through education or practical experience, the equivalent of a bachelor's degree in biomedical engineering, electrical engineering, mechanical engineering, or a related field and at least an additional two to three years of work experience developing or implementing electrosurgical devices.

Ex. 1002 ¶ 47. Patent Owner does not provide evidence or argument on the level of ordinary skill. Prelim. Resp. 11 n.3. We adopt Dr. Pearce's definition for purposes of this Decision.

### *B. Claim Construction*

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a

claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While our claim interpretation cannot be divorced from the specification and the record evidence, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes express constructions for two claim terms, "frame" and "flexure." Pet. 15–17. Patent Owner does not propose an express construction for any claim term. Prelim. Resp. 9–10,

*1. "frame"*

Claim 1 recites "a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a *frame*" (emphasis added). Petitioner proposes to construe the term "frame" "to include a structure coupled (*e.g.*, removably or continuously) to a handle grip, that surrounds or encloses another component (*e.g.*, inner sleeve)." Pet. 16.

We have considered Petitioner's proposed claim construction, but determine that the term "frame" does not require explicit construction for purposes of our Decision. We note, however, that this term was construed in a related case (IPR2016-00685).

*2. flexures*

Claim 1 recites "a deflecting mechanism including *flexures* disposed within the applicator head" (emphasis added). Petitioner argues that the term "flexure" "should be construed to include a component designed to be bent or curved." *Id.* at 17. Petitioner asserts that its proposed claim construction is consistent with the use of "flexure" in the Specification and the term's ordinary meaning. *Id.* at 16–17 (citing Ex. 1001, 13:65–67, 13:56–14:31, Figs. 23, 30; Ex. 1002 ¶¶ 54–56; Ex. 1013, 3).

We do not agree with Petitioner's proposed construction because it is not consistent with the Specification's description of flexures 124, 136 as strips that are capable of being bent or curved. *See*, *e.g.*, Ex. 1001, 4:1–9, 13:8–14:31, Figs. 23, 28–30. Figures 23 and 28, for example, depict flexures 124 as strips that have been bent or curved as the result of relative motion between hypotubes 120 and 122. *Id.* at 13:8–15, 14:29–30, Figs. 23, 28. Indeed, Petitioner's declarant, Dr. Pearce, testifies that "a person of skill in the art would understand the term 'flexure' to refer to a component capable of being bent or curved." Ex. 1002 ¶ 56.

On this record, we determine that the broadest reasonable interpretation consistent with the Specification of "flexures" is strips that are capable of being bent or curved. We note that a distinction with Petitioner's proposed construction is that "designed to be bent," for example, could mean a structure that has been bent but is no longer bendable or a structure that is bendable. "Capable of being bent," on the other hand, means that the structure is further bendable.

*C. Asserted Obviousness*

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art ("POSA") to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A patent claim composed of several elements, however, is not proved obvious merely by demonstrating that each of its elements was known, independently, in the prior art. *Id.* at 418. In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, when in evidence. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In this case, Petitioner challenges claims 1–15 as unpatentable for obviousness. Pet. 14–15. Specifically, Petitioner contends that claims 1–7, 10–13, and 15 would have been obvious over Yoon, Nady-Mohamed,

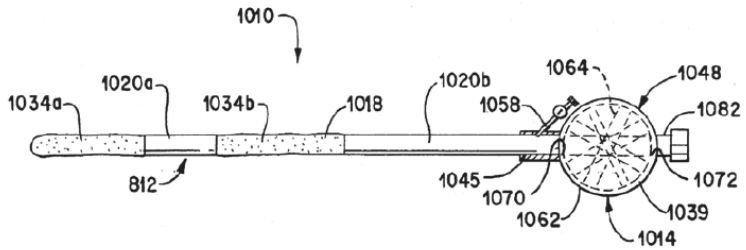
Ortiz, and Jing and claims 8, 9, and 14 would have been obvious over Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman. *Id.* For the reasons discussed below, Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of the challenged claims.

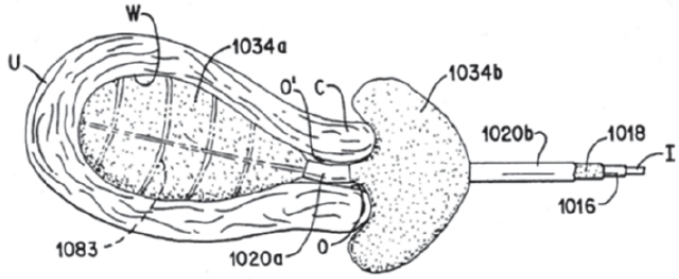
*1. Overview of Asserted References*

*a. Yoon*

Yoon discloses several distinct embodiments, including multifunctional instrument 410, which can be used for performing various diverse operative procedures, including uterine ablation. Ex. 1007, 20:9–38. Instrument 410 includes inner member 416 and middle member 418. *Id.* at 20:19. Middle member 418 is made as a collapsible bag, balloon, or membrane. *Id.* at 19:67–20:5. The middle member defines expandable portions 434a and 434b, which have "preformed predetermined" shapes. *Id.* at 19:55–59. Expandable portions 434 are introduced through an opening in the body in a collapsed state, and fluid is supplied between middle member 418 and inner member 416 to move the expandable portions from the collapsed state to an expanded state in which they form enlargements or protrusions having configurations corresponding to the preformed predetermined shapes. *Id.* at 20:9–38, Fig. 13. Middle member 418 may include electrically conductive material, such as an electrically conducting spine, for use in performing uterine ablation. *Id.* at 20:34–38

Yoon also discloses multifunctional instrument 1110. *Id.* at 24:63–29:7, Figs. 23–27. Figures 23 and 24 are reproduced below.




The first figure above is Figure 23, which shows a side view of instrument 1010 with expandable portions 1034 in the unexpanded state, and the second above figure is Figure 24, which shows expandable portions 1034 in the expanded position. *Id.* at 5:33–38, 25:20–31. "Multifunctional instrument 1010 is particularly advantageous for performing endometrial ablation to treat, for example, dysfunctional uterine bleeding in that an electrically conductive spine 1083, shown in dotted lines in FIG. 24, can be disposed within or on middle member 1018 for contacting anatomical tissue." *Id.* at 26:26–32.

Figures 25–27 illustrate a further modification of instrument 1010. *Id.* at 26:41–29:7. As modified, instrument 1010 includes inner member 1116, middle member 1118, and collar 1120. *Id.* at 26:43–48. Middle member 1118 includes a transparent stretchable or elastic membrane or a non-elastic or rigid preformed membrane having distal end wall 1126, which closes

off or seals the lumen of the middle member; inner member 1116 carries expandable spine 1183 for mechanically shaping or expanding middle member 1118. *Id.* at 26:43–48, 27:40–44. Spine 1183 includes plurality of legs 1192 pivotally or hingedly attached to inner member 1116 at pivots, joints, or hinges. *Id.* at 26:54–56. The legs can be attached pivotally to the inner member 1116 at various locations in accordance with the configuration desired for expandable portion 1134 in the expanded position. *Id.* at 26:56–61. Figure 26 of Yoon is reproduced below.

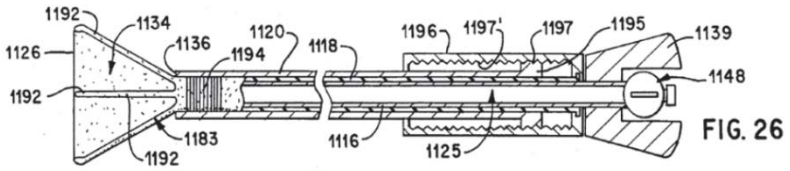


FIG. 26

As shown in Figure 26, spine 1183 is biased to, or normally disposed in, an expanded position wherein legs 1192 are disposed angularly outwardly of inner member 1116. *Id.* at 26:61–63. The legs are equally spaced about a longitudinal axis of the instrument. *Id.* at 26:56–61. Yoon discloses that:

> As shown in FIG. 26, operating cylinder 1196 is rotated until forward edge 1136 of collar 1120 is disposed proximally of expandable portion 1134 causing spine 1183 to move automatically to the expanded position with legs 1192 disposed in a direction angularly outwardly of the instrument longitudinal axis as shown in FIG. 26.

*Id.* at 28:41–46. Yoon also discloses that:

> Movement of spine 1183 to the expanded position causes movement of expandable portion 1134 to the expanded position forming an enlargement or protrusion between end wall 1126 and collar

> forward edge 1136. *If desired, fluid can be supplied to expandable portion 1134* via valve assembly 1148 and the lumen 1125 of inner member 1116 to further shape or maintain the shape of or to increase the size of expandable portion 1134 in the expanded position. In the expanded position, the expandable portion 1134 can be used to manipulate tissue or organ structure in the anatomical cavity for various medical procedures.

*Id.* at 28:46–57 (emphasis added).

*b. Nady-Mohamed*

Nady-Mohamed relates to barrier-forming or shielding means insertable into a cavity within the body through a small incision. Ex. 1009, 1:6–10. A disclosed embodiment includes cylindrical tube 10, plunger 11, and flexible arms 13, 14, which are preformed to their operative extended shapes. *Id.* at 3:45–4:6. "A membrane 20 is disposed between the arms 13 and 14, and is fixed to each arm along the lengths of its outer edges." *Id.* at 3:67–4:1. Nady-Mohamed discloses:

> In the retracted position, as illustrated in FIG. 1, the membrane 20 is folded or otherwise compressed for storage between the arms. In the extended position, as illustrated in FIGS. 2 and 3, the previously deformed arms 13 and 14 attain their natural shape, and membrane 20 is thereby spread to occupy the space between them.

*Id.* at 4:1–6. Figure 3 of Nady-Mohamed is reproduced below.

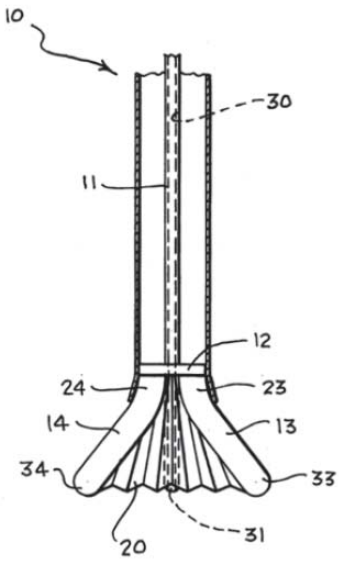
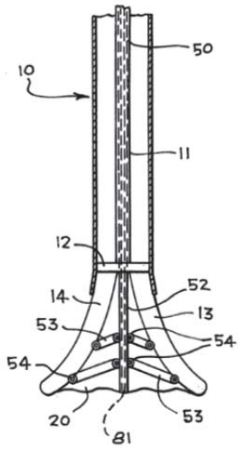



Figure 3 is a cross-section view of the barrier-forming apparatus showing plunger 11 and arms 13, 14 in an extended position, with membrane 20 spread between them. *Id.* at 3:17–19. Plunger 11 is slidably disposed within tube 10, "and the arms and membrane are expelled from the distal end of the tube or withdrawn into the tube by sliding the plunger in the desired direction." *Id.* at 4:53–56. In use, for example, "the distal end of the tube is placed in the vicinity of the organ or tissue of interest, and the membrane and arms are extended from within the tube, thereby forming a solid barrier for shielding or retraction of the organ." *Id.* at 5:52–56.

Figure 6 of Nady-Mohamed, reproduced below, depicts a structure for adding rigidity to arms 13, 14 in their extended position. *Id.* at 5:12–14.

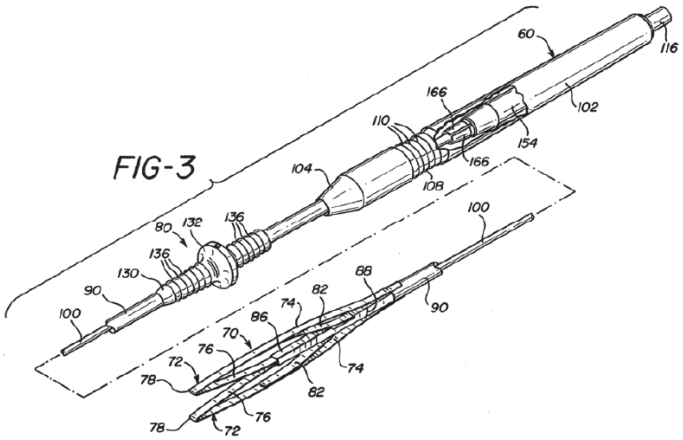



As shown in Figure 6, plunger 11 terminates at disc 12, which has a longitudinal bore within which rod 50 is slidably disposed. *Id.* at 5:14–17. "The rod near its distal end 52 is provided with a plurality of *rigid* ribs 53 which are pivotally joined to the outer surface of the rod at pivotal joints 54." *Id.* at 5:18–21 (emphasis added). "The ribs extend laterally from the rod and are pivotally joined at their opposite ends to the arms 13 and 14, such that, when the arms are urged by the plunger to their extended position, the rod is drawn forward with the arms, and the ribs are spread by the expansion of the arms." *Id.* at 5:21–26. A locking feature prevents movement of the rod toward the proximal end of the apparatus. *Id.* at 5:32–39. "The locking feature is of *critical importance* in applications in which it is necessary for the arms to resist a collapsing force." *Id.* at 5:39–43 (emphasis added).

*c. Ortiz*

Ortiz relates to an endoscopic tissue manipulator that can be inserted through an endoscopic tube to enable a surgeon to manipulate tissue inside a body cavity. Ex. 1006, 1:10–12. A preferred embodiment

includes a proximal handle assembly and a distal expandable platform 70. *Id.* at 4:37–39. Figure 3 of Ortiz is reproduced below:




As shown in Figure 3, platform 70 consists of a plurality of flexible, interconnected strips adapted to expand laterally outward to form a pair of fingers 72. *Id.* at 4:52–55. Each of fingers 72 comprises outer strip 74 and inner strip 76. *Id.* at 4:55–58. Outer strip 74 is attached to the distal end of actuator tube 90, and inner strip 76 is attached to the distal end of shaft or push rod 100 inside of actuator tube 90. *Id.* at 4:59–63. "[W]hen actuator tube 90 is retracted, i.e., moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration." *Id.* at 5:28–31. "The outer strips 74 are pulled in the proximal direction by the actuator tube 90 and the guide tube 86 is moved proximally along the inner strips 76 by the struts 82." *Id.* at 5:32–34. Figure 7 of Ortiz is reproduced below.

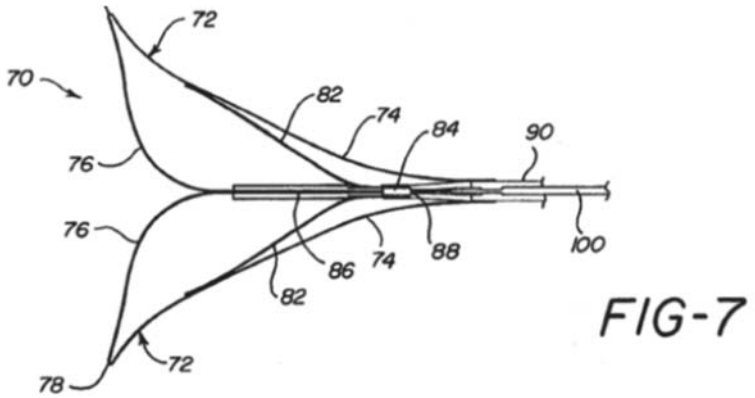



FIG-7

Figure 7 depicts a longitudinal cross section illustrating platform 70 in a tulip-shaped configuration. *Id.* at 3:29–30, 4:10–11. As shown in Figure 7, each of fingers 72 comprises flexible strut 82, having its distal end secured to outer strip 74 and its proximal end attached to connector sleeve 84, which is slidably mounted on inner strip 76. *Id.* at 4:63–5:1. Connector sleeve 84 is located within guide tube 86, which is slidably received in the distal end of actuator tube 90. *Id.* at 5:1–4. Struts 82 provide for shape control of platform 70 in its expanded configuration. *Id.* at 6:1–2. "The expanded platform 70 has a generally planar configuration which provides two flat tissue manipulating surfaces on its opposite sides." *Id.* at 8:36–39.

*d. Jing*

Jing relates to a computer-controlled apparatus for measuring and displaying data of the morphology of a woman's uterine cavity. Ex. 1011, 3:5–7, 20–23, 4:25–30.[2] "An object of the present invention is to provide a computer-controlled measurement apparatus for measuring and displaying data of the morphology of

[2] We cite to the certified translation of Jing (Ex. 1011).

the uterine cavity, thereby increasing the success rate of the IUD technique and facilitating the modification of IUDs." *Id.* at 3:20–23. Figure 2 of Jing is reproduced below.

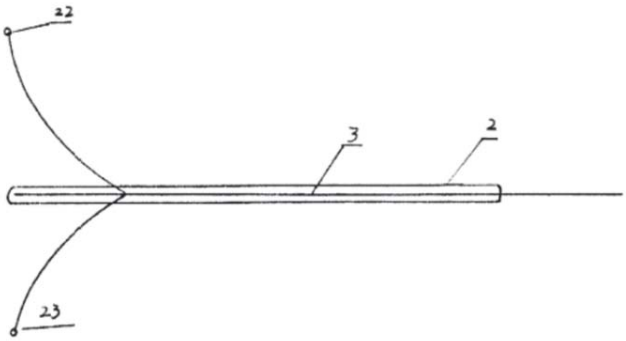



Figure 2 illustrates measuring rod 3 and dovetail-type contacts 22, 23. *Id.* at 5:9–13. Jing discloses:

> When a transverse dimension of the uterine cavity is to be measured, the measurement push button may be pushed by hand, such that two dovetail-type contacts (22, 23) of the transverse dimension measuring rod protrude from through-holes (10) at two sides of the measurement sleeve and expend [sic] to the transverse dimension being measured.

*Id.*

*2. Petitioner's Contentions with Respect to Claims 1 and 11*

With respect to the requirement of claims 1 and 11 for an elongate member comprising an inner sleeve slidably and coaxially disposed within an outer sleeve, Petitioner relies on Yoon's instrument 1110 as depicted in Figure 25. Pet. 22–23. Petitioner also argues: "To the extent that Yoon does not expressly describe an inner sleeve slidably disposed within the

outer sleeve as recited in the claim, these aspects of the limitation are fully disclosed by Nady-Mohamed." *Id.* at 23 (citing Ex. 1002 ¶ 182). Relying on the embodiment depicted in Nady-Mohamed's Figure 6, Petitioner asserts that Nady-Mohamed's rod 50 (i.e., the inner sleeve) is slidably disposed within Nady-Mohamed's plunger 11 (i.e., the outer sleeve). *Id.* (citing Ex. 1009, 5:14–18, Fig. 6; Ex. 1002 ¶ 183). As reasons for combining the teachings of Yoon and Nady-Mohammed, Petitioner asserts:

> One of ordinary skill in the art would have incorporated an expansion mechanism as in Nady-Mohamed into an ablation device as disclosed by Yoon, because Yoon teaches that different expansion mechanism designs can be used and Nady-Mohamed's mechanical expansion elements are specifically designed for engaging the uterine walls. Ex. 1002 ¶¶ 169-171, 184. In addition, as Dr. Pearce also explains, use of the mechanical expansion elements taught by Nady-Mohamed, including the inner sleeve slidable within an outer sleeve, would have been preferable over the fluid expansion media disclosed in Yoon because it would have simplified the device design and obviated potential safety issues such as fluid leakage or contamination.

*Id.* at 24 (citing Ex. 1002 ¶¶ 173, 184).

With respect to the "deflecting mechanism" limitation requiring "external flexures being coupled to the outer sleeve" and "internal flexures being coupled to the inner sleeve," Petitioner relies on combining features of Yoon's instrument 1010 as depicted in Figures 25–27 with the embodiment depicted in Nady-Mohamed's Figure 6. *Id.* at 31–32. Petitioner asserts that Nady-Mohamed's flexible arms

13, 14 correspond to the "external flexures" limitation and that Nady-Mohamed's rigid ribs 53 correspond to the "internal flexures" limitation. *Id.* Petitioner argues that a skilled artisan would have improved Yoon's ablation device by incorporating Nady-Mohamed's mechanical expansion design:

> Moreover, a skilled artisan would have recognized that an endometrial ablation device as in Yoon would benefit from improved contact between the expandable applicator head and the uterine wall. [Ex. 1002 ¶ 171.] The mechanical expansion design disclosed in Yoon utilizes straight, rigid "legs" in its "expandable spine." Ex. 1007 at 26:53–56, FIGS. 25–27 (elements 1192). Nady-Mohamed discloses a similar triangular shape for its expandable head, but teaches the use of flexible supports for the structure, teaching that its flexible arms are beneficial for "firmly engag[ing] the walls of the lumen of the uterus without risk of tearing or other damage to the tissue." *See* Ex. 1009 at 4:30-33. It would have been apparent to the skilled artisan that this arrangement would be beneficial for maintaining stable contact between the applicator head and uterine walls during endometrial ablation. Ex. 1002 ¶ 171.

*Id.* at 50–51.

Petitioner additionally contends that, "[t]o the extent the ribs 53 pivotally coupled to the sleeve 81 and flexures 13, 14 themselves do not satisfy as flexures, it would have been obvious to use bendable components such as those described in Ortiz." *Id.* at 32 (citing Ex. 1002 ¶ 206). Petitioner asserts that "Ortiz discloses first and second outer flexures, each referred to as 'outer strip 74,' and first and second inner

flexures, each referred to as 'flexible strut 82.'" *Id.* (citing Ex. 1002 ¶ 206). As reasons to combine Yoon, Nady-Mohamed, and Ortiz, Petitioner contends:

> Dr. Pearce explains that it would have been obvious to a person of ordinary skill in the art to implement flexible reinforcing ribs capable of achieving some degree of curvature, since this would merely be a simple substitution of one known element for another. [Ex. 1002 ¶ 207.] Substituting pivoting ribs 53 with fixed flexible members would still provide structural definition for the expandable device while at the same time providing flexibility and ability to conform to the walls of the uterus. *Id.*
>
> Additionally, a person of ordinary skill would reasonably have incorporated a flexible design as in Ortiz's expandable platform, including its bendable inner flexures, into an ablation device such as disclosed by Yoon. *Id.* ¶¶ 172–173. Utilizing a "plurality of flexible, interconnected strips" and "flexible struts" such as taught by Ortiz would further improve the ability of the device to conform to the shape of the uterus and accommodate different morphologies while also providing sufficient support to maintain an appropriate shape for uterine treatment. Ex. 1006 at 4:34–42, 52–55; Ex. 1002 ¶¶ 172–173.

*Id.* at 33; *see also id.* at 51–52 (advancing similar arguments).

With respect to the requirement of claims 1 and 11 for "an indicator mechanism coupled to the inner sleeve . . . configured to indicate a dimension of the uterus," Petitioner relies on Jing's device for measuring a transverse dimension of the uterine

cavity. Pet. 35–37. Petitioner contends that a skilled person would have incorporated Jing's measurement apparatus into the ablation device taught by Yoon, Nady-Mohamed, and Ortiz "in order to provide dimension information that would assist a physician in accounting for patient-to-patient variations in uterine morphology, and thereby increase the safety and efficacy of the ablation treatment." *Id.* at 37, 52–54 (citing Ex. 1002 ¶ 176). Petitioner further argues that "it would have been common sense to the skilled artisan at the time that information regarding internal morphology would be useful when operating a surgical device within a confined space such as the uterus without direct observation." *Id.* at 54 (citing Ex. 1002 ¶ 176).

*3. Patent Owner's Responsive Contentions*

In response, Patent Owner argues, *inter alia*, that Petitioner has not explained sufficiently why a person of ordinary skill in the art would have combined the prior art teachings to arrive at the challenged claims as a whole. *See* Prelim. Resp. 14–15, 39, 60. Patent Owner argues, for example, that "Petitioner relies on a combination of three prior art references for the 'deflecting mechanism' limitations of claims 1 and 11," but "fails to provide a rationale (or provides only insufficient conclusory assertions) for combining these references." *Id.* at 29.

Patent Owner also asserts that Petitioner has failed to show why or how incorporating Nady-Mohamed's deflecting mechanism into Yoon's embodiment 1110 would have improved contact between Yoon's expandable applicator head and the uterine wall as Petitioner contends. *Id.* at 31–32. Patent Owner further argues that "the straight, rigid ribs 53 of Nady-Mohamed are not 'flexures.'" *Id.* at 31.

Patent Owner additionally contests Petitioner's rationale "for combining Ortiz's struts 82 with Nady-Mohamed's deflecting mechanism." *Id.* at 32–33. Patent Owner argues that, even if the references are, as Petitioner contends, in the same field of endeavor, that fact alone is insufficient to show a rationale for combining the references. *Id.* at 33. Patent Owner characterizes Petitioner's further argument that "the 'flexible construction' of Ortiz's struts 82 would 'improve the ability of [Nady-Mohamed's] device to accommodate different uterine morphologies'" as conclusory and lacking "any factual support or reasoning as to how Ortiz's struts 82 could improve Nady-Mohamed's ability to accommodate different uterine morphologies if used as inner flexures." *Id.* (quoting Pet. 51).

Patent Owner asserts that "Nady-Mohamed's arms 13 and 14 are described as 'preformed to their operative extended shape' and 'attain their natural shape' in the extended position—i.e., Nady-Mohamed's arms 13 and 14 are intended to expand to their predetermined shape regardless of whether Ortiz's struts 82 are used." *Id.* at 33–34 (quoting Ex. 1009, 3:55–58, 4:3–6). Patent Owner additionally asserts that "Petitioner also has not provided any evidence that a person of ordinary skill would have recognized the alleged benefit of the Ortiz struts in the context of the claimed invention (i.e., to accommodate different uterine morphologies) without hindsight." *Id.* at 34.

With respect to "an indicator mechanism operably coupled to the inner sleeve . . . configured to indicate a dimension of the uterus," Patent Owner asserts that Jing's transverse-dimension-measurement device is a stand-alone-apparatus with dovetail-type contacts

that must extend across the full width of the uterus. *Id.* at 39–41 (Ex. 1011, 5:9–13). As such, Patent Owner argues, Jing is "inapposite to the devices described in Yoon, Nady-Mohamed, and Ortiz," and would not satisfy the "operably coupled to the inner sleeve" aspect of the claim limitation if coupled to Nady-Mohamed's outer sleeve to measure the width of the uterine cavity. *Id.* Patent Owner further asserts that Petitioner fails to explain sufficiently why or how a person of ordinary skill in the art would have used Jing's apparatus in combination with Yoon's expandable member 1034. *Id.* at 59–60.

*4. Analysis*

An analysis under 35 U.S.C. § 103(a) requires more than "mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Upon consideration of the Petition and the Preliminary Response, we agree with, and adopt, Patent Owner's argument, as summarized above, that the reasons advanced by Petitioner for combining elements of Yoon, Nady-Mohamed, Ortiz, and Jing to make the claimed invention are conclusory and insufficient. We provide additional analysis below.

Petitioner primarily relies on Nady-Mohamed for the inner-sleeve-slidably-disposed-within-an-outer-sleeve requirement.[3] In reference to the embodiment

[3] Petitioner also appears to contend that Yoon's instrument 1110 as depicted in Yoon's Figures 25–27 teaches an inner sleeve slidably disposed within an outer sleeve. *See* Pet. 22–23. Petitioner, however, does not identify the elements of Yoon's instrument 1110 that allegedly satisfy the claim requirements.

depicted in Nady-Mohamed's Figure 6, Petitioner identifies rod 50 of Nady-Mohamed as corresponding to the "inner sleeve" and Nady-Mohamed's plunger 11 as corresponding to the "outer sleeve." Pet. 23–24 (citing Ex. 1009, 5:14–18, Fig. 6; Ex. 1002 ¶ 183). While the identified elements would satisfy the "inner sleeve" and "outer sleeve" requirements, we determine, as discussed below, that Petitioner's asserted reasons for modifying Yoon's instrument 1110 to incorporate these and other elements are insufficient to support a legal conclusion of obviousness. *See id.* at 24.

In Yoon's instrument 1110 as depicted in Figures 25–27, cylinder 1196 is rotated to retract collar 1120 relative to spine 1183, which, when uncovered, expands automatically to deploy expandable portion 1034 via legs 1192. Ex. 1007, 28:41–46, Figs. 25–27. In the expanded position, legs 1192 extend angularly outward, and expandable portion 1134 forms an enlargement or protrusion between end wall 1126 and collar forward edge 1136. *Id.* at 28:46–50. Fluid can be supplied to expandable portion 1134 to further shape or maintain the shape of or to increase the size of expandable portion 1134 in the expanded position. *Id.* at 28:50–54.

Petitioner argues that Nady-Mohamed's mechanical expansion elements, including the slidable sleeves, are designed for engaging the uterine walls, but this argument does not explain sufficiently how the slidable sleeves contribute to this design, or why a skilled person would have substituted Yoon's rotatable

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Indeed, Petitioner's declarant, Dr. Pearce, testifies that "Yoon does not expressly describe an inner sleeve slidably disposed within the outer sleeve as recited in the claim." *See* Ex. 1002 ¶ 181.

cylinder/collar with Nady-Mohamed's slidable sleeves. *See* Pet. 24 (citing Ex. 1002 ¶¶ 173, 184). Dr. Pearce's testimony is similarly conclusory. For example, Dr. Pearce testifies:

> [U]se of the mechanical expansion elements taught by Nady-Mohamed, including the inner sleeve slidable within an outer sleeve, would have been preferable over the fluid expansion media disclosed in Yoon because it would have simplified the device design and obviated potential safety issues such as fluid leakage or contamination. Such a combination would result in a device where an inner sleeve slidably and coaxially disposed within an outer sleeve as taught by Nady-Mohamed would be used to deploy the expandable member of Yoon within the uterus.

Ex. 1002 ¶ 184. Dr. Pearce's testimony fails to explain sufficiently why using an inner sleeve slidably disposed within an outer sleeve would have "simplified" Yoon's rotatable cylinder/collar deployment mechanism. Dr. Pearce's testimony also fails to explain sufficiently why substituting Nady-Mohamed's slidable sleeves for Yoon's rotatable cylinder/collar would have obviated using fluid expansion media to further shape or maintain the shape of or to increase the size of expandable portion 1134 in the expanded position (as disclosed in Yoon).

Petitioner also relies on Nady-Mohamed for "external flexures being coupled to the outer sleeve" and "internal flexures being coupled to the inner sleeve." Specifically, Petitioner contends that Nady-Mohamed's arms 13, 14 and ribs 53 correspond, respectively, to the required "external flexures" and "internal flexures." Pet. 31–32. We agree with Patent Owner, however, that ribs 53 as disclosed in Nady-

Mohamed are "rigid"; they are not flexible or bendable, and, thus, do not constitute "flexures" under a proper claim construction. *See supra* Section II.B.2; Prelim. Resp. 31.

Alternatively, Petitioner argues that Ortiz remedies the lack of "internal flexures" in Yoon and Nady-Mohamed. Pet. 32. Petitioner relies on Dr. Pearce's testimony that substituting Nady-Mohamed's rigid pivoting ribs 53 with "flexible reinforcing ribs capable of achieving some degree of curvature," such as flexible struts 82 of Ortiz, would have been obvious as "a simple substitution of one known element for another." Pet. 33 (citing Ex. 1002 ¶ 207).

We are not persuaded that substituting Nady-Mohamed's ribs 53 with Ortiz's struts 82 would have amounted to a simple substitution of one known element for another. The functions of the two elements are significantly different. The function of Nady-Mohamed's ribs 53 is to add rigidity to flexible arms 13, 14 in response to a collapsing force, while the function of Ortiz's struts 82 is to provide for shape control of outer strips 74 and platform 70 in response to an expanding force (pulling or pushing of outer strips 74 by retraction or advancement of actuator tube 90). *Compare* Ex. 1009, 5:12–43, *with* Ex. 1006, 5:28–6:6. The different known functions of ribs 53 (Nady-Mohammed) and struts 82 (Ortiz) are in keeping with the different expansion mechanisms that they complement. Flexible arms 13, 14 of Nady-Mohamed are preformed such that they spring naturally into their extended position when unrestrained (Ex. 1009, 3:55–4:6), while Ortiz's outer strips 74 do not expand unless pulled or pushed by retraction or advancement of actuator tube 90 (Ex. 1006, 5:28–67). We are not persuaded, therefore, that

Ortiz teaches or suggests flexible reinforcing ribs as Dr. Pearce asserts, or that a skilled person would have combined the teachings of Nady-Mohamed and Ortiz as Petitioner contends.

Petitioner, moreover, has not provided a sufficient rationale for combining the teachings of Jing with those of Yoon, Nady-Mohamed, and Ortiz. Petitioner's argument that dimension information provided by Jing's measurement device would assist a physician in accounting for patient-to-patient variations in uterine morphology does not explain sufficiently why a person of ordinary skill in the art would have incorporated Jing's measurement device into Yoon's ablation device, rather than simply use Jing's device separately to obtain the information. We are unpersuaded by Dr. Pearce's testimony that "it would have been *common sense* to the skilled artisan at the time that information regarding internal morphology would be useful when operating a surgical device within a confined space such as the uterus without direct observation." *See* Ex. 1002 ¶ 176 (emphasis added); *Arendi S.A.R.L. v. Apple Inc.*, Appeal No. 2015-2073, 2016 WL 4205964, at *5 (Fed. Cir. Aug. 10, 2016) (stating that "'common sense' . . . cannot be used as a wholesale substitute for reasoned analysis and evidentiary support"). Dr. Pearce's testimony does not contain sufficient reasoning or evidentiary support to explain why obtaining a transverse dimension of the uterus while concurrently operating Yoon's ablation device would have been useful.

For these reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to independent claims 1 and 11 as obvious over Yoon, Nady-Mohamed, Ortiz, and Jing. As Petitioner's arguments and evidence with respect

to dependent claims 2–10 and 12–15 do not remedy the deficiencies in the arguments and evidence with respect to the independent claims, discussed above, we also determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to dependent claims 2–10 and 12–15.

## III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to: claims 1–7, 10–13, and 15 as obvious over Yoon, Nady-Mohamed, Ortiz, and Jing; and claims 8, 9, and 14 as over Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman.

## IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner's Petition for an *inter partes* review of claims 1–15 of the '348 Patent is *denied*, and no *inter partes* review will be instituted pursuant to 35 U.S.C. § 314 as to any claim of the '348 Patent on any of the grounds of unpatentability alleged by Petitioner in the Petition.

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Paper 8
Entered: September 12, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MINERVA SURGICAL, INC.,
*Petitioner*,

v.

HOLOGIC, INC.,
*Patent Owner.*

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Case IPR2016-00685
Patent 9,095,348 B2

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Before WILLIAM V. SAINDON, RICHARD E. RICE, and NEIL T. POWELL, *Administrative Patent Judges*.

RICE, *Administrative Patent Judge*.

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DECISION
Denying Institution of *Inter Partes* Review
*37 C.F.R. § 42.108*

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## I. INTRODUCTION

### *A. Background*

Minerva Surgical, Inc. ("Petitioner") filed a Petition (Paper 3, "Pet.") requesting an *inter partes* review of claims 1–15 ("the challenged claims") of U.S. Patent No. 9,095,348 B2 (Ex. 1001, "the '348 Patent").

Petitioner supported the Petition with a Declaration from John Anthony Pearce, Ph.D. (Ex. 1002). Hologic, Inc. ("Patent Owner") filed a Preliminary Response (Paper 7, "Prelim. Resp.").

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the Petition and the Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Accordingly, we do not institute *inter partes* review.

### *B. Related Proceedings*

We are informed that Petitioner is named as a defendant in a federal district court case involving the '348 Patent (Case No. 1:15-cv-01031-SLR pending in the U.S. District Court for the District of Delaware). Pet. 14. We also are informed that Petitioner has filed a second Petition for *inter partes* review of the '348 Patent (IPR2016-00680). *Id.*

### *C. The '348 Patent*

The '348 Patent, titled "Moisture Transport System for Contact Electrocoagulation," issued from an application filed August 8, 2013, and claims priority to May 8, 1998. Ex. 1001, at (54), (21), (22), (60), 1:6–13. The '348 Patent relates to an apparatus for ablating the interior linings of body organs such as the uterus. *Id.* at 1:19–21. Ablation of the interior lining of a body organ, the '348 Patent explains, "involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins for hemostasis." *Id.* at 1:26–28. Ablation may be performed, for

example, to treat chronic bleeding of the endometrial layer of the uterus. *Id.* at 1:28–30. The '348 Patent states that conventional methods of effecting ablation include "application of RF energy [i.e., radio frequency energy] to the tissue to be ablated." *Id.* at 1:31–35. Problems addressed by the '348 Patent include the need for a device that eliminates steam and liquid buildup at the ablation site and that allows control of the depth of ablation in the treated tissue. *Id.* at 1:48–2:30.

Figure 21 of the '348 Patent, which is reproduced below, illustrates ablation device 100:

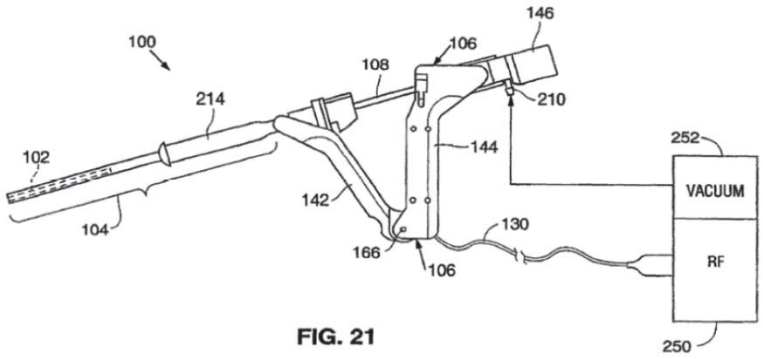



FIG. 21

Figure 21 is a side elevation view of ablation device 100 showing sheath 104, tubing 108, handle 106, and RF applicator head 102 slidably disposed within sheath 104. *Id.* at 11:59–62, 12:2–5. After insertion of the device into the uterine cavity, manipulation of handle 106 causes the applicator head to extend from the distal end of the sheath and to expand into contact with body tissue. *Id.* at 11:63–12:5. The ablation device can be used to measure the width of the uterus, and gauge 146 displays the measured width. *Id.* at 14:33–36. The measured width is entered into RF generator system 250 and used to calculate the

ablation power. *Id.* at 18:37–39. Vacuum source 252 is connected to inner hypotube 122 (discussed below) via suction port 210. *Id.* at 18:40–41.

As illustrated in Figure 23 of the '348 Patent, which is reproduced below, applicator head 102 extends from the distal end of tubing 108. *Id.* at 12:2–5.

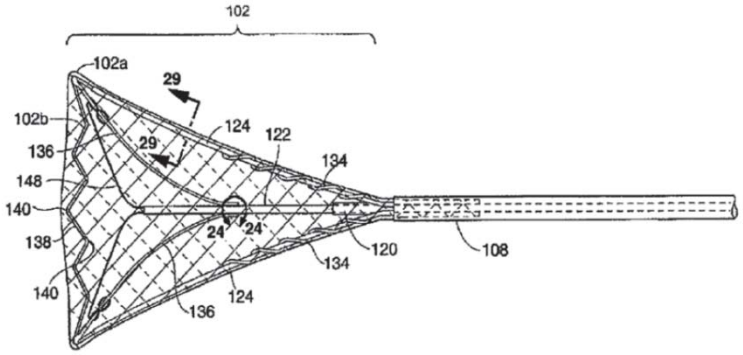



Figure 23 illustrates applicator head 102 in the expanded or deployed state.[1] *See id.* at Fig. 23. Applicator head 102 includes: external electrode array 102a, which is formed of a stretchable metallized fabric mesh; an internal deflecting mechanism 102b, which is used to expand and tension the electrode array for positioning into contact with uterine tissue; and non-conductive suturing threads 148, which extend from hypotube 122 for use in measuring the width of the uterus. *Id.* at 12:5–12, 14:33–39.

The deployment structure for deflecting mechanism 102b includes external hypotube 120, which extends from tubing 108, and internal hypotube 122, which is slidably and co-axially disposed within hypotube 120. *Id.* at 13:8–12. Outer flexures 124 extend laterally and

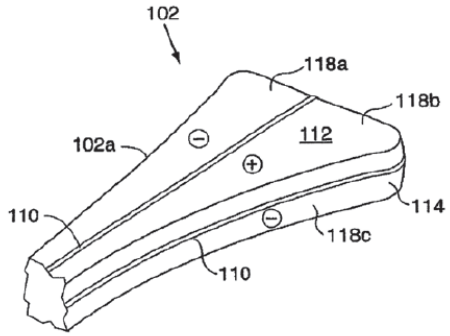
[1] The '348 Patent states that, for clarity, sheath 104 is not shown in Figure 23. *Id.* at 12:2–3.

longitudinally from tubing 108 on opposite sides of external hypotube 120. *Id.* at 13:12–13. Internal flexures 136 extend laterally and longitudinally from the exterior surface of internal hypotube 122. *Id.* at 13:56–58. Each internal flexure 136 is connected at its distal end to one of the outer flexures 124, and a transverse ribbon 138 extends between the distal portions of the internal flexures 136. *Id.* at 13:58–61. As described in the '348 Patent,

> during use distal and proximal grips 142, 144 forming handle 106 are squeezed towards one another to withdraw the sheath and deploy the applicator head. This action results in relative rearward motion of the hypotube 120 and relative forward motion of the hypotube 122. The relative motion between the hypotubes causes deflection in flexures 124, 136 which deploys and tensions the electrode array 102a.

*Id.* at 14:25–31.

Deflecting mechanism 102b and its deployment structure are enclosed within electrode array 102a. *Id.* at 13:8–9. Figure 25A of the '348 Patent is a perspective view of electrode array 102a in the deployed or expanded state. *Id.* at 3:52–53, 12:53–55. Figure 25A is reproduced below.




As shown in Figure 25A, insulating regions 110 are formed on the applicator head to divide the mesh into electrodes 118a–118d. *Id.* at 12:59–13:7. As power is supplied to the electrodes, the tissue is heated, releasing moisture. *Id.* at 18:44–47. Moisture is withdrawn from the uterine cavity through internal hypotube 122, which is connected to vacuum source 252. *Id.* at 18:47–49. Apertures formed in outer flexures 124 facilitate moisture withdrawal by preventing trapping of moisture between the flexures and the lateral walls of the uterus. *Id.* at 18:49–52.

Handle 106 comprises distal and proximal grip sections 142, 144, which are pivotally attached to one another at a pivot pin. *Id.* at 16:13–16, Figs. 21– 22. Proximal grip section 144 is coupled to hypotube 122 via yoke 168, overload spring 170, and spring stop 172. *Id.* at 16:17–19, 17:38–40, Figs. 34, 37A, 37B. Distal grip section 142 is coupled to external hypotube 120 via male and female couplers 174, 176. *Id.* at 16:20–22, Figs. 32A, 32B, 34. Figure 34 of the '348 Patent is reproduced below.

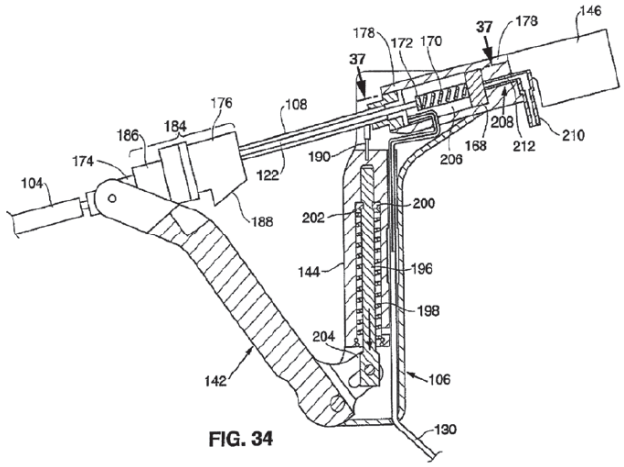


FIG. 34

Figure 34 is a side elevation view of handle 106 as depicted in Figure 21 (reproduced above). *Id.* at 4:19–21.

As the distal and proximal grips are moved towards one another, sheath 104 is withdrawn from array 102a until female coupler 176 contacts and bears against frame member 178. *Id.* at 17:54–59, Fig. 37A, 37B. "Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube 120." *Id.* at 17:59–61. "An opposing force is developed in yoke 168, which causes a relative forward motion in hypotube 122." *Id.* at 17:61–63, Figs. 37A, 37B. "The relative motion between the hypotubes causes deflection in flexures 124, 136 which deflect in a manner that deploys and tensions the electrode array." *Id.* at 17:63–66.

### *D. Illustrative Claims*

Claims 1 and 11 are independent. Claims 2–10 and 12 depend, directly or indirectly, from claim 1; claims 13–15 depend directly from claim 11. Claims 1 and 11

are illustrative of the claimed subject matter, and are reproduced below:

> 1. A device for treating a uterus comprising:
>
> an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;
>
> an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;
>
> a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;
>
> a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured

so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

*Id.* at 19:9–42.

11. A device for treating a uterus comprising:

an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;

a handle coupled to the proximal portion;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating one of the inner and outer

sleeves relative to the other causes the applicator head to transition from the contracted state to the expanded state;

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus; and

wherein when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.

*Id.* at 20:17–47.

*E. The Asserted References*

Petitioner relies upon the following references (Pet. 14):

| **Reference** | **Patent No./ Pub. No.** | **Date** | **Exhibit No.** |
|---|---|---|---|
| Edwards | US 6,024,743 | Feb. 15, 2000 | Ex. 1005 |
| Ortiz | US 5,358,496 | Oct. 25, 1994 | Ex. 1006 |
| Lichtman | US 5,620,459 | Apr. 15, 1997 | Ex. 1008 |
| Jing | CN 1060594A | Published Apr. 29, 1992 | Exs. 1010, 1011 (translation) |

*F. The Asserted Grounds*

Petitioner challenges claims 1–15 of the '348 Patent on the following grounds (Pet. 14):

| References | Basis | Claim(s) Challenged |
|---|---|---|
| Edwards, Ortiz, Lichtman, and Jing | § 103(a) | 1–15 |

## II. ANALYSIS

We turn now to Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a) for instituting review.

### *A. Level of Skill in the Art*

Dr. Pearce testifies that a person of ordinary skill in the art

> would include someone who had, through education or practical experience, the equivalent of a bachelor's degree in biomedical engineering, electrical engineering, mechanical engineering, or a related field and at least an additional two to three years of work experience developing or implementing electrosurgical devices.

Ex. 1002 ¶ 47. Patent Owner does not provide evidence or argument on the level of ordinary skill. Prelim. Resp. 10 n.3. We adopt Dr. Pearce's definition for purposes of this Decision.

### *B. Claim Construction*

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of

ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While our claim interpretation cannot be divorced from the specification and the record evidence, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes express constructions for two claim terms, "frame" and "flexure." Pet. 15–17. Patent Owner does not propose an express construction for any claim term. Prelim. Resp. 8–9.

*1. "frame"*

Claim 1 recites "a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a *frame*" (emphasis added). Petitioner proposes to construe "frame" "to include a structure coupled (*e.g.*, removably or continuously) to a handle grip, that surrounds or encloses another component (*e.g.*, inner sleeve)." Pet. 16. Petitioner asserts that "[a]lthough 'frame' is not specifically defined, the specification does describe a 'frame member 178' mounted on the proximal grip section and enclosing various components of the handle and expansion mechanism including the 'yoke 168,' 'spring stop 172,' 'compression spring 170,' and 'hypotube 122.'" *Id.* at 15 (citing Ex. 1001, 4:28–36, 17:37–53, Fig. 34; Ex. 1002 ¶ 52). Petitioner also asserts that this construction "is

consistent with the plain and ordinary meaning of the word 'frame' as a structure that surrounds or encloses something." *Id.* at 15–16 (citing Ex. 1013, 4; Ex. 1014, 3).

On this record, we agree that the Specification uses "frame" in accordance with its ordinary meaning. *See*, *e.g.*, Ex. 1001, 17:37–49 (referring to "frame member 178" and "the frame"); Ex. 1013, 4; Ex. 1014, 3. We do not agree with Petitioner's proposed claim construction, however, because it encompasses only one (apparently, the narrower) of the two dictionary definitions of "frame" cited in the Petition. *See* Pet. 15–16 (citing Ex. 1013, 4 ("an enclosing structure or case"); Ex. 1014, 3("an arrangement of structural parts that gives form or support")). Petitioner has not explained sufficiently why the broadest reasonable claim construction should not encompass both of the dictionary definitions.

We determine that the broadest reasonable interpretation consistent with the Specification of "frame" encompasses: an arrangement of structural parts that gives form or support; and a structure coupled (*e.g.*, removably or continuously) to a handle grip, that surrounds or encloses another component (*e.g.*, inner sleeve).

*2. flexures*

Claim 1 recites "a deflecting mechanism including *flexures* disposed within the applicator head" (emphasis added"). Petitioner argues that the term "flexure" "should be construed to include a component designed to be bent or curved." *Id.* at 16–17. Petitioner asserts that its proposed claim construction is consistent with the use of "flexure" in the Specification and the term's ordinary meaning. *Id.* at 16 (citing Ex.

1001, 13:65–67, 13:56–14:31, Figs. 23, 30; Ex. 1002 ¶¶ 54–56; Ex. 1013, 3).

We do not agree with Petitioner's proposed claim construction because it is not consistent with the Specification's description of flexures 124, 136 as strips that are capable of being bent or curved. *See*, *e.g.*, Ex. 1001, 4:1–9, 13:8–14:31, Figs. 23, 28–30. Figures 23 and 28, for example, depict flexures 124 as strips that have been bent or curved as the result of relative motion between hypotubes 120 and 122. *Id.* at 13:8–15, 14:29–30, Figs. 23, 28. Indeed, Petitioner's declarant, Dr. Pearce, testifies that "a person of skill in the art would understand the term 'flexure' to refer to a component capable of being bent or curved." Ex. 1002 ¶ 56.

On this record, we determine that the broadest reasonable interpretation consistent with the Specification of "flexures" is strips that are capable of being bent or curved. We note that a distinction with Petitioner's proposed construction is that "designed to be bent," for example, could mean a structure that has been bent but is no longer bendable or a structure that is bendable. "Capable of being bent," on the other hand, means that the structure is further bendable.

*C. Asserted Obviousness*

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art ("POSA") to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A patent claim composed of several elements, however, is not proved

obvious merely by demonstrating that each of its elements was known, independently, in the prior art. *Id.* at 418. In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, when in evidence. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In this case, Petitioner challenges claims 1–15 as unpatentable for obviousness over Edwards, Ortiz, Lichtman, and Jing. Pet. 14. For the reasons discussed below, Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of the challenged claims.

*1. Overview of Asserted References*

*a. Edwards*

Edwards "relates generally to a method and apparatus to controllably create cell necrosis of at least a portion of the uterus, and more particularly to a [a] method and apparatus to create selective cell necrosis of target sites of the uterus." Ex. 1005, 1:21–

24. Cell necrosis apparatus 10 includes expandable member 12, which is introduced into the uterus through introducer sleeve 14 "in a folded, or non-distended configuration." *Id.* at 5:4–5, 6:1–4. Following introduction, sleeve 14 is withdrawn, and expandable member 12 is expanded. *Id.* at 6:4–5. Figure 1B of Edwards is reproduced below.

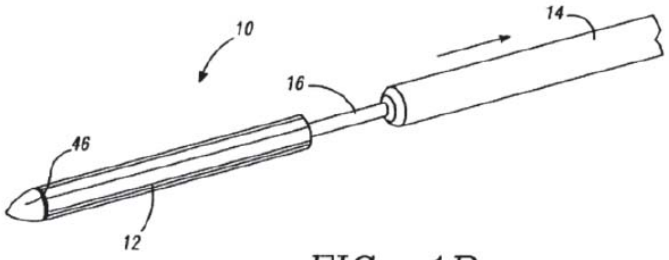



FIG. – 1B

Figure 1B is a perspective view of cell necrosis apparatus 10 in a non-deployed position as introducer sleeve 14 is withdrawn. *Id.* at 3:22–24.

Expandable member 12 can be expanded "either mechanically, with the introduction of a fluid or gaseous expanding medium, such as [an] electrolytic solution, or a combination of both." *Id.* at 6:4–8. Figure 1C is reproduced below.

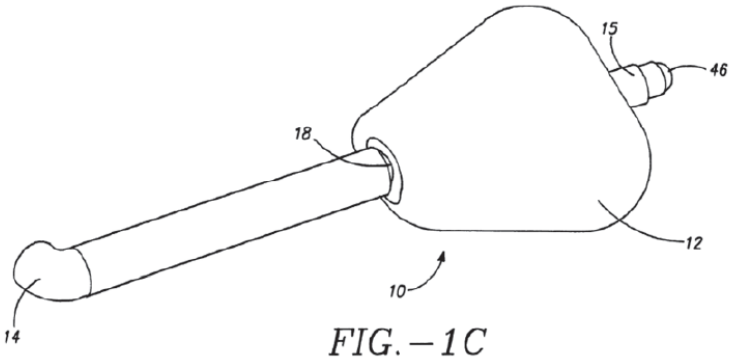



FIG.—1C

Figure 1C is a perspective view of cell necrosis apparatus 10 in a deployed position showing expandable member 12 expanded. *Id.* at 3:25–26. "Electrolytic solution is introduced into expandable member 12, causing it to become distended and be self-retained in the uterus." *Id.* at 6:10–12. In the treatment phase, "[c]ell necrosis apparatus 10 automatically conforms to the interior of the uterus." *Id.* at 6:33–34. Edwards teaches using ultrasound to create a map of the interior of the uterus:

> The amount of cell necrosis can vary. However, it is desirable to ablate about 2 to 3 mm, with approximately 1 mm of the myometrium. Ultrasound can be used to create a map of the interior of the uterus. This information is input to a controller. Individual electrodes are multiplexed and volumetrically controlled. If desired, the area of cell necrosis can be substantially the same for each cell necrosis event.

*Id.* at 6:48–54.

Figure 4 of Edwards is reproduced below.

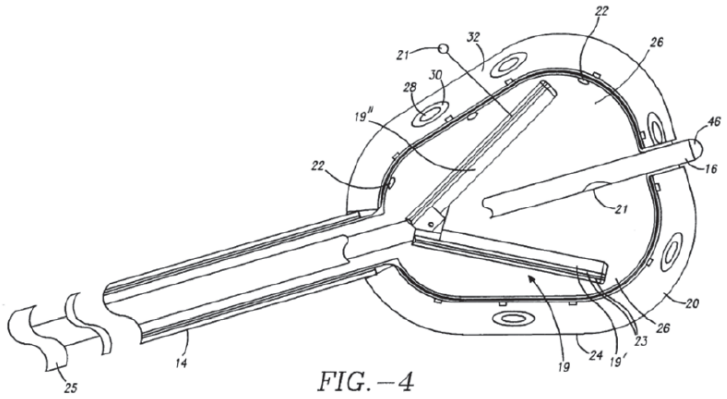
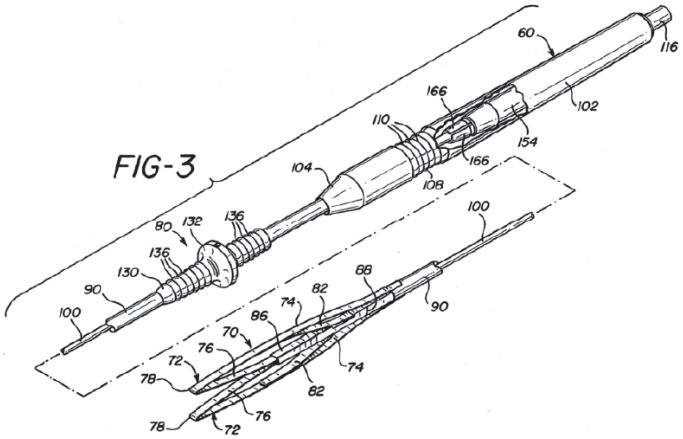



FIG.—4

Figure 4 is a cross-sectional view of an embodiment of cell necrosis apparatus 10 in which expandable member 12 is substantially surrounded by conforming member 20. *Id.* at 7:4–10. "Conforming member 20 receives electrolytic solution from expandable member 12 . . . through a plurality of apertures 22 formed in expandable member 12." *Id.* at 7:10–13. Frame 19, with arms 19', is used to assist in opening expandable member 12. *Id.* at 7:19–21. Edwards discloses that, "[i]n one embodiment, cell necrosis apparatus 10 conforms lightly with the interior of the uterus so that all, or almost all, of the endometrium is in contact with a conductive surface 24 of conforming member 20." *Id.* at 7:37–40.

*b. Ortiz*

Ortiz relates to an endoscopic tissue manipulator that can be inserted through an endoscopic tube to enable a surgeon to manipulate tissue inside a body cavity. Ex. 1006, 1:10–12. A preferred embodiment includes a proximal handle assembly and a distal expandable platform 70. *Id.* at 4:37–39. Figure 3 of Ortiz is reproduced below:




As shown in Figure 3, platform 70 consists of a plurality of flexible, interconnected strips adapted to expand laterally outward to form a pair of fingers 72. *Id.* at 4:52–55. Each of fingers 72 comprises outer strip 74 and inner strip 76. *Id.* at 4:55–58. Outer strip 74 is attached to the distal end of actuator tube 90, and inner strip 76 is attached to the distal end of shaft or push rod 100 inside of actuator tube 90. *Id.* at 4:59–63. "[W]hen actuator tube 90 is retracted, i.e., moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration." *Id.* at 5:28–31. "The outer strips 74 are pulled in the proximal direction by the actuator tube 90 and the guide tube 86 is moved proximally along the inner strips 76 by the struts 82." *Id.* at 5:32–34. Figure 7 of Ortiz is reproduced below.

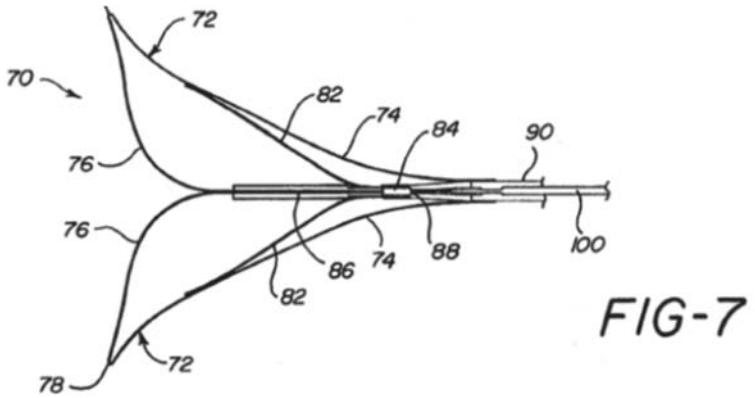



FIG-7

Figure 7 depicts a longitudinal cross section illustrating platform 70 in the tulip-shaped configuration. *Id.* at 3:29–30, 4:10–11. As shown in Figure 7, each of fingers 72 comprises flexible strut 82, having its distal end secured to outer strip 74 and its proximal end attached to connector sleeve 84, which is slidably mounted on inner strip 76. *Id.* at 4:63–5:1. Connector sleeve 84 is located within guide tube 86, which is slidably received in the distal end of actuator tube 90. *Id.* at 5:1–4. Struts 82 provide for shape control of platform 70 in its expanded configuration. *Id.* at 6:1–2. "The expanded platform 70 has a generally planar configuration which provides two flat tissue manipulating surfaces on its opposite sides." *Id.* at 8:36–39.

*c. Lichtman*

Lichtman discloses handle mechanisms for surgical instruments employing movable jaws, and mechanisms for moving the jaws, typically involving coaxial telescoping elements. Ex. 1008, 5:19–21, 40–42. Figure 1 of Lichtman is reproduced below.

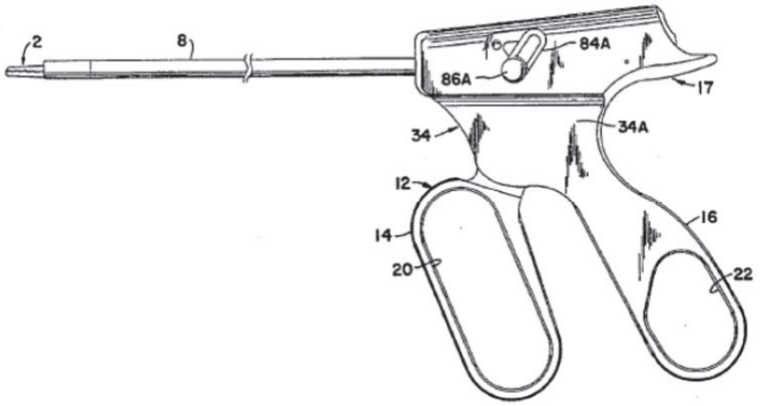



Figure 1 shows a side view of a preferred embodiment that includes unitary jaw piece 2, outer hollow shaft 8, and handle assembly 12 including stationary handle member 16 and movable handle member 14. *Id.* at 6:13–22.

Figure 9 of Lichtman is reproduced below.

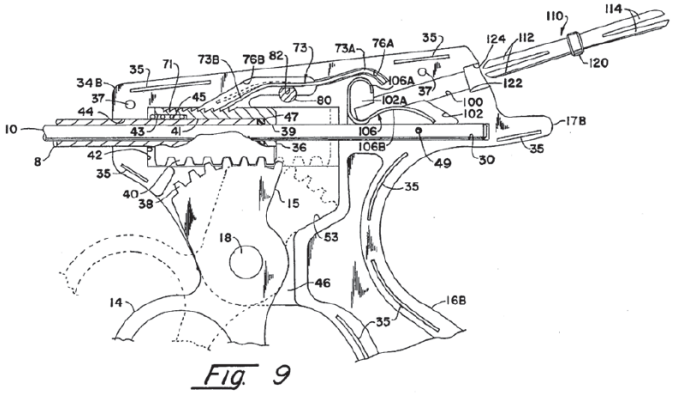



Fig. 9

Figure 9 is a partially exploded view showing outer shaft 8, inner shaft 10, and movable handle member 14, which is rotatable about pivot pin 18. *Id.* at 4:40–43, 6:15–21. Outer shaft 8, which coaxially surrounds

and is free to slide axially relative to inner tube 10, is rigidly joined to gear rack tube 36. *Id.* at 6:31–33.

*d. Jing*

Jing relates to a computer-controlled apparatus for measuring and displaying data of the morphology of a woman's uterine cavity. Ex. 1011, 3:5–7, 20–23, 4:25–30.[2] "An object of the present invention is to provide a computer-controlled measurement apparatus for measuring and displaying data of the morphology of the uterine cavity, thereby increasing the success rate of the IUD technique and facilitating the modification of IUDs." *Id.* at 3:20–23. Figure 2 of Jing is reproduced below.

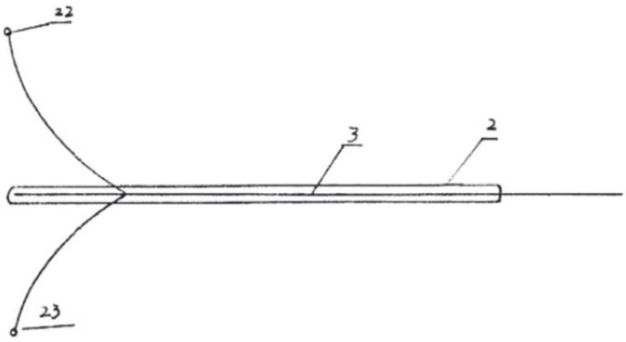



Figure 2 illustrates measuring rod 3 and dovetail-type contacts 22, 23. *Id.* at 5:9–13. Jing discloses:

> When a transverse dimension of the uterine cavity is to be measured, the measurement push button may be pushed by hand, such that two dovetail-type contacts (22, 23) of the transverse dimension measuring rod protrude from through-holes (10) at two sides of the measurement sleeve and expend [sic] to the transverse dimension

[2] We cite to the certified translation of Jing (Ex. 1011).

being measured.

*Id.*

*2. Petitioner's Contentions with Respect to Claims 1 and 11*

Petitioner argues that "Edwards on its own fully discloses" the "applicator head" limitation of claims 1 and 11. Pet. 26. While conceding that "Edwards does not specifically describe an inner sleeve slidably and coaxially disposed within an outer sleeve," as required by the "elongate member" limitation of claims 1 and 11, Petitioner contends that "these aspects are fully disclosed by Ortiz." *Id.* at 23 (citing Ex. 1002 ¶ 77). Petitioner asserts that "use of the mechanical expansion elements taught by Ortiz, including the inner sleeve slidable within an outer sleeve, would have been preferable over the fluid or gaseous expansion media disclosed in Edwards because it would have simplified the device design and obviated potential safety issues such as fluid leakage or contamination." *Id.* at 25 (citing Ex. 1002 ¶¶ 64, 82); *see also id.* at 53 (arguing that "a skilled artisan would also have recognized that an endometrial ablation device as in Edwards would benefit from improved contact between the expandable applicator head and the uterine wall") (citing Ex. 1002 ¶ 63).

With respect to the "deflecting mechanism" limitation requiring "external flexures being coupled to the outer sleeve" and "internal flexures being coupled to the inner sleeve," Petitioner again relies on Ortiz. *Id.* at 33 (citing Ex. 1002 ¶ 103). Petitioner argues that Figure 7 of Ortiz discloses first and second outer flexures ("outer strip 74") and first and second inner flexures ("flexible strut 82"). *Id.* (citing Ex. 1002 ¶ 103). Petitioner asserts that "Ortiz's deflecting

mechanism with flexures would have been a reasonable design choice enabling improved contact with the uterine wall." *Id.* at 35 (citing Ex. 1002 ¶¶ 62, 108); *see also id* at 53 ("It would have been apparent to the skilled artisan that the 'plurality of flexible, interconnected strips" and "flexible struts" taught by Ortiz would be well matched to the shape of the uterus and well suited for use as an expansion device in an endometrial ablation device.") (citing Ex. 1006 at 4:34–42, 52–55; Ex. 1002 ¶ 63). Petitioner also argues that "the combination of Edwards and Ortiz would have the added benefits of simplifying the device design by removing the need for fluid or gaseous expansion medium." *Id.* at 36 (citing Ex. 1002 ¶¶ 63–64, 108).

Petitioner contends that "Ortiz also discloses that translation of the inner sleeve (shaft 100) relative to a frame causes an applicator head to transition from a contracted to an expanded state," as required by claim 1.[3] *Id.* at 34 (citing Ex. 1002 ¶ 105). Petitioner argues:

> Ortiz discloses that "[b]y pulling the finger slide 80 proximally, as shown in FIG. 6, the actuator tube 90 is retracted relative to the shaft 100 to expand the platform 70 into its tulip-shaped configuration (FIG. 7)." *Id.* at 8:10-19. Since the finger slide 80 is secured to the tube 90, the shaft 100 also moves relative to the finger slide 80. Ex. 1002 ¶ 105.

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[3] We note that the claims 1 and 11 use different language to define the mechanism causing the applicator head to transition from a contracted state to an expanded state. Claim 1 recites "translating the inner sleeve relative to the frame," while claim 11 recites "translating one of the inner and outer sleeves relative to the other."

*Id.* at 34; *see also id.* at 51–52 (advancing similar arguments).[4] Petitioner identifies Ortiz's shaft 100 as corresponding to the "inner sleeve" and Lichtman's gear rack tube 36 as corresponding to the "frame." *Id.* at 34–35.

With respect to the requirement of claims 1 and 11 for an indicator mechanism configured to indicate a dimension of the uterus, Petitioner relies on Jing's device for measuring a transverse dimension of the uterine cavity. *Id.* at 36–38. Petitioner contends that incorporating Jing's measurement apparatus into the ablation device taught by Edwards would have allowed "measurement of a dimension of the uterus and thus the mapping expressly contemplated by Edwards." *Id.* at 37 (citing Ex. 1002 ¶¶ 111–112). Petitioner further contends that "[a] person of ordinary skill would have had reason to apply Jing's indicator mechanism to provide low cost dimension information." *Id.* at 38 (citing Ex. 1002 ¶¶ 70, 112).

Claim 11 additionally requires "when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator." Petitioner concedes that "Jing does not specifically describe whether the components receiving the dimension information would include a generator configured to deliver current to electrodes."

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[4] Petitioner similarly argues that Ortiz discloses "translating one of the inner and outer sleeves relative to the other," as required by claim 11. *Id.* at 39 ("As Dr. Pearce explains, this limitation is disclosed by Ortiz, which teaches that '[b]y pulling the finger slide 80 proximally, as shown in FIG. 6, the actuator tube 90 is retracted relative to the shaft 100 to expand the platform 70 into its tulip-shaped configuration (FIG. 7).'") (citing Ex. 1006 at 8:10–19; Ex. 1002 ¶ 155).

*Id.* at 39. Petitioner contends that "these aspects of the limitation are disclosed by Edwards." *Id.* (citing Ex. 1005, 11:34–35; Ex. 1002 ¶ 137). Petitioner argues that "addition of the dimension measuring components disclosed in Jing to the RF ablation device disclosed in Edwards would have been obvious" because "[a] person of ordinary skill in the art would have been motivated to combine Jing and Edwards in this manner in order to obtain automatic transmission of data useful for controlling the generator without requiring manual data entry, thus improving convenience." *Id.* at 40 (citing Ex. 1002 ¶ 140).

*3. Patent Owner's Responsive Contentions*

In response, Patent Owner argues, *inter alia*, that Petitioner has not explained sufficiently why a person of ordinary skill in the art would have combined the prior art teachings to arrive at the challenged claims as a whole. *See* Prelim. Resp. 3, 14, 57. Patent Owner asserts, for example, that Petitioner's "arguments are legally insufficient, contrary to the teachings of the prior art references, and lack any articulated reasoning with rational underpinning." *Id.* at 3.

More specifically, regarding Petitioner's asserted reasons for combining teachings of Edwards and Ortiz, Patent Owner argues that "Petitioner fails to explain how or why Ortiz's distal platform 70 improves contact with the uterine wall relative to Edwards's expandable member 12." *Id.* at 36–37. Patent Owner also challenges Petitioner's argument that "Ortiz's distal platform 70 would have 'simplif[ied] the device design by removing the need for fluid or gaseous expansion medium.'" *Id.* at 37 (citing Pet. 36). According to Patent Owner, Petitioner baselessly assumes that any combination of Ortiz with Edwards would involve a complete replacement of the fluid-actuated

components of Edwards with the mechanical components of Ortiz. *Id.* Patent Owner asserts that, contrary to Petitioner's assumption, "Edwards describes the use of mechanical components to 'assist' in the expansion of the fluid-actuated components." *Id.* Patent Owner further asserts:

> Moreover, even if the fluid-actuated components of Edwards were completely replaced by the mechanism of Ortiz, that would not simplify the device design. Ortiz's actuation mechanism requires multiple components (some fixed, some slidable), a specific handle mechanism, and a multitude of interconnected struts.

*Id.* at 37–38.

With respect to the limitation of claim 1 requiring a deflecting mechanism capable of "translating the inner sleeve relative to the frame," Patent Owner disputes Petitioner's contention that Ortiz's shaft 100 (the asserted "inner sleeve") is capable of translating relative to a frame. Patent Owner asserts:

> Petitioner concedes that Ortiz describes movement of actuator tube 90 relative to fixed shaft 100. (Petition at 34; *see* Ortiz col. 5:28–38 ("[W]hen actuator tube 90 is retracted, *i.e.*, moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration.").) Petitioner's argument confirms that Ortiz contains an outer tube and frame that translates relative to a fixed inner shaft. This is different than the claimed requirement that the inner tube translates relative to a fixed frame.

*Id.* at 33–34.

With respect to the requirement of claims 1 and 11 for an indicator mechanism configured to indicate a dimension of the uterus, Patent Owner asserts that a person of ordinary skill in the art would not have combined Jing with Edwards. *Id.* at 41. Patent Owner argues, for example, that "Jing's apparatus is not . . . a low cost replacement for Edwards's ultrasound [as Petitioner contends], but rather an unnecessary additional structure that would only add to the manufacturing costs." *Id.*

Patent Owner also disputes Petitioner's arguments with respect to the additional limitation of claim 11 that "when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator." Patent Owner argues that "the width dimension provided by the Jing device is not relevant to Edwards's operation." *Id.* at 42 (citing Ex. 1005, 6:30–47); *see also id.* at 43 ("There is no evidence that the 'map' described in Edwards relates to a dimension of the uterus (*e.g.*, the width), as Petitioner asserts.").

*4. Analysis*

Upon consideration of the Petition and the Preliminary Response, we agree with, and adopt, Patent Owner's arguments, as summarized above, that the reasons advanced by Petitioner for combining elements of Edwards, Ortiz, Lichtman, and Jing to make the claimed invention are conclusory and insufficient, and that the asserted combination does not teach or suggest all of the claimed features. We provide additional analysis below.

As discussed above, Petitioner relies on Edwards for the "applicator head" limitation of claims 1 and 11. *See*

Pet. 26. Edwards's applicator head includes expandable member 12, into which electrolytic solution is introduced for use in ablation treatment of the uterus. *See* Ex. 1005, 6:10–12, 6:33–41, 7:4–18.

Petitioner's argument that using Ortiz's mechanical expansion elements to expand Edwards's applicator head would have simplified the device design by removing the need for a fluid or gaseous expansion medium is unpersuasive because it does not take into account that electrolytic solution is used in Edwards's applicator head, not just for expansion, but also for ablation treatment. As such, Petitioner does not explain why using Ortiz's mechanical expansion elements for expansion of Edwards's applicator head, while continuing to use electrolytic solution in the applicator head for ablation treatment, would have resulted in any simplification or benefit. Dr. Pearce's testimony that replacing the use of fluid or gaseous media with Ortiz's mechanical expansion elements would have obviated potential safety issues, such as fluid leakage or contamination, similarly fails to account for the use of electrolytic solution in Edwards's applicator head for ablation treatment and is, therefore, unpersuasive. *See* Ex. 1002 ¶ 64.

Dr. Pearce's testimony that incorporating Ortiz's expansion elements would have improved contact between Edwards's applicator head and the uterine walls is also unpersuasive. *See* Ex. 1002 ¶ 63. In particular, Dr. Pearce does not explain sufficiently why replacing the two rigid arms extending outward toward the walls of the uterus (as depicted in Figure 4 of Edwards) with the asserted flexures taught by Ortiz would have improved the ability of the device to conform to the shape of the uterus. *See id.* For example, Dr. Pearce's testimony does not address or

explain the disclosure in Edwards that "[c]ell necrosis apparatus 10 automatically conforms to the interior of the uterus." *See* Ex. 1005, 6:33–41; *see also id.* at 7:37–40 (disclosing that, in one embodiment, "cell necrosis apparatus 10 conforms lightly with the interior of the uterus so that all, or almost all, of the endometrium is in contact with a conductive surface 24 of conforming member 20").

We also are not persuaded by Petitioner's argument that Ortiz teaches or suggests the requirement of claim 1 for a deflecting mechanism capable of "translating the inner sleeve relative to the frame." *See* Pet. 34 (citing Ex. 1002 ¶105). Petitioner identifies Ortiz's shaft 100 as corresponding to the "inner sleeve" and Lichtman's gear rack tube 36 as corresponding to the "frame." *Id.* at 34–35. As disclosed in Ortiz, however, shaft 100 does not move. For example, Ortiz discloses that "when actuator tube 90 is retracted, i.e., moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration." Ex. 1006, 5:28–31, Fig. 4. Similarly, Ortiz discloses: "By pulling the finger slide 80 proximally, as shown in FIG. 6, the actuator tube 90 is retracted relative to the shaft 100 to expand the platform 70 into its tulip-shaped configuration (FIG. 7)." *Id.* at 8:10–14. Petitioner and Dr. Pearce have not explained sufficiently how Ortiz's shaft 100, which does not move, is capable of translating relative to Lichtman's gear rack tube 36 in the asserted combination.

Further, Petitioner has not provided a sufficient rationale for combining the teachings of Jing with those of Edwards, Ortiz, and Lichtman to teach or suggest either: (1) an indicator mechanism configured to indicate a dimension of the uterus, as required by

claims 1 and 11; or (2) the additional limitation of claim 11 that "when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator." Petitioner argues that incorporating Jing's device into an endometrial ablation device as described by Edwards "would allow measurement of a dimension of the uterus and thus the mapping expressly contemplated by Edwards." Pet. 37 (citing Ex. 1002 ¶¶ 111–112). Petitioner also argues:

> Edwards expressly discloses the use of ultrasound "to create a map of the interior of the uterus" that is used to determine the appropriate parameters of the ablation treatment. Ex. 1005 at 6:50–54. A person of ordinary skill would have had reason to apply Jing's indicator mechanism to provide low cost dimension information. Ex. 1002 ¶¶ 70, 112.

*Id.* at 38. These arguments are conclusory, and the cited testimony from Dr. Pearce does not shed further light on why a skilled person would have combined the teachings of Jing and Edwards. *See* Ex. 1002 ¶¶ 70, 111–112. In particular, the record does not explain sufficiently why a person of ordinary skill in the art would have considered measurement of a dimension of the uterus (e.g., a transverse dimension), as taught by Jing, to constitute "the mapping expressly contemplated by Edwards," as Petitioner argues.

For these reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to independent claims 1 and 11 as obvious over Edwards, Ortiz, Lichtman, and Jing. As Petitioner's arguments and evidence with respect to dependent claims 2–10 and 12–15 do not remedy the deficiencies in the arguments and evidence with

respect to the independent claims, discussed above, we also determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to dependent claims 2–10 and 12–15.

## III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to: claims 1–15 as obvious over Edwards, Ortiz, Lichtman, and Jing.

## IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner's Petition for an *inter partes* review of claims 1–15 of the '348 Patent is *denied*, and no *inter partes* review will be instituted pursuant to 35 U.S.C. § 314 as to any claim of the '348 Patent on any of the grounds of unpatentability alleged by Petitioner in the Petition.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

1:15-cv-1031

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
*Plaintiffs*,

vs.

MINERVA SURGICAL, INC.,
*Defendant.*

# MEMORANDUM AND ORDER

This matter is before the Court on defendant Minerva Surgical Inc.'s ("Minerva") renewed motion for judgment as a matter of law of no patent damages or, in the alternative, for a new trial for reasonable royalty (D.I. 521); Minerva's motion for a new trial for Lanham Act and breach of contract claims (D.I. 523); Minerva's motion for an injunction under the Delaware Deceptive Trade Practices Act, 6 Del. C. § 2532 (D.I. 525); plaintiffs Hologic, Inc.'s and CYTYC Surgical Products, LLC's (collectively, "Hologic") motion for attorney fees and related nontaxable costs (D.I. 528); Hologic's motion for enhanced damages (D.I. 530); Hologic's motion for a permanent injunction (D.I. 532); and Hologic's motion for an accounting, supplemental damages, ongoing royalties, pre-judgment interest, and post-judgment interest (D.I. 534).

## I. BACKGROUND

In this patent infringement action, Hologic alleged that Minerva infringed its patents involving a system

and method to detect uterine perforations during uterine ablation. Hologic alleged that Minerva infringed U.S. Patent No. 6,872,183 ("the '183 Patent"), titled "System and Method for Detecting Perforations in a Body Cavity," filed May 24, 2004, and issued March 29, 2005, and U.S. Patent No. 9,095,348 ("the '348 Patent"), titled "Moisture Transport System for Contact Electrocoagulation," filed August 8, 2013, and issued August 4, 2015 (collectively "the Patents-in-Suit"). The '183 patent involves method claims and the asserted claim of the '348 patent is a system or apparatus claim.

Prior to trial, the Court addressed cross-motions for summary judgment on invalidity and infringement and Hologic's motion for summary judgment on the issue of assignor estoppel. Minerva asserted the patent claims at issue were invalid for lack of written description and enablement. The Court found Minerva's invalidity defenses were barred by assignor estoppel.[1] The Court also stated that even if Minerva

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[1] The determination of estoppel was based on undisputed evidence that:

> [the inventor of the '183 and '348 patents, Csaba] Truckai founded Minerva. He used his expertise to research, develop, test, manufacture, and obtain regulatory approval for the Minerva EAS. It is undisputed that Truckai's job responsibilities as Minerva's President and CEO included bringing the accused product to market to directly compete with Hologic. Hologic contends the accused product incorporates the same patented technology that Truckai's company sold to Hologic. It is undisputed that Truckai, an inventor on each of the Patents-in-Suit, executed broad assignments of his inventions to NovaCept, which was then sold to Hologic's predecessor for $325 million dollars.

D.I. 407, Memorandum and Order at 18). Hologic argued in essence "that—more than 19 years after Mr. Truckai executed his initial patent assignment—Minerva and Truckai attempt[ed] to

was not estopped from asserting the defense, its arguments lacked merit in that Minerva's Section 112 arguments rested on a flawed definition of the claims that ignored the Court's claim constructions, and Hologic had shown that the '183 and '348 patent disclosures adequately described the claims as construed by the Court (D.I. 407, at 25-26). The Court further found as a matter of law that, under the Court's claim construction, Hologic had shown that Minerva's accused product infringed the asserted claims of the patents. *Id.* at 26.

The action proceeded to trial on the patent issues of damages and willfulness and on Minerva's counterclaims for false advertising and breach of contract. Those matters were tried to a jury from July 16, 2018, to July 27, 2018. The jury found Hologic was entitled to damages for lost profits in the amount of $4,200,529.75, and for royalties not included in lost profits in the amount of $587,138.48.[2] The jury further found that Hologic's infringement was not willful. Hologic prevailed on Minerva's counterclaims—the jury rejected Minerva's counterclaims for breach of contract and false advertising under the Lanham Act violations (D.I. 498). The Court entered judgment on the verdict, subject to revision pursuant to any rulings on post-trial motions, on August 13, 2018 (D.I. 520).

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destroy the value of what Truckai sold to Hologic so that Minerva [could] directly compete with Hologic using the patented technology he already sold to Hologic." *Id.* at 18-19. The Court found that the balance of equities favored a finding of privity between Truckai and Minerva and required the application of assignor estoppel to Minerva's defenses to Hologic's patent infringement claims (*Id.* at 21).

[2] The jury verdict totaled $4,787,668.23, which Hologic argues represents an effective rate of 16.1% of total Minerva handpiece revenues.

In its pending motions, Hologic argues that this case warrants enhanced damages and asks the Court to amend the judgment by doubling Hologic's damages award of $3,752,550. Hologic contends Minerva's failure to abide by the Court's claim construction justifies enhancement and argues that Minerva should have known that its proposed claim constructions were baseless, knew that owning its own patents was no defense to infringement of Hologic's patents, knew that the presence of additional features on its device was not a defense to infringement, and should have known that it had no invalidity defense. Hologic also points to other allegedly egregious conduct by Minerva such as its failure to take remedial action, infringement after entry of judgment, its copying of the NovaSure system, and its attempts to conceal its infringement of the '348 patent by adding false statements to its operator's manual. Hologic further argues that Minerva's size and financial condition also weigh in favor of enhancement of damages.

Minerva argues in response that a finding of willfulness is a prerequisite to awarding enhanced damages under Section 284. Further, it argues that even if the Court were to consider enhancement, the evidence would not support imposition of enhanced damages under 35 U.S.C. § 284.

Hologic also moves for an award of supplemental damages from the date of the last sales records produced (April 1, 2018) to the date of judgment based on an effective royalty rate of 16.1%. It seeks an accounting and an ongoing royalty for post-judgment infringing sales at the rate of 20% plus a 10% enhancement. It also seeks prejudgment interest calculated at the prime rate compounded quarterly

from the dates of infringement through the date of judgment ($270,533) and post-judgment interest at the legal rate under 28 U.S.C. § 1961.

Minerva opposes the motion for supplemental damages and argues Hologic's calculation is not supported by any evidence. Though it concedes that Hologic is entitled to recover prejudgment interest, it urges the Court to apply the treasury bill rate. It does not challenge Hologic's right to postjudgment interest at the legal rate.

Minerva also renews its motion for JMOL, it contends the Court should award no damages to Hologic, contending that none were proven at trial. It contends the award of lost profits was improper and is not supported by evidence. It also argues Hologic failed to prove its reasonable royalty damages because the jury was not instructed to apportion the damages to reflect the infringing features of the product. Alternatively, it moves for a new trial on reasonable royalty.

Minerva also moves for a new trial on its Lanham Act and breach of contract claims. It argues that Hologic violated Federal Rule of Civil Procedure 26(e) and withheld highly relevant evidence relating to Minerva's counterclaims. It also contends the Court erred in striking and precluding testimony on the quantum of Minerva's harm resulting from false advertising and an intertwined breach of a Non-disclosure Agreement. Further, it contends the Court erred in dismissing Minerva's state-law counterclaim that Hologic falsely advertised the efficacy rates for its product. It argues that the Court's rulings made it impossible for Minerva to fully present its case on its complicated claims involving Hologic's continuous scheme to attack Minerva as a competitor with

misleading efficacy rates for products and "Scorched Earth" campaign to prevent competition.

Minerva also seeks a permanent injunction under the DTPA.[3] It seeks an order enjoining Hologic from engaging in conduct that disparages Minerva's Endometrial Ablation System ("Minerva's EAS") through their false and misleading representations about Minerva's characteristics and safety. Specifically, it moves for (1) an injunction prohibiting Hologic from disparaging the safety of Minerva's EAS, including prohibiting the use of the 20-year old liver videos that have nothing to do with Minerva's technology, and (2) a corrective disclosure to the market explaining Hologic's false and misleading use of the videos.

In response, Hologic argues that because all of Minerva's counterclaims were rejected by the jury or the Court, there is no basis for granting Minerva any equitable relief. It contends that, although the Court reserved ruling on an equitable remedy, that issue became moot when the jury returned a verdict in favor of Hologic on Minerva's Lanham Act claim.

As a threshold matter, the Court of Appeals for the Federal Circuit has now affirmed the finding by the United States Patent and Trademark Office, Patent

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[3] Minerva stated at trial that the core of its theories "are the same under the state law claims as they are under the Lanham Act." (D.I. 514, Trial Transcript (T. Tr.) at 2214) It further stated it primarily relied on the Lanham Act, but asserted the state law DTPA claim "in particular for injunctive relief." (*Id.*, T. Tr. at 2216) At the conclusion of the parties' presentation of evidence, the Court indicated dismissed the DTPA claim as it related to loss damages but reserved the issue of whether Minerva was entitled to equitable relief (i.e., an injunction) for resolution later by the Court. (*Id.*, Trial Tr. at 2217-18)

Trial and Appeal Board ("PTAB") on *inter partes* review ("IPR") that claims 1-15 of the '183 are invalid as obvious. (D.I. 614-1, Ex. A, Federal Circuit Opinion) The claims challenged in the IPR include all claims of the '183 patent Hologic asserted at trial. Minerva argues that Hologic no longer has any cause of action based on the '183 patent, and any pending litigation with respect to that patent is moot. Hologic argues that the matters are not moot unless and until the Patent Office cancels the patent.[4]

The Court finds the Federal Circuit's determination does not affect the jury verdict in this case. The jury was asked to assess damages for infringement of the asserted claims of both the '183 patent and the '348 patent, without separately apportioning damages between the asserted claims of the two patents. The jury's damages determination can be adequately supported by the finding of infringement of Claim 1 of the '348 patent. The infringement of the '348 patent apparatus claim and the '183 patent method claims were interrelated, but a finding that the method claims are not valid does not affect the finding of infringement as to the apparatus claim. In other words, one can infringe the apparatus claim even if the method claims are invalid.

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[4] The Patent Office cannot cancel claims of patents until after appeal. *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 645 (Fed. Cir. 2011). Although the PTAB has been affirmed, the time to file petitions for rehearing, reconsideration and/or certiorari has not expired. Nonetheless, the Court finds it unnecessary at this point to address Hologic's motion for injunctive relief. It is not likely that the Federal Circuit will reconsider its decision or that the Supreme Court will grant certiorari. Should the decision be reversed, Hologic may again move for an injunction.

Hologic's motion for a permanent injunction against Minerva's continued infringement of the '183 patent, however, will be rendered moot by the Federal Circuit decision. Similarly, Hologic's motions for supplemental and/or enhanced damages and ongoing royalties for infringement of the '183 patent will be moot. Any supplemental or enhanced damages for infringement of the '348 patent can be awarded only up the date of expiration of the '348 patent.[5] The Federal Circuit's findings as to the '183 patent (method claims) do not affect the Court's findings of assignor estoppel on the asserted claim of the '348 patent.[6]

The Court held oral argument on the present motions on February 26, 2019. The Court has considered the record in this case, the substantial evidence in the record, the parties' post-trial submissions, and the applicable law, and finds as follows.

## II. LAW

### A. Standard of Review

The law of the regional circuit—here the Third Circuit—governs the standards for deciding motions for JMOL under Fed. R. Civ. P. 50(b) and new trial under Fed. R. Civ. P. 59(a). *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1325 (Fed. Cir. 2016); *Leader Techs., Inc. v. Facebook, Inc.*, 678 F.3d 1300, 1305

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[5] The '348 Patent expired on November 19, 2018.

[6] The PTAB did not address the assignor estoppel issue. The Federal Circuit recently concluded "by allowing 'a person who is not the owner of a patent' to file an IPR, [35 U.S.C. § 311(a)] unambiguously dictates that assignor estoppel has no place in IPR proceedings." *Arista Networks, Inc. v. Cisco Sys., Inc.*, 908 F.3d 792, 804 (Fed. Cir. 2018).

(Fed. Cir. 2012). Under Rule 50(b), in ruling on a renewed motion, "the court may: (1) allow judgment on the verdict, if the jury returned a verdict; (2) order a new trial; or (3) direct the entry of judgment as a matter of law." Fed. R. Civ. P. 50(b). A judgment as a matter of law is appropriate when "the verdict is not supported by legally sufficient evidence." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993). In the Third Circuit, a "court may grant a judgment as a matter of law contrary to the verdict only if 'the record is critically deficient of the minimum quantum of evidence' to sustain the verdict." *Acumed LLC v. Advanced Surgical Servs., Inc.*, 561 F.3d 199, 211 (3d Cir. 2009) (quoting *Gomez v. Allegheny Health Servs., Inc.*, 71 F.3d 1079, 1083 (3d Cir.1995)).

"In considering that issue the court 'may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version.'" *Id.* (quoting *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir.1993)). "Entry of judgment as a matter of law is a 'sparingly' invoked remedy, granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007) (citation omitted). A renewed post-verdict JMOL motion under Federal Rule of Civil Procedure Rule 50(b) "may not be made on grounds not included in the earlier [Rule 50(a)] motion." *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1105 (Fed. Cir. 2003).

Federal Rule of Civil Procedure 59(e) expressly recognizes a court's authority to alter or amend its judgments. Fed. R. Civ. P. 59(e). "Consistently with

this original understanding, the federal courts generally have invoked Rule 59(e) only to support reconsideration of matters properly encompassed in a decision on the merits[,]" and legal issues collateral to the main cause of action. *White v. New Hampshire Dep't of Emp't Sec.*, 455 U.S. 445, 451 (1982). The principal limitation on that discretion is that a motion to amend "may not be granted where to do so would undermine the jury's fact-finding role and trample on the defendant's Seventh Amendment right to a jury trial." *Robinson v. Watts Detective Agency, Inc.*, 685 F.2d 729, 742 (1st Cir. 1982). Specifically, Rule 59(e) has been invoked to correct damage awards that were improperly calculated, and to include prejudgment interest to which a party was entitled. *See Lubecki v. Omega Logging, Inc.*, 674 F. Supp. 501 (W.D. Pa. 1987), *aff'd*, 865 F.2d 251 (3d Cir. 1988); 11 Wright and Miller, Federal Practice and Procedure, § 2817 n. 28–29.

The rule governing motions to alter or amend judgment is the proper basis for bringing a request for prejudgment interest. *J.A. McDonald, Inc. v. Waste Sys. Int'l Moretown Landfill, Inc.*, 247 F. Supp. 2d 542, 546 (D. Vt. 2002). The method used to calculate amount of judgment and prejudgment interest involves matters of law and is based on undisputed facts, and therefore is appropriately resolved by way of a motion to amend judgment. *Commercial Assocs. v. Tilcon Gammino, Inc.*, 801 F. Supp. 939, 942 (D.R.I. 1992), *aff'd* 998 F.2d 1092 (1st Cir. 1993).

B. Patent Damages

"To recover lost profits, 'a patent owner must prove a causal relation between the infringement and its loss of profits.'" *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1240–41 (Fed. Cir. 2017) (quoting

*Crystal Semiconductor Corp. v. TriTech Microelecs. Int'l, Inc.*, 246 F.3d 1336, 1353 (Fed. Cir. 2001) (internal quotation marks and citation omitted). The burden is on the patentee to show a reasonable probability that but for the infringing activity, the patentee would have made the infringer's sales. *Id.* "'There is no particular required method to prove but for causation' in patent cases." *Id.* (quoting *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1284 (Fed. Cir. 2017)). A useful, but non-exclusive, method to establish the patentee's entitlement to lost profits is the four-factor test articulated in *Panduit Corp. v. Stahlin Brothers Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978). *Id.* "The Panduit test requires the patentee to show: (1) 'demand for the patented product'; (2) 'absence of acceptable noninfringing substitutes'; (3) 'manufacturing and marketing capability to exploit the demand'; and (4) 'the amount of profit that . . . would have [been] made.'" *Id.* (quoting *Panduit*, 575 F.2d at 1156).

The proper inquiry under the first Panduit factor "asks whether demand existed in the marketplace for the patented product, i.e., a product 'covered by the patent in suit or that directly competes with the infringing device.'" *Id.* (quoting *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009) (internal quotation marks and citation omitted)). "All a patentee must do is 'sell[ ] some item, the profits of which have been lost due to infringing sales.'" *Id.* at 1241-42 (quoting *Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1265 (Fed. Cir. 2013) (internal quotation marks and citation omitted)). "[T]he first Panduit factor 'does not require any allocation of consumer demand among the various limitations recited in a patent claim.'" *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702

F.3d 1351, 1360 (Fed. Cir. 2012) (quoting *DePuy Spine*, 567 F.3d at 1330). For purposes of the first *Panduit* factor, products are interchangeable when "the patent owner and the infringer sell products sufficiently similar to compete against each other in the same market segment." *BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1219 (Fed. Cir. 1993).

With respect to the second *Panduit* factor—absence of acceptable noninfringing substitutes—a patentee need not negate every possibility, absent the infringement, that the purchaser might not have purchased a product other than its own. *Presidio Components*, 702 F.3d at 1360 (quoting *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995). The patentee need only show that there was a reasonable probability that the sales would have been made "but for" the infringement. *Id.*

The Federal Circuit has held that a patent owner may satisfy the second *Panduit* element by substituting proof of its market share for proof of the absence of acceptable substitutes. *BIC Leisure Prods.*, 1 F.3d at 1219; *see, e.g.*, *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 805 F.3d 1368, 1380 (Fed. Cir. 2015) (affirming analysis based on "market share" approach). This market share approach allows a patentee to recover lost profits, despite the presence of acceptable, noninfringing substitutes, because it nevertheless can prove with reasonable probability sales it would have made "but for" the infringement. *Id. Panduit's* second factor, properly applied, ensures that any proffered alternative competes in the same market for the same customers as the infringer's product. *Id.* Similarity of products is necessary in order for market share proof to show correctly

satisfaction of *Panduit's* second factor. *Id.* Consistent with Federal Circuit precedent, a patentee can reconstruct the 'but for' market by segmenting the market and determining lost profits based on its market share, assuming the patent owner and the infringer compete in the same market. *Bic Leisure*, at 1219; *see also Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1378 (Fed. Cir. 2003).

C. Interest

"Prejudgment interest on a damages award for patent infringement 'is the rule' under 35 U.S.C. § 284[.]" *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1574 (Fed. Cir. 1996). The purpose of prejudgment interest is "to ensure that the patent owner is placed in as good a position as he would have been had the infringer entered into a reasonable royalty agreement." *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 655 (1983). An award of interest from the time that the royalty payments would have been received merely serves to make the patent owner whole, since his damages consist not only of the value of the royalty payments but also of the foregone use of the money between the time of infringement and the date of the judgment. *Id.* at 655-56. "The rate of prejudgment interest and whether it should be compounded or uncompounded are matters left largely to the discretion of the district court" and "must be guided by the purpose of prejudgment interest, which is to ensure that the patent owner is placed in as good a position as he would have been had the infringer entered into a reasonable royalty agreement." *Bio-Rad Labs., Inc. v. Nicolet Instrument Corp.*, 807 F.2d 964, 969 (Fed. Cir. 1986) (internal quotation marks and citations omitted).

Regarding the rate at which prejudgment interest is calculated, the district court has the discretion to determine whether to use the prime rate, the prime rate plus a percentage, the U.S. Treasury rate ("T-bill rate"), a state statutory rate, the corporate bond rate, or whatever rate the court deems appropriate under the circumstances. *See generally Allen Archery, Inc. v. Browning Manuf. Co.*, 898 F.2d 787, 789 (Fed. Cir. 1990). "A case survey indicates that the prime rate is often selected by courts where the patentee is a large, established and credit-worthy corporation." *The Boeing Co. v. United States*, 86 Fed. Cl. 303, 323 & n.22 (Fed. Ct. Cl. 2009) (citing cases). The selection of the prime rate makes even more sense if it is consistent with the interest rate charged to the patent holder for short-term, unsecured borrowing, i.e., its cost of capital. *Id.* Similarly, courts most often compound interest, reflecting, in this regard, not only the expectation of a prudent, commercially reasonable investor, but also the way that post-judgment interest is calculated under 28 U.S.C. § 1961(c)(3). *Id.* In making a determination regarding the frequency of compounding, i.e. annually, semi-annually, quarterly, etc., courts consider how often the licensee would have made payments in accordance with the hypothetical negotiation. *See Boeing*, 86 Fed. Cl. at 323; *see Datascope*, 879 F.2d at 829 (finding no error in compounding annually); *Brunswick Corp. v. United States*, 36 Fed. Cl. 204, 219 (Fed. Cl. 1996), *aff'd*, 152 F.3d 946 (Fed. Cir. 1998) (stating that compounding interest annually is more likely to place the patentee in the same financial position it otherwise would have held had royalties been timely paid "and has expressly been approved of by the Federal Circuit"). Interest compensates the patent owner for the use of its money between the date of injury and the date of judgment.

*Oiness v. Walgreen Co.*, 88 F.3d 1025, 1033 (Fed. Cir. 1996). In a patent case, "[g]enerally, the interest rate should be fixed as of the date of infringement, with interest then being awarded from that date to the date [the judgment is actually paid.]" *Exmark Mfg. Co. Inc. v. Briggs & Stratton Power Prod. Grp., LLC*, No. 8:10CV187, 2016 WL 6246590, at *2 (D. Neb. May 11, 2016).

An award of prejudgment interest at the T-bill rate of 28 U.S.C. § 1961 has been held to adequately compensate a patentee. *Datascope Corp.*, 879 F.2d at 829; *see also Cornell Univ. v. Hewlett–Packard Co.*, No. 01–cv–1974, 2009 WL 1405208, at *3 (N.D.N.Y. May 15, 2009) (Rader, Fed. Cir. C.J.) ("[T]he T-bill rate has been accepted and employed by many courts in patent cases as a reasonable method of placing a patent owner in a position equivalent to where it would have been had there been no infringement"); *Enzo Biochem, Inc. v. Applera Corp.*, No. 3:04cv929 (JBA), 2014 WL 29126, at *2 (D. Conn. Jan. 3, 2014) (limiting prejudgment interest to the Treasury rate to ensure that the plaintiff did not receive "excessive compensation," noting that the plaintiff should not be "financially rewarded" for its delay); *Century Wrecker Corp. v. E.R. Buske Mfg. Co.*, 913 F. Supp. 1256, 1283 (N.D. Iowa 1996) (applying the Treasury rate rather than the prime or corporate borrowing rate as reflective of the six-year delay in filing suit). Prejudgment interest is awarded for compensatory and not punitive purposes. *Oiness*, 88 F.3d at 1033. Thus, "the merits of the infringer's challenges to the patent are immaterial in determining the amount of prejudgment interest." *Bio-Rad Labs., Inc. v. Nicolet Instrument Corp.*, 807 F.2d 964, 969 (Fed. Cir. 1986).

Post judgment interest should accrue at the statutory rate as specified in 28 U.S.C. § 1961(a). *Amgen Inc. v. Hospira, Inc.*, 336 F.Supp.3d 333, at 364 (D.Del. 2018). Section 1961(a) provides, "Interest shall be allowed on any money judgment in a civil case recovered in a district court. . . . Such interest shall be calculated from the date of the entry of the judgment . . . ." 28 U.S.C. § 1961(a). Section 1961(a) does not provide for interest until a money judgment fixing the amount owed to the prevailing party. *Eaves v. Cty. of Cape May*, 239 F.3d 527, 534 (3d Cir. 2001). "The statute does not, by its terms, mandate that the judgment from which interest is calculated must be a final judgment." *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1177-78 (3d Cir. 1993); *see also Skretvedt v. E.I. DuPont De Nemours*, 372 F.3d 193, 216 (3d Cir. 2004) ("The fact that the December 13, 2001, judgment was not a final order for purposes of appeal would not otherwise prevent postjudgment interest from running under § 1961 . . . .").

D. Delaware Deceptive Trade Practices Act ("DTPA")

The DTPA prohibits "disparage[ment] of the goods, services or business of another by false or misleading representations of fact," committed "in the course of a business, vocation, or occupation or that generally "creates a likelihood of confusion or of misunderstanding." 6 Del. C. §§ 2532(a)(8) & (a)(12). "The DTPA has a lower burden of proof than the Lanham Act since 'a complainant need not prove competition between the parties or actual confusion or misunderstanding' to prevail in an action under the DTPA, 6 Del. C. § 2532(b)." *Keurig, Inc. v. Strum Foods, Inc.*, 769 F. Supp. 2d 699, 712 (D. Del. 2011). The Act is intended to address unfair or deceptive trade practices that

interfere with the promotion and conduct of another's business. *Wright v. Portfolio Recovery Affiliates*, No. CIV.A. 09-612-GMS, 2011 WL 1226115, at *5 (D. Del. Mar. 30, 2011). The elements of a false advertising claim under the Lanham Act are: 1) that the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc. *CollegeSource, Inc. v. AcademyOne, Inc.*, 597 F. App'x 116, 131 (3d Cir. 2015).

E. Enhanced Damages

"[A]n award of enhanced damages requires a showing of willful infringement." *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (en banc) (emphasis added); *accord i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 858 (Fed. Cir. 2010). "Awards of enhanced damages" are reserved for "egregious infringement behavior" the [Supreme] Court has "variously described . . . as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, — U.S. —, —, 136 S. Ct. 1923, 1932 (2016). In other words, reprehensible conduct undertaken with knowledge of its wrongfulness. *See id.* at 1930-32. Willfulness "is a classical jury question of intent. When trial is had to a jury, the issue should be decided by the jury." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1341 (Fed. Cir. 2016).

F. Attorney Fees, Nontaxable Expenses and Costs

Section 285 provides, in its entirety, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. "When deciding whether to award attorney fees under § 285, a district court engages in a two-step inquiry." *MarcTec, LLC v. Johnson & Johnson*, 664 F.3d 907, 915 (Fed. Cir. 2012). The court first determines whether the case is exceptional and, if so, whether an award of attorney fees is justified. *Id.* at 915-16. The Supreme Court defines "an 'exceptional' case [as] simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Octane Fitness LLC v. Icon Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014). An "exceptional" case is "'uncommon,' 'rare,' or 'not ordinary[.]'" *Id.* at 553. District courts may "consider a 'nonexclusive' list of 'factors,' including 'frivolousness, motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence.'" *Id.* at 554 n.6 (quoting *Fogerty v. Fantasy, Inc.*, 510 U.S. 517, 534 n.19 (1994)).

III. DISCUSSION

A. Minerva's Motions

1. Renewed Motion for JMOL or, Alternatively, a New Trial (D.I. 521)

The Court finds Minerva's motion for JMOL should be denied. The Court finds the evidence at trial supports the jury's determination of damages.

Hologic's damages expert, Mr. Christopher Barry presented substantial evidence of NovaSure sales. Since the parties stipulated that the NovaSure system embodies the asserted claims, NovaSure system sales alone established "demand for the patented product" under the first *Panduit* factor. Hologic need not show that the Minerva and NovaSure systems are identical. The jury was instructed that the treatments must be "sufficiently similar" to be viable alternatives in the same market (D.I. 496, Revised Initial Jury Instructions, Instruction No. 18). The jury was also instructed that "the amount of sales that Hologic lost may be shown by proving its share of the relevant market." *Id.* The record shows that Hologic's damages expert testified that he considered "alternative treatments"—such as birth control pills, IUDs, and hysterectomy—for his market share analysis but concluded those other treatments had different characteristics, belonged to a different market segment, and should not be included in the market share allocation (D.I. 509, Trial Transcript (T. Tr.) at 1053-60). Mr. Berry's analysis conformed to Federal Circuit precedent. The experts identified the pertinent market for analyzing a market share allocation was global endometrial ablation ("GEA") devices because hysterectomy, IUDs, and birth control pills are not sufficiently similar to GEA devices (D.I. 509, T. Tr. at 1056-57). The Court finds Hologic properly identified the market. Minerva's arguments against Mr. Barry's market share allocation merely goes to the weight of the evidence, which is a determination left to the jury.

The Court finds Minerva's argument that the jury failed to apportion the damages to reflect the infringing features of the product is unavailing. The jury was instructed "where there are multiple components in the accused product, patent royalty

damages must only reflect the value attributable to the infringing features of the accused product, here Minerva's EAS." D.I. 496, Revised Initial Instructions, Instruction No. 21A. The Court presumes the jury followed that instruction.

There is evidence in the record that supports the jury's calculation. The jury apparently credited some testimony from both experts, which it was entitled to do. It was ultimately up to the jury, however, to weigh the credibility of the parties' opposing theories and evidence. The Court declines to overturn a jury's determination as to the amount of a damages award when, as in this case, that verdict was supported by substantial evidence.

The Court finds Minerva's alternative motion for a new trial on reasonable royalties should also be denied. There is evidence in the record that supports the jury's royalty award. To the extent Minerva argues that the verdict form is internally inconsistent, that issue should have been raised at trial. Moreover, the Court finds the verdict form is not inconsistent. The award falls within the range of royalties the parties argued at trial. Because the verdict form did not ask the jury to specify its methodology or calculations, the Court cannot divine the method the jury used. Let it suffice to say that there are several ways it could legitimately arrived at the figure. The jury apparently credited Hologic's evidence as to comparable licenses and found that Minerva had not rebutted it. Evidence of gross profit premium also supported the jury's verdict.

2. Motion for a New Trial for Lanham Act and Breach of Contract Claims (D.I. 523)

The Court finds Minerva's motion for a new trial on its counterclaims should be denied. Though Minerva contends FDA correspondence that was allegedly withheld in discovery definitively demonstrates that Hologic's advertising for NovaSure was improper, the Court stands by its determination that the FDA correspondence was not relevant to Minerva's Lanham Act claims. Further, the Court stands by its other evidentiary rulings. The Court found there was sufficient evidence on the Lanham Act and breach of contract claims to get the claims to the jury and the jury decided against Minerva. The Court will not disturb the jury's determination.

3. Motion for an Injunction (D.I. 525)

The Court finds an injunction under the DTPA would be inappropriate in light of the jury's finding that there was no false advertising under the Lanham Act. The elements of claims for relief under the federal and state laws are sufficiently similar that the Court finds the jury's verdict is conclusive as to the state law claim as well as the federal claim. The same conduct is involved in both claims. Further, the Court finds, even if Minerva's DTPA claim had not been resolved by the jury, Minerva has not shown the irreparable harm necessary to justify injunctive relief. There is insufficient evidence of a systematic problem that would warrant an injunction in any event. The evidence at trial established that the alleged wrongful conduct was not pervasive.

B. Hologic's Motions

1. Motion for Attorney Fees and Related Nontaxable Costs (D.I. 528)

The Court finds that this is not a case so exceptional as to justify an award of such fees and expenses under 35 U.S.C. § 285. Although this patent case was hotly contested and involved numerous disputes between the parties, the record does not show that the either party adopted unreasonable or frivolous litigation positions, litigated in an unreasonable manner, or acted in bad faith. Such zealous representation is the rule, not the exception, in most patent cases.

2. Hologic's Motion for Enhanced Damages (D.I. 530)

The Court finds Hologic's motion for enhanced damages for infringement of the '183 patent is moot in view of the Federal Circuit finding of invalidity. With respect to the '348 patent, the Court finds the damages are adequate to compensate Hologic for infringement through the life of the patent.

3. Hologic's Motion for a Permanent Injunction (D.I. 532)

This motion relates only to the '183 patent and is moot.

4. Hologic's Motion for an Accounting, Supplemental Damages, Ongoing Royalties, Prejudgment Interest, and Postjudgment Interest (D.I. 534)

Hologic seeks calculation of supplemental damages from April 1, 2018 to the August 13, 2018, date of judgment. It argues that the 16.1% "effective rate," which combines both the lost profits and the reasonable royalty awarded by the jury, should be

used to calculate the supplemental damages. Minerva contends that rate is not supported by the evidence and argues that supplemental damages cannot be calculated. It argues that lost profits and reasonable royalty are two distinct damages theories and are calculated and proven in different ways.

Because the Court rejects Minerva's contention that the jury's verdict is not supported by the evidence, its argument that the jury's determination is wholly speculative is unavailing. The parties apparently agree that the jury determined the reasonable royalty rate was 8% for infringing products sold but not part of Hologic's lost profits. The jury declined to accept Minerva's contention that damages should be limited to only a reasonable royalty rate and not lost profits (D.I. 498, Jury Verdict at 1, § I.1.b). Hologic's damages expert testified that 78.6% of the products sold by Minerva represent Hologic's lost sales. Without evidence to the contrary, it is only reasonable to assume the same proportion of lost sales continued through the life of the '348 patent. The Court finds Hologic's proposal of 16.1% as a combined lost profit and reasonable royalty rate is reasonable. Accordingly, the Court finds Hologic is entitled to recover a reasonable running royalty from the last-produced date of sales (April 1, 2018) to the date the '348 patent expired (November 19, 2018). The record contains some evidence of Minerva's sales to the date of judgment, but not to the date of the expiration of the '348 patent. The Court finds Hologic is entitled to recover a 16.1% royalty for infringing sales that are not reflected in the jury verdict and the Court will order an accounting of such sales. The Court finds, however, that no enhanced royalty for infringing sales post-verdict should be awarded. Hologic has not shown that enhanced damages are warranted.

With respect to prejudgment interest, Hologic seeks prejudgment interest in the amount of $270,533, which represents interest calculated at the prime rate compounded quarterly from the date of infringement through the date of judgment. Minerva concedes Hologic is entitled to recover prejudgment interest but argues the Treasury bill ("T-bill") rate will provide adequate compensation to Hologic. The Court agrees with Hologic and finds prejudgment interest at the prime rate, compounded quarterly, from and after August of 2015 to the date of judgment is appropriate (D.I. 536, Declaration of Christopher C. Barry at 8-10; Schedule D). Accordingly, Hologic will be awarded $270,533 in prejudgment interest. There is no dispute that Hologic is also entitled to postjudgment interest and Hologic will also be awarded postjudgment at the legal rate from and after August 13, 2018. Accordingly,

IT IS ORDERED:

1. Defendant's renewed motion for judgment as a matter of law (D.I. 521) is denied.

2. Defendant's motion for a new trial (D.I. 523) is denied.

3. Defendant's motion for an injunction under the Deceptive Trade Practices Act (D.I. 525) is denied.

4. Plaintiffs' motion for attorney fees (D.I. 528) is denied.

5. Plaintiffs' motion for enhanced damages (D.I. 530) is denied.

6. Plaintiffs' motion (D.I. 532) for a permanent injunction and accounting is denied as moot.

7. Plaintiffs' motion for an accounting, supplemental damages, ongoing royalties, prejudgment interest, and postjudgment interest (D.I.

534) is granted in part and denied in part as set forth in this order.

8. Defendant shall submit an accounting of infringing sales from April 1, 2018, to November 19, 2018, within two weeks of the date of this order.

9. The parties shall each submit a proposed final judgment to the Court within three weeks of the date of this order, in conformity with this Memorandum and Order.

10. A final judgment in accordance with this Memorandum and Order will thereafter issue.

Dated this 1st day of May 2019.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civ. No. 15-1031-JFB

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
*Plaintiffs*,

vs.

MINERVA SURGICAL, INC.,
*Defendant.*

# FINAL JUDGMENT

Pursuant to the Memorandum and Order entered on May 2, 2019 (D.I. 616) and the Jury Verdict (D.I 498),

1. Judgment is entered in favor of plaintiffs/ counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC, and against defendant/ counterclaimant Minerva, Inc., on plaintiffs/ counterclaim defendants claim for infringement of U. S. Patent No. 9,9095,348 in the amount of $4,787,668.23; plus prejudgment interest in the amount of $270,533, plus postjudgment interest at the statutory rate of 2.44% under 35 U.S.C. § 1961(a).

2. Judgment is entered in favor of plaintiffs/ counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC, and against defendant/ counterclaimant Minerva, Inc., on plaintiffs'/ counterclaim defendants' claim for infringement of U. S. Patent No. 9,9095,348 in the amount of $1,629,304.08 in supplemental damages for Minerva's infringing sales from April 1, 2018,

through August 13, 2018, plus prejudgment interest on that amount at the prime rate compounded quarterly from the date of infringement to August 13, 2018, (D.I. 520), plus postjudgment interest thereafter at the legal rate under 28 U.S.C. § 1961 until such time as the judgment is paid.

3. Judgment is entered in favor of plaintiffs/counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC, and against defendant/counterclaimant Minerva, Inc. on defendant/counterclaimant Minerva's counterclaims.

4. Defendant/counterclaimant Minerva's counterclaims are hereby dismissed.

IT IS SO ORDERED.

DATED this 31st day of May 2019.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge

BUSINESS WIRE
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LOGO

# Cytyc to Acquire Novacept in $325 Million Cash Transaction; Expands Women's Health Franchise

March 01, 2004 06:00 AM Eastern Standard Time

BOXBOROUGH, Mass.--(BUSINESS WIRE)--March 1, 2004--Cytyc Corporation (Nasdaq:CYTC), the market leader in cervical cancer screening. today announced that it has entered into a definitive merger agreement with Novacept, a privately-held company that manufactures and markets the NovaSure(TM) System. NovaSure is an innovative endometrial ablation device to treat menorrhagia, or excessive menstrual bleeding. It is estimated that in the United States alone, one in five women between the ages of 35¬55 suffers from excessive menstrual bleeding.

Under the terms of the agreement, Cytyc will acquire all of the outstanding shares and options of Novacept in exchange for approximately $325 million in cash, or $311 million net of Novacept's cash balance. Morgan Stanley is acting as financial advisor to Cytyc and has provided a commitment for up to $250 million in senior bank financing. The balance of the purchase price will be paid with Cytyc's available cash. Cytyc is also exploring other financing options. Cytyc expects the acquisition to break-even in 2004 and to be accretive to Cytyc's 2005 earnings. In addition, the transaction is expected to result in a one-time charge of approximately $20 million, largely for in-process R&D. The transaction is expected to close by the end of the first quarter of 2004 and will be subject to the satisfaction of customary closing conditions and clearance under the Hart-Scott Rodino Antitrust Improvements Act.

Patrick J. Sullivan, Cytyc's chairman, president, and chief executive officer, said, "We believe this is a great strategic opportunity for Cytyc for several reasons: First, it builds on our reputation and leadership position in providing innovative medical devices for women's health. We believe Novacept is a rapidly growing company in this space with the "best in class" device for treating women for this condition. Second, this acquisition significantly increases our sales and marketing resources to OBGYN physicians. We have approximately 100 physician sales representatives currently calling on OBGYNs. As a result of this acquisition and our 2004 growth plans, our OBGYN salesforce will double to increase our competitive position for the ThinPrep(R) Pap Test and ThinPrep(R) Imaging System as well as to marke and sell the Novacept product to our existing OBGYN customer base. This product will also leverage our international infrastructure. And third, we believe this acquisition will put us on a strong and diversified financial growth trajectory on both the top and bottom line and will position us to become a worldwide leader in providing innovative products for women's health."

Mr. Sullivan continued, "We are excited about the Novacept opportunity because we believe its patented, innovative technology for the treatment of menorrhagia offers a unique clinical solution to women who suffer from this condition. Novacept launched its NovaSure System in January 2002 and generated $38.4 million in annual sales in 2003, up from $8.3 million in sales in 2002. Reimbursement is well established nationwide. The company is cash flow positive and was profitable for the second half of 2003."

"We are very proud of our product and our accomplishments to date," said David Clapper, Novacept's

president and chief executive officer. "This merger represents an ideal fit. Our specialized expertise in this emerging market, combined with Cytyc's substantial resources and proven track record, will accelerate adoption of this important new technology, which will significantly benefit physicians and their patients. Our team is very excited to become part of Cytyc." Piper Jaffray acted as advisor to Novacept for this transaction.

It is estimated that as many as 7 million pre-menopausal women between the ages of 35-55 suffer from menorrhagia and 2.5 million women seek treatment for this condition each year. Current treatment options include hormone therapy, xystemommy, and endometrial ablation. Published studies have demonstrated the clinical efficacy of the NovaSure System and the potential cost- effectiveness of endometrial ablation compared to hysterectomy.

Mr. Sullivan concluded, "We believe this is a great strategic opportunity for Cytyc to build on our OBGYNfranohine. We will maintain the existing NovaSure sales force, which will be integrated into Cytyc's current sales organization. We plan to operate Novacept's Research and Development and Operations organizations as separate entities in Palo Alto and to continue to expand Novacept's manufacturing operation in Costa Rica. We look forward to working closely with the Novacept team to become the world-wide market leader in providing innovative products for women's health."

Cytyc management will discuss the acquisition and update earnings guidance during a conference call on March 1, at 9:00 a.m. (Eastern). Investors may access the call by dialing 877-692-2086 or 973-582- 2749. A live webcast of the call may be accessed at Cytyc's

website, http://ir.cytyc.com, and the event will be available for replay at this site approximately two hours following the call until March 15, 2004. In addition, a telephonic replay of the call will be available through March 15, 2004, by dialing 877- 519-4471 (Reservation 4564738). International callers may call 973-341-3080; reservation number is the same.

About Cytyc Corporation

Cytyc Corporation designs, develops, manufactures, and markets the ThinPrep(R) System for use in medical diagnostic applications primarily focused on women's health. The ThinPrep System is widely used for cervical cancer screening and is the platform from which the Company has launched its expansion into breast cancer risk assessment with the FirstCyte(R) Breast Test. The ThinPrep System consists of the ThinPrep(R) 2000 Processor, ThinPrep(R) 3000 Processor, ThinPrep(R) Imaging System, and related reagents, filters, and other supplies. Cytyc is traded on The Nasdaq Stock Market under the symbol CYTC.

Cytyc, ThinPrep, and FirstCyte are registered trademarks of Cytyc Corporation.

NovaSure is a trademark of Novacept.

About Novacept

Novacept designs, develops and sells medical devices for the treatment of excessive menstrual bleeding, a condition that affects one in five pre-menopausal women. Novacept sells the NovaSure Impedance Controlled Endometrial Ablation System, or the NovaSure System, which consists of a single-use device and a controller that deliver radiofrequency, or RF, energy to the uterus. The NovaSure System allows physicians to treat women with excessive menstrual bleeding in a

minimally invasive manner to eliminate or reduce their bleeding to normal levels In September 2001, the Food and Drug Administration (FDA) granted premarket approval for the NovaSure System to treat excessive menstrual bleeding due to benign causes in women for whom childbearing is complete. The product was commercially launched in the United States in early 2002. Since market introduction the company estimates that it has sold over 45,000 disposable devices, primarily to hospitals and outpatient surgery centers in the United States.

Forward-looking statements in this press release are made pursuant to the provisions of Section 21 E of the Securities Exchange Act of 1934. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, statements relating to the Company's financial condition, operating results and future economic performance, and management's expectations regarding future growth opportunities, product acceptance and business strategy, constitute forward-looking statements. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from those statements. Risks and uncertainties include, among others, dependence on key personnel and proprietary technology, uncertainty of product development efforts, product acceptance, management of growth, risks associated with competition and competitive pricing pressures, risks associated with the FDA regulatory approval processes and any healthcare reimbursement policies, risks associated with litigation, and other risks detailed in the Company's filings with the Securities and Exchange Commission, including under the heading "Certain Factors Which May

Affect Future Results" in its 2003 Annual Report on Form 10-K filed with the Commission. The Company cautions readers not to place undue reliance on such forward-looking statements, which speak only as of the date they were made. The Company disclaims any to publicly update or revise any such statements to reflect any change in Company expectations or events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Contacts

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AGREEMENT AND PLAN OF MERGER

This Agreement and Plan of Merger (this "Agreement") is made and entered into as of March 1, 2004 (the "Agreement Date"), by and among (i) Cytyc Corporation, a Delaware corporation (the "Parent"), (ii) Radio Acquisition Corp., a California corporation and a wholly owned Subsidiary of Parent ("Merger Sub"), (iii) Novacept, a California corporation (the "Company"), and (iv) for the limited purposes of agreeing to perform the duties specified in Section 2.5, David Clapper and Edward Unkart, acting jointly as the Shareholder Representative referred to herein. Capitalized terms used herein without definition shall have the respective meanings set forth in Section 10.2 hereof.

WHEREAS, Merger Sub will merge with the Company (the "Merger"), upon the terms and subject to the conditions set forth in this Agreement and in accordance with the provisions of the California Corporations Code ("California Law");

WHEREAS, the board of directors of the Company (the "Company Board") has approved and adopted this Agreement and the consummation of the transactions contemplated hereby, and has determined to submit this Agreement and the performance of the transactions contemplated hereby to the holders (the "Company Shareholders"), of the shares of the Company's Common Stock, par value $0.001 per share (the "Company Common Stock"), and Preferred Stock, par value $0.001 per share (the "Company Preferred Stock"), for their approval in accordance with California Law; and

WHEREAS, the Company Board has carefully considered the terms of this Agreement and has determined that the terms and conditions of the transactions con-

templated hereby, including the Merger, are fair and in the best interests of, and are advisable to, the Company and the Company Shareholders, and the Company Board has recommended that the Company Shareholders vote for the approval of this Agreement and the transactions contemplated hereby.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and agreements herein contained and intending to be legally bound hereby, Parent, Merger Sub, the Company and, for the limited purposes of agreeing to perform the duties specified in Section 2.5, the Shareholder Representative hereby agree as follows:

## ARTICLE 1
## THE MERGER

1.1 The Merger.

(a) Merger. Subject to the other terms and conditions of this Agreement, including those set forth in Article 7 hereof, and in accordance with California Law, at the Effective Time, Merger Sub shall be merged with and into the Company, and as a result of the Merger, the separate corporate existence of Merger Sub shall cease and the Company shall continue as the surviving corporation of the Merger (the "Surviving Corporation").

(b) Closing; Effective Time. Subject to the fulfillment or waiver of all of the conditions contained in Article 7, as soon as is reasonably practicable following the satisfaction or waiver of all of the conditions contained in Article 7, or at such other date and time as theparties hereto may agree upon, a closing (the "Closing") will be held at the offices of Bingham McCutchen LLP in East Palo Alto, California (or such other place as the parties may agree). The date on

which the Closing is actually held is referred to herein as the "Closing Date." On the Closing Date, Parent, Merger Sub and the Company shall cause the Merger to be consummated by filing an agreement of merger with the California Secretary of State, substantially in the form attached hereto as Exhibit A, and with such changes as may be made after review by the California Secretary of State (the "Merger Document"). The term "Effective Time" means the date and time of the filing of the Merger Document with the California Secretary of State (or such later time as may be agreed by each of the parties hereto and specified in the Merger Document in accordance with California Law). In the event of a conflict between the Merger Document and this Agreement, the terms of this Agreement shall govern.

1.2 Effect of the Merger. At the Effective Time, the effect of the Merger shall be as provided in the Merger Document and as provided by the applicable provisions of California Law. Without limiting the generality of the foregoing, and subject thereto, upon the consummation of the Merger, all the property (including, but not limited to, Intellectual Property and licenses to Intellectual Property), rights, privileges, powers and franchises of the Company and the Merger Sub shall vest in the Surviving Corporation, and all debts, liabilities, obligations, restrictions, disabilities and duties of each of those corporations shall become the debts, liabilities, obligations, restrictions, disabilities and duties of the Surviving Corporation.

1.3 Charter; Bylaws.

(a) At the Effective Time, the Articles of Incorporation of the Surviving Corporation (the "Surviving Corporation Charter") shall be the Articles of

Incorporation of the Company, as amended by the Merger Document.

(b) At the Effective Time, the bylaws of the Surviving Corporation shall be the bylaws of Merger Sub, as in effect immediately prior to the Effective Time, until thereafter amended as provided by California Law, the Surviving Corporation Charter and such bylaws.

1.4 Directors and Officers. The directors of Merger Sub immediately prior to the Effective Time shall be the initial directors of the Surviving Corporation, each to hold office in accordance with the Surviving Corporation Charter and the bylaws of the Surviving Corporation, and until their respective successors are duly elected and qualified or until their earlier death, disability, resignation or removal. The officers of Merger Sub immediately prior to the Effective Time shall be the initial officers of the Surviving Corporation, in each case until their respective successors are duly elected or appointed and qualified or until their earlier death, disability, resignation or removal.

1.5 Closing Date Consideration; Initial Escrow Amount; Representative Reimbursement Amount.

(a) The consideration to be paid by Parent to the Participating Rights Holders at the Closing in connection with the Merger shall be the amount of the Closing Payment Amount in cash allocated to each of such Participating Rights Holders pursuant to Section 2.1.

(b) Notwithstanding the foregoing, a portion of the Closing Payment Amount payable to the Participating Rights Holders equal to $27,500,000 (the "Initial Escrow Amount"), shall not be paid to the

Participating Rights Holders at the Closing, but shall instead be deposited with Sovereign Bank or such other escrow agent as shall be mutually agreed-upon by Parent and the Company (the "Escrow Agent"), to be held in trust by the Escrow Agent pursuant to an Escrow Agreement, substantially in the form of the attached Exhibit B, and with such changes as may be reasonably requested by the Escrow Agent (the "Escrow Agreement"), and distributed in accordance therewith. At the Closing, Parent, the Shareholder Representative and the Escrow Agent will execute and deliver the Escrow Agreement.

(c) In addition, a portion of the Closing Payment Amount otherwise payable to the Participating Rights Holders equal to $250,000 (the "Representative Reimbursement Amount"), shall not be paid to the Participating Rights Holders at the Closing, but shall instead be deposited in cash with the Shareholder Representative, to be held by the Shareholder Representative for the payment of expenses incurred by the Shareholder Representative in performing its duties pursuant to this Agreement. Any of the Representative Reimbursement Amount originally deposited with the Shareholder Representative at the Closing that has not been consumed by the Shareholder Representative pursuant to the terms of this Agreement on or prior to the end of the period in which Parent, the Surviving Corporation and their Affiliates may make claims for indemnification pursuant to Section 9.2 or, if later, the date on which all indemnification claims of Parent, the Surviving Corporation or any of their Affiliates outstanding at the end of such period have been discharged in full, shall be distributed by the Shareholder Representative to the Escrow Agent for further distribution by the Escrow Agent to the Participating Rights Holders *pro rata*

based on their respective rights to participate in receipt of the remaining Escrowed Funds, if any. Notwithstanding the delivery of any remaining portion of the Representative Reimbursement Amount to the Escrow Agent, such remaining portion shall not be deemed part of the Initial Escrow Amount or part of the Escrowed Funds and shall not be available to satisfy indemnification or other obligations to Parent hereunder.

## ARTICLE 2
## CONVERSION OF SECURITIES; EXCHANGE OF CERTIFICATES; PAYMENTS

2.1 Conversion of Securities.

(a) Common Stock. Each share of the Company Common Stock issued and outstanding immediately prior to the Effective Time and held by Participating Rights Holders will be converted at the Effective Time into the right to receive from Parent, in cash, an amount equal to the Per Share Common Closing Payment. All such shares of Company Common Stock, when so converted, shall no longer be outstanding and shall automatically be cancelled and retired and shall cease to exist, and each holder of a certificate representing any such shares of Company Common Stock shall cease to have any rights with respect thereto, except the right to receive the Per Share Common Closing Payment upon the surrender of such certificate in accordance with Section 2.2 and this Section 2.1. Notwithstanding the foregoing, portions of the Closing Payment Amount attributable to the Company Common Stock shall be deposited in escrow and a portion of the Closing Payment Amount shall be paid to the Shareholder Representative as the Representative Reimbursement Amount in accordance with Section 1.5.

(b) Preferred Stock. Each share of each series, if any, of Company Preferred Stock issued and outstanding immediately prior to the Effective Time and held by Participating Rights Holders will be converted at the Effective Time into the right to receive, in cash, an amount equal to the Per Share Preferred Closing Payment associated with such series of Company Preferred Stock. All shares of Company Preferred Stock, when so converted, shall no longer be outstanding and shall automatically be cancelled and retired and shall cease to exist, and each holder of a certificate representing any such shares of Company Preferred Stock shall cease to have any rights with respect thereto, except the right to receive the Per Share Preferred Closing Payment associated with the applicable class of Company Preferred Stock upon the surrender of such certificate in accordance with Section 2.2 and this Section 2.1. Notwithstanding the foregoing, portions of the Closing Payment Amount attributable to the Company Preferred Stock shall be deposited in escrow and a portion of the Closing Payment Amount shall be paid to the Shareholder Representative as the Representative Reimbursement Amount in accordance with Section 1.5. For avoidance of doubt, shares of Company Preferred Stock converted into Company Common Stock immediately prior to the Effective Time in connection with the Merger shall not be entitled to consideration under this Section 2.1(b), but instead shall be entitled to consideration on an as-converted basis as Company Common Stock pursuant to Section 2.1(a).

(c) Exchange of Options and Warrants.

(i) Options. Each option to purchase Company Common Stock issued under the Company's 1997 Stock Option Plan (the "Company Option Plan") or

otherwise listed in Section 3.2(c) of the Company Disclosure Schedule, whether or not exercisable, whether or not vested, and whether or not performance-based, which is outstanding at the Effective Time (each a "Company Option"), shall not be assumed by the Surviving Corporation or Parent, but shall instead be converted at the Effective Time into the right to receive payment as of the Closing of an amount in cash equal to the excess, if any, of the aggregate Per Share Common Closing Payment that would be payable with respect to all shares of Company Common Stock that would be issuable upon exercise of such Company Option (regardless of whether or not any such Company Option is then "vested" or exercisable) (the "Option Shares") over the aggregate exercise price per share otherwise payable by the holder thereof to acquire such Option Shares. Notwithstanding the foregoing, portions of the Closing Payment Amount attributable to the Company Options shall be deposited in escrow and a portion of the Closing Payment Amount shall be paid to the Shareholder Representative as the Representative Reimbursement Amount in accordance with Section 1.5.

(ii) Warrants. Any unexercised rights, warrants or options that are not described in Section 2.1(c)(i) above to purchase shares of Company Common Stock or Company Preferred Stock and that are outstanding immediately prior to the Effective Time (each a "Company Warrant") and are tendered to Parent for payment at the Closing in compliance with Section 2.2(a) shall be discharged by Parent out of the aggregate merger consideration for an amount equal to the excess, if any, of the aggregate Per Share Common Closing Payment that would be payable with respect to all shares of Company Common Stock that would be issuable upon exercise of such Company

Warrant (the "Warrant Shares") over the aggregate exercise price otherwise payable by the holder to acquire such Warrant Shares. For the purposes of the calculating the portion of the Closing Payment Amount to be paid to the holder of a Company Warrant to purchase Company Preferred Stock, such Company Warrant shall be deemed exercisable for that number of shares of Company Common Stock equal to the number of shares of Company Preferred Stock for which such Company Warrant may be exercised multiplied by the applicable conversion rate for the series of Company Preferred Stock specified in such Company Warrant. In addition, the per share exercise price for such Company Warrant shall be deemed to be the per share exercise price specified in the Company Warrant divided by the applicable conversion rate for the series of Preferred Stock specified in such Company Warrant. For avoidance of doubt, the intent of the foregoing provisions regarding Company Warrants exercisable for Company Preferred Stock is the effect the exchange of such Company Warrants for a portion of the aggregate merger consideration on an as-converted to Company Common Stock basis. Notwithstanding the foregoing, portions of the Closing Payment Amount attributable to the Company Warrants shall be deposited in escrow and a portion of the Closing Payment Amount shall be paid to the Shareholder Representative as the Representative Reimbursement Amount in accordance with Section 1.5.

(d) Treasury Stock. Each share of Company Common Stock or Company Preferred Stock held in the treasury of the Company or held by any Subsidiary of the Company immediately prior to the Effective Time shall be cancelled and extinguished at the

Effective Time without any conversion thereof and no payment shall be made with respect thereto.

(e) Stock Held by Parent. Each share of Company Common Stock or Company Preferred Stock held by Parent or any Affiliate of Parent shall be cancelled and extinguished at the Effective Time without any conversion thereof and no payment shall be made with respect thereto.

(f) Stock of Merger Sub. Each share of common stock of Merger Sub issued and outstanding immediately prior to the Effective Time shall be converted into one (1) validly issued fully paid and nonassessable share of common stock of the Surviving Corporation.

2.2 Exchange of Certificates and Instruments for Closing Payment Amount.

(a) Exchange Procedures.

(i) Within a reasonable period of time prior to the Closing, Parent will deliver to the Company forms of the transmittal materials which Parent will reasonably require from those Participating Rights Holders entitled to receive a portion of the Closing Payment Amount in respect of their shares of Company Common Stock or Company Preferred Stock, or in respect of their Company Options or Company Warrants, which materials may include any certifications Parent may request with respect to compliance with any withholding obligations of Parent or the Surviving Corporation under the Code. The Company will distribute such materials to eligible Participating Rights Holders. As promptly as practicable following the Effective Time, Parent will deliver to each Participating Rights Holder who has completed such transmittal materials and returned them to Parent at or prior to the Closing, together with the certificate or

certificates representing outstanding shares of Company Common Stock or Company Preferred Stock (the "Certificates"), or certificates or instruments representing outstanding Company Options or Company Warrants ("Derivative Instruments"), a check (or, at the election of the Shareholder Representative, a wire transfer to the extent that the aggregate amount owed to any such holder is in excess of $1,000,000) representing that portion of the Closing Payment Amount that such Participating Rights Holder is entitled to receive in cash. The (i) delivery of such checks (or wire transfers, as applicable) by Parent to the Participating Rights Holders and (ii) deposit of the Initial Escrow Amount with the Escrow Agent and (iii) delivery of the Representative Reimbursement Amount to the Shareholder Representative shall be deemed, for all purposes, to have satisfied in full Parent's Closing Payment Amount obligations to such Participating Rights Holders and Parent shall have no further obligation for such payments. Parent shall not be required to pay any amount of the Closing Payment Amount to a particular Participating Rights Holder until receipt from such Participating Rights Holder of properly completed and executed transmittal materials in the form prepared by Parent. Parent shall be entitled to rely entirely on the information contained in the Capitalization Certificate and any transmittal materials delivered hereunder for purposes of satisfying Parent's obligation to deliver the Closing Payment Amount.

(ii) As promptly as practicable after the Effective Time, Parent will send to each Participating Rights Holder who does not submit completed transmittal materials to Parent at or before the Closing, as permitted by Section 2.2(a)(i) above, transmittal materials for use in exchanging his, her or its Certificates

or Derivative Instruments for the applicable portion of the Closing Payment Amount into which such shares of Company Common Stock or Company Preferred Stock (other than any Dissenting Shares) or Company Options or Company Warrants, have been converted. Until surrendered as contemplated by this Section 2.2, each Certificate or Derivative Instrument shall be deemed at any time after the Effective Time to represent only the right to receive upon such surrender the applicable portion of the Closing Payment Amount payable pursuant to Section 2.1. Upon receipt of the completed transmittal materials and the applicable Certificates and Derivative Instruments from a Participating Rights Holder, Parent will deliver to such Participating Rights Holder a check (or, at the election of the Shareholder Representative, a wire transfer to the extent that the aggregate amount owed to any such holder at the Closing is in excess of $1,000,000) representing that portion of the Closing Payment Amount that such Participating Rights Holder is entitled to receive in cash.

(b) No Further Rights in Certificates or Derivative Instruments. After the Effective Time, holders of Company Common Stock, Company Preferred Stock, Company Options or Company Warrants outstanding immediately prior to the Effective Time will cease to be, and will have no rights as, shareholders or rightsholders of the Company or the Surviving Corporation, other than (i) in the case of Company Common Stock and Company Preferred Stock (other than Dissenting Shares), and Company Options and Company Warrants, the rights to receive the applicable portion of the Closing Payment Amount; (ii) in the case of Dissenting Shares, the rights afforded to the holders thereof under Sections 1300-1312 of California Law,

as applicable, and (iii) rights under this Agreement and the Escrow Agreement.

(c) No Liability. Neither Parent, the Surviving Corporation nor the Company shall be liable to any holder of Company Common Stock, Company Preferred Stock, Company Options or Company Warrants for any portion of the Closing Payment Amount delivered to an appropriate public official pursuant to any abandoned property, escheat or similar law.

(d) Withholding Rights. Each of the Surviving Corporation and Parent shall be entitled to deduct and withhold from the consideration otherwise payable pursuant to this Agreement to any holder of Company Common Stock, Company Preferred Stock, Company Options or Company Warrants such amounts as it is required to deduct and withhold with respect to the making of such payment under the Code, or any provision of state, local or foreign Tax Law. To the extent that amounts are so withheld by the Surviving Corporation or Parent, as the case may be, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to such holder in respect of which such deduction and withholding was made by the Surviving Corporation or Parent, as the case may be.

(e) Lost Instrument or Certificate Procedure. If a Certificate or Derivative Instrument held by a Participating Rights Holder has been lost, destroyed or mutilated, in lieu of receipt of the original instrument, the Parent will accept from such Participating Rights Holder a lost certificate affidavit in a form reasonably satisfactory to Parent attesting that such loss, destruction or mutilation has occurred and agreeing to indemnify and hold harmless the Parent for any losses in connection therewith.

2.3 Stock Transfer Books. At the Effective Time, the stock transfer books of the Company shall be closed and there shall be no further registration of transfers of Company Common Stock or Company Preferred Stock thereafter on the records of the Company. From and after the Effective Time, the holders of certificates representing such shares outstanding immediately prior to the Effective Time shall cease to have any rights with respect to such shares except as otherwise provided herein or by any applicable laws.

2.4 Dissenting Shares.

(a) Notwithstanding any provision of this Agreement to the contrary, shares of Company Common Stock or Company Preferred Stock that are outstanding immediately prior to the Effective Time and which are held by shareholders who shall have not voted in favor of the Merger or consented thereto in writing and who shall have exercised dissenters' rights or rights of appraisal for such shares of Company Common Stock or Company Preferred Stock in accordance with California Law, if any, and who, as of the Effective Time, have not effectively withdrawn or lost such dissenters' rights (collectively, the "Dissenting Shares"), shall not be converted into or represent the right to receive any portion of the amounts to be paid pursuant to Section 2.1, but the holders thereof shall only be entitled to such rights as are granted by California Law, if any. All Dissenting Shares held by shareholders who shall have failed to perfect or who effectively shall have withdrawn or lost their dissenters' rights shall thereupon be deemed to have been converted into and to have become exchangeable for, as of the later of the Effective Time or the occurrence of such event, the right to receive an

appropriate portion of the amounts to be paid pursuant to Section 2.1, without any interest thereon, upon surrender, in the manner provided in Section 2.2, of the Certificates that formerly evidenced such shares.

(b) The Company shall give Parent (i) prompt notice of any demands for fair value of shares of Company Common Stock or Company Preferred Stock received by the Company, withdrawals of such demands, and any other instruments served pursuant to California Law, if any, and received by the Company, and (ii) the opportunity to direct all negotiations and proceedings with respect to demands for fair value under California Law, if any. The Company shall not, except with the prior written consent of Parent, make any payment with respect to any demands for the fair value of shares of Company Common Stock or Company Preferred Stock or settle or offer to settle any such demands other than by operation of law or pursuant to a final order of a court of competent jurisdiction.

2.5 Shareholder Representative.

(a) Appointment of Shareholder Representative. By virtue of the adoption of this Agreement and the approval of the Merger by the Company Shareholders, each Participating Rights Holder (regardless of whether or not such Participating Rights Holder votes in favor of the adoption of the Agreement and the approval of the Merger, whether at a meeting or by written consent in lieu thereof) shall be deemed to have appointed, effective from and after the Effective Time of the Merger, David Clapper and Edward Unkart (each a "Joint Representative") to act jointly as the Shareholder Representative under this Agreement in accordance with the terms of this Section 2.5

and the Escrow Agreement. For clarity, each Joint Representative, acting jointly, shall be deemed the Shareholder Representative, and all actions required or permitted to be approved by the Shareholder Representative shall be deemed approved when approved by both Joint Representatives. If either David Clapper or Edward Unkart resigns, is removed or is no longer able to perform duties as a Joint Representative, the remaining Joint Representative shall continue as a sole Shareholder Representative, with the authority to act alone and to exercise all powers of the Shareholder Representative without the approval or joint action of another person. In the event that both David Clapper and Edward Unkart have resigned, are removed or are no longer able to perform duties as Joint Representative or as sole Shareholder Representative, as the case may be, a successor Shareholder Representative shall be selected from the following list, in the order specified, to serve as the sole Shareholder Representative, with power to act alone as the Shareholder Representative: (1) Michael Kaplan, (2) Barclay Phillips and (3) Ross Jaffee. Notwithstanding anything to the contrary in this Agreement or the Escrow Agreement: (i) unless removed, with the consent of the next enumerated successor named in the foregoing list, an outgoing sole Shareholder Representative may designate a successor Shareholder Representative different than such enumerated successor; (ii) if no enumerated successors remain in the foregoing list, an outgoing sole Shareholder Representative, unless removed, may designate a successor without the consent of any other person or Participating Rights Holder; provided, such outgoing Shareholder Representative shall use commercially reasonable efforts to provide notice of the name and address of such successor to the

Participating Rights Holders representing at least three-fourths of the Escrowed Funds then in possession of the Escrow Agent. Notwithstanding the foregoing, or anything else to the contrary in the Agreement or the Escrow Agreement, the Participating Rights Holders entitled to a majority in amount of the Escrowed Funds then in the possession of the Escrow Agent may by written action remove a Joint Representative or sole Shareholder Representative or appoint a new Shareholder Representative, whether or not named above, or may change the order of succession specified above. Any person appointed to replace a former Joint Representative or sole Shareholder Representative shall execute a statement agreeing to perform the duties set forth in this Section 2.5 and such appointment shall become effective upon delivery of such statement to the Parent and the Surviving Corporation.

(b) Authority After the Effective Time. From and after the Effective Time, the Shareholder Representative shall be authorized to:

(i) take all actions required by, and exercise all rights granted to, the Shareholder Representative in this Agreement or the Escrow Agreement;

(ii) receive all notices or other documents given or to be given to the Shareholder Representative by Parent pursuant to this Agreement or the Escrow Agreement;

(iii) negotiate, undertake, compromise, defend, resolve and settle any suit, proceeding or dispute under this Agreement or the Escrow Agreement;

(iv) execute and deliver all agreements, certificates and documents required by the Shareholder Representative in connection with any of the

transactions contemplated by this Agreement (including executing and delivering the Escrow Agreement);

(v) engage special counsel, accountants and other advisors and incur such other expenses in connection with any of the transactions contemplated by this Agreement or the Escrow Agreement;

(vi) apply the Representative Reimbursement Amount to the payment of (or reimbursement of the Shareholder Representative for) expenses and liabilities which the Shareholder Representative may incur pursuant to this Section 2.5; and

(vii) take such other action as is necessary on behalf of the Participating Rights Holders as is necessary in connection with this Agreement, the Escrow Agreement and the transactions contemplated hereby, including:

(A) taking any actions required or permitted under the Escrow Agreement; and

(B) all such other matters as the Shareholder Representative may deem necessary or appropriate to carry out the intents and purposes of this Agreement and the Escrow Agreement.

(c) Reimbursement of Expenses. The Shareholder Representative shall be entitled to receive reimbursement from any Representative Reimbursement Amounts retained on behalf of the Shareholder Representative and then, immediately prior to its distribution to the Participating Rights Holders, against the consideration held as Escrowed Funds pursuant to the Escrow Agreement, for any and all expenses, charges and liabilities, including reasonable attorneys' fees, incurred by the Shareholder Representative in the performance or discharge of its rights

and obligations under this Agreement (the "SR Expenses").

(d) Release from Liability; Indemnification; Authority of Shareholder Representative. By virtue of the adoption of this Agreement and the approval of the Merger by the Company Shareholders, each Participating Rights Holder shall be deemed to hereby release the Shareholder Representative from, and each Participating Rights Holder shall be deemed to have agreed to indemnify the Shareholder Representative against, liability for any action taken or not taken by him, her or it in his, her or its capacity as such agent, except for the liability of the Shareholder Representative to a Participating Rights Holder for loss which such holder may suffer from fraud committed by the Shareholder Representative in carrying out his, her or its duties hereunder. By virtue of the adoption of this Agreement and the approval of the Merger by the Company Shareholders, each Participating Rights Holder (regardless of whether or not such Participating Rights Holder votes in favor of the adoption of the Agreement and the approval of the Merger, whether at a meeting or by written consent in lieu thereof) shall be deemed to have appointed, as of the Agreement Date, the Shareholder Representative as his, her or its true and lawful agent and attorney-in-fact to enter into any agreement in connection with the transactions contemplated by this Agreement, to exercise all or any of the powers, authority and discretion conferred on him under any such agreement, to give and receive notices on their behalf and to be his, her or its exclusive representative with respect to any matter, suit, claim, action or proceeding arising with respect to any transaction contemplated by any such agreement, including, without limitation, the defense, settlement or compromise of any claim,

action or proceeding for which Parent or the Surviving Corporation may be entitled to indemnification. All actions, decisions and instructions of the Shareholder Representative shall be conclusive and binding upon all of the Participating Rights Holders.

(e) Acceptance. By virtue of his approval and execution of this Agreement, the Shareholder Representative hereby agrees to act as, and to undertake the duties and responsibilities of, the Shareholder Representative as set forth in this Section 2.5.

## ARTICLE 3
## REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Except for representations and warranties that speak as of a particular date, which representations and warranties are made only as of such particular date, the Company hereby represents and warrants to Parent as follows as of each of (a) the Agreement Date and (b) the Closing Date, subject in each case to such exceptions as are set forth in the attached Disclosure Schedule of the Company (the "Company Disclosure Schedule"). Notwithstanding any other provision of this Agreement or the Company Disclosure Schedule, each exception set forth in the Company Disclosure Schedule will be deemed to qualify only each representation and warranty set forth in this Agreement (i) that is specifically identified (by cross-reference or otherwise) in the Company Disclosure Schedule as being qualified by such exception, or (ii) with respect to which the relevance of such exception is reasonably apparent on the face of the disclosure of such exception set forth in the Company Disclosure Schedule. The Company Disclosure Schedule shall be organized by section number (e.g., 3.1, 3.2 and 3.3) and may be organized by subsection number at the election of the

Company (e.g., 3.2(b), 3.9(d) and 3.10(a)), but any disclosure made in any subsection shall be effective as disclosure for the entire section, unless disclosure by subsection is specifically required by the applicable section. Cross-references by section number shall be effective, and cross-references by subsection number shall not be required.

3.1 Organization, Good Standing and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of California. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify has resulted in or could be reasonably expected to result in a Material Adverse Effect on the Company. The Company has all requisite corporate power and authority to own and operate its properties and assets, to execute and deliver this Agreement, to perform its obligations under the provisions of this Agreement, and to carry on its Principal Business as presently conducted and as the Company currently proposes it be conducted.

3.2 Capitalization and Voting Rights.

(a) The authorized capital of the Company consists of:

(i) Preferred Stock. 25,245,152 shares of Company Preferred Stock, of which 133,334 shares have been designated Series A Preferred Stock, 200,000 shares have been designated Series B Preferred Stock, 230,000 shares have been designated Series C Preferred Stock, 1,000,000 shares have been designated Series D Preferred Stock, 1,500,000 shares have been designated Series D-1 Preferred Stock, 681,818 shares have been designated Series E

Preferred Stock, 3,500,000 shares have been designated Series F Preferred Stock, 3,000,000 shares have been designated Series F-1 Preferred Stock, 6,000,000 shares have been designated Series G Preferred Stock, and 9,000,000 shares have been designated Series H Preferred Stock. The respective rights, restrictions, privileges and preferences of the Company Preferred Stock are as stated in the Restated Articles.

(ii) Common Stock. 100,000,000 shares of Company Common Stock.

(b) As of the Agreement Date, the number of shares of each series of Company Preferred Stock and of Company Common Stock issued and outstanding is set forth on Section 3.2(b) of the Company Disclosure Schedule.

(c) Except as set forth in Sections 3.2(c) or 3.2(f) of the Company Disclosure Schedule, as of the Agreement Date, there are not outstanding any options, warrants, instruments, rights (including conversion or preemptive rights and rights of first refusal), proxy or stockholder agreements, or other agreements or instruments of any kind, including convertible debt instruments, for the purchase or acquisition from the Company of any of its Securities. The Company is not a party or subject to any agreement or understanding and, to the Company's knowledge, there is no agreement or understanding between any other persons, that affects or relates to the voting or giving of written consents with respect to any Security or by a director of the Company.

(d) All of the issued and outstanding shares of the Company Common Stock and Company Preferred Stock (i) have been duly authorized and validly issued

and are fully paid and nonassessable, and (ii) were issued in compliance with all applicable state and federal laws concerning the issuance of securities.

(e) Except as set forth in the Disclosure Schedule, each series of Company Preferred Stock is presently convertible into Company Common Stock on a one-for-one basis and the consummation of the transactions contemplated hereunder will not result in any anti-dilution adjustment or other similar adjustment to the outstanding shares of Company Preferred Stock.

(f) Section 3.2(f) of the Company Disclosure Schedule sets forth the name and address of each Securityholder and the Securities beneficially owned by each Securityholder, and, in the case of options, warrants, instruments and other rights to acquire capital stock of the Company, (i) the per-share exercise price payable therefor, (ii) the number of shares of the Company's capital stock each option, warrant, instrument or other right are vested or exercisable as of the Agreement Date, (iii) whether the holder of such option, warrant, instrument or other right is an employee of the Company, (iv) whether such option, warrant, instrument or other right will survive the Effective Time, if not exercised prior thereto, and (v) whether or not any such options, warrants, instruments or other rights are intended to be "incentive stock options" as such term is defined in the Code.

3.3 Subsidiaries. Except as set forth in Section 3.3 of the Company Disclosure Schedule, the Company has no Subsidiaries. The Company does not presently own or control, directly or indirectly, any interest in any other corporation, association, partnership, limited liability company or other business entity. The

Company is not a participant in any joint venture or similar arrangement.

3.4 Authorization; Binding Obligations; Governmental Consents.

(a) Subject to the Shareholder Approval, all corporate action on the part of the Company, its officers, directors and shareholders necessary for the authorization, execution and delivery of this Agreement and the performance of all obligations of the Company hereunder have been taken prior to the Agreement Date. This Agreement is the valid and legally binding obligation of the Company, enforceable in accordance with its terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, and other laws of general application affecting enforcement of creditors' rights, and (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies.

(b) No consent, approval, permit, order or authorization of, or registration, qualification, designation, declaration or filing with, any Governmental Authority on the part of or with respect to the Company is required in connection with the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby, except the filing of the Merger Document with the California Secretary of State and pre-merger notification filings under the HSR Act with the U.S. Department of Justice and Federal Trade Commission.

3.5 Financial Statements.

(a) The Company has made available to the Parent or its counsel, and included in the Company Disclosure Schedule are, the Financial Statements.

The Financial Statements are complete and correct in all material respects and have been prepared in accordance with GAAP, except that the unaudited financial statements do not contain footnotes required by GAAP. The Financial Statements fairly present the financial condition of the Company on a consolidated basis as of the dates and during the periods indicated therein, subject, in the case of the unaudited financial statements, to normal year-end audit adjustments which are neither individually nor in the aggregate material. The Company maintains a standard system of accounting established and administered in accordance with GAAP.

(b) Except for Indebtedness reflected in the Financial Statements, the Company and its Subsidiaries have no Indebtedness outstanding at the date hereof. The Company and its Subsidiaries are not in default with respect to any outstanding Indebtedness or any instrument relating thereto, nor is there any event which, with the passage of time or giving of notice, or both, would result in a default, and no such Indebtedness or any instrument or agreement relating thereto purports to limit the issuance of any Securities by the Company or the operation of the business of the Company. Complete and correct copies of all instruments (including all amendments, supplements, waivers and consents) relating to any Indebtedness of the Company or its Subsidiaries have been furnished to the Parent or its counsel.

3.6 Liabilities. The Company and its Subsidiaries have no liabilities or, to the knowledge of the Company, contingent liabilities not disclosed in the Financial Statements, except current liabilities incurred in the ordinary course of business consistent with past practice subsequent to the date of the latest balance

sheet included in the Financial Statements and liabilities that, individually or in the aggregate, have not resulted in or could not reasonably be expected to result in a Material Adverse Effect on the Company.

3.7 Minute Book. The minute books of the Company and its Subsidiaries made available to the Parent or its counsel contain minutes of all meetings and copies of all other actions taken by written consent in lieu of a meeting of the directors or shareholders of the Company and its Subsidiaries since the time of incorporation and reflect all transactions referred to in such minutes accurately in all material respects.

3.8 Litigation. Except as set forth in Section 3.8 of the Company Disclosure Schedule, there is no action, suit or proceeding pending or, to the knowledge of the Company, currently threatened and, to the knowledge of the Company, there is no pending or currently threatened investigation pertaining to any potential action, suit or proceeding against the Company and its Subsidiaries or any of its officers or directors. The foregoing includes, without limitation, actions, suits and proceedings pending or, to the knowledge of the Company, threatened involving the prior employment of any of the employees of the Company or its Subsidiaries, their use in connection with the Company's business of any information or techniques allegedly proprietary to any of their former employers, or their obligations under any agreements with prior employers. The Company has not received any communication from any third party that could reasonably lead the Company to believe that any such action, suit, proceeding or investigation is forthcoming. The Company and its Subsidiaries are not a party or subject to the provisions of any order, writ, injunction, judgment or decree of any court or govern-

ment agency or instrumentality. There is no action, suit, or proceeding by the Company or any of its Subsidiaries currently pending or that the Company or any of its Subsidiaries intends to initiate or is investigating whether to initiate.

3.9 Intellectual Property.

(a) Section 3.9(a) of the Company Disclosure Schedule sets forth a complete and accurate list of (i) all registered Intellectual Property owned, licensed or used by the Company or any of its Subsidiaries, all applications therefor, and all written licenses and assignments (excluding assignments of patent applications by inventors to the Company) to which the Company or any of its Subsidiaries is a party, and (ii) all licenses relating to technology, know-how and processes which the Company or any of its Subsidiaries has licensed or authorized for use by others.

(b) To the knowledge of the Company, the operation of the Principal Business of the Company and its Subsidiaries as presently conducted and as the Company and its Subsidiaries currently propose it be conducted does not interfere with, conflict with, infringe upon, misappropriate or otherwise violate the Intellectual Property rights of any third party. Section 3.9(b) of the Company Disclosure Schedule sets forth a complete and accurate list of third party Intellectual Property rights for which the Company or one of its Subsidiaries has sought a legal opinion regarding any potential interference with, conflict with infringement upon, misappropriation of or other violation of such third party Intellectual Property rights by the Company or its Subsidiaries. After informally applying a similar standard to all other third party Intellectual Property rights of which the Company has knowledge, the Company has determined not to seek opinions of

counsel regarding such other third party Intellectual Property.

(c) The Company is the sole owner of the entire right, title and interest in and to all Company Owned Intellectual Property and has sufficient title, ownership or interest in and to, or has a valid license or other legal right under the Company Licensed Intellectual Property used in or necessary to the operation of its Principal Business as presently conducted and as the Company currently proposes it be conducted, subject to the terms of the license agreements governing the Company Licensed Intellectual Property.

(d) Except as set forth in Section 3.9(d) of the Company Disclosure Schedule, there are no outstanding options, licenses, or agreements of any kind relating to the Company Owned Intellectual Property and neither the Company nor any of its Subsidiaries has granted any license or other right to any third party with respect to the Company Licensed Intellectual Property or Company Owned Intellectual Property. Except as set forth in Section 3.9(d) of the Company Disclosure Schedule, neither the Company nor its Subsidiaries are bound by or a party to any options, licenses or agreements of any kind with respect to the patents, trademarks, service marks, trade names, copyrights, trade secrets, licenses, information, proprietary rights and processes of any other person.

(e) The Company has no present knowledge from which it could reasonably conclude that the Company Owned Intellectual Property and any Intellectual Property licensed to the Company under the Company Licensed Intellectual Property, are invalid or unenforceable, and the same have not been

adjudged invalid or unenforceable in whole or in part. To the knowledge of the Company, the Company Owned Intellectual Property and the Company Licensed Intellectual Property constitute all of the Intellectual Property necessary for the operation of the Principal Business of the Company and its Subsidiaries as presently conducted and as the Company and its Subsidiaries currently propose it be conducted. To the knowledge of the Company, the Company has complied with all of its obligations of confidentiality in respect of the claimed trade secrets or proprietary information of others and knows of no violation of such obligations of confidentiality as are owed to it.

(f) Except as set forth in Section 3.9(f) of the Company Disclosure Schedule, no claims or actions have been asserted, are pending or, to the knowledge of the Company, threatened against the Company or any of its Subsidiaries (i) based upon or challenging or seeking to deny or restrict the ownership by or license rights of the Company or any of its Subsidiaries of any of the Company Owned Intellectual Property or Company Licensed Intellectual Property, (ii) alleging that any services provided by, processes used by, or products manufactured or sold by the Company or any of its Subsidiaries or the operation of the Principal Business of the Company and its Subsidiaries as presently conducted and as the Company and its Subsidiaries currently propose it be conducted, interferes with, conflicts with, infringes upon, misappropriates or otherwise violates any Intellectual Property right of any third party, or (iii) alleging that the Company Licensed Intellectual Property is being licensed or sublicensed in conflict with the terms of any license or other agreement, and, the Company has not received any communication from any third party that could reasonably lead the Company to believe that such a

claim or action is forthcoming and, to the knowledge of the Company, there is no reasonable basis for such a claim or action. The Company and its Subsidiaries have not received any offers of licenses to patents that may cover any of the Company Products.

(g) As of the Agreement Date, to the knowledge of the Company, no person is engaging or has engaged in any activity that infringes or misappropriates the Company Owned Intellectual Property or Company Licensed Intellectual Property. Neither the Company nor any of its Subsidiaries has ever delivered any communication to any party (each, a "Notified Party") that could reasonably lead any such Notified Party to believe that the Company or its Subsidiaries allege that any services provided by, processes used by, or products manufactured or sold by such Notified Party, or the operation of such Notified Party's actual or proposed business, interferes with, conflicts with, infringes upon, misappropriates or otherwise violates any Company Owned Intellectual Property or Company Licensed Intellectual Property. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated by this Agreement by the Company will not breach, violate or conflict with any instrument or agreement concerning the Company Owned Intellectual Property, will not cause the forfeiture or termination or give rise to a right of forfeiture or termination of any of the Company Owned Intellectual Property or materially impair the right of the Parent to license or dispose of, or to bring any action for the infringement of, any material Company Owned Intellectual Property.

(h) The Company has made available to the Parent or its counsel correct and complete copies of all the licenses of the Company Licensed Intellectual

Property, other than licenses of commercial off-the-shelf computer software. With respect to each such license:

(i) such license is valid and binding and in full force and effect and represents the entire agreement between the respective licensor and licensee with respect to the subject matter of such license;

(ii) such license will not cease to be valid and binding and in full force and effect on terms identical in all material respects to those currently in effect as a result of the consummation of the transactions contemplated by this Agreement, nor will the consummation of the transactions contemplated by this Agreement constitute a material breach or default under such license or otherwise so as to give the licensor or any other person a right to terminate such license;

(iii) neither the Company nor any of its Subsidiaries has (A) received any notice of termination or cancellation under such license, (B) received any notice of breach or default under such license, which breach has not been cured, or (C) granted to any other third party any rights, adverse or otherwise, under such license that would constitute a material breach of such license; and

(iv) neither the Company nor, to the knowledge of the Company, any other party to such license (including any Subsidiaries of the Company) is in material breach or default thereof, and, to the knowledge of the Company, no event has occurred that, with notice or lapse of time, would constitute such a material breach or default or permit termination, modification or acceleration under such license.

(i) Except as set forth in Section 3.9(i) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries has knowledge that any of its respective employees, officers, directors, agents or consultants is (i) subject to confidentiality restrictions in favor of any third person the breach of which could subject the Company or any of its Subsidiaries to any liability, or (ii) obligated under any contract (including licenses, covenants or commitments of any nature) or other agreement, or subject to any judgment, decree or order of any court or administrative agency, that would interfere with their duties to the Company or any of its Subsidiaries, as applicable, or that would conflict with the Principal Business of the Company and its Subsidiaries as the Company and its Subsidiaries currently propose it be conducted. Each employee and consultant to the Company and any of Subsidiaries of the Company has executed a proprietary information and inventions agreement in substantially the form of Exhibit C attached hereto. No current or former employee or officer of or consultant to the Company or any of its Subsidiaries that has contributed to the development of registered Company Owned Intellectual Property has excluded works or inventions made prior to his or her employment or relationship with the Company or any of its Subsidiaries from his or her assignment of inventions to the Company pursuant to such employee's, officer's or consultant's proprietary information and inventions agreement. Each of the Company and its Subsidiaries has taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of its trade secrets and other confidential Intellectual Property.

(j) To the knowledge of the Company:

(i) there has been no misappropriation of any material trade secrets or other material confidential Company Owned Intellectual Property by any person;

(ii) no employee, independent contractor or agent of the Company or any of its Subsidiaries has misappropriated any trade secrets of any other person in the course of such performance as an employee, independent contractor or agent; and

(iii) no employee, independent contractor or agent of the Company or any of its Subsidiaries is in material default or breach of any term of any employment agreement, non-disclosure agreement, assignment of invention agreement or similar agreement or contract relating in any way to the protection, ownership, development, use or transfer of Company Owned Intellectual Property.

(k) To the Company's knowledge, neither the execution nor delivery of this Agreement, nor the carrying on of the Principal Business by the employees of and consultants to the Company or any of its Subsidiaries, as the case may be, nor the conduct of Principal Business of the Company and its Subsidiaries as presently conducted or as the Company and its Subsidiaries currently propose it be conducted, would, to the knowledge of the Company, conflict with or result in a breach of the terms, conditions or provisions of, or constitute a default under, any contract, covenant or instrument under which any of such employees or consultants is now obligated. Except to the extent already assigned to the Company or any of its Subsidiaries, neither the Company nor any of its Subsidiaries believes that it is or will be necessary to

utilize any inventions or proprietary information of any of its respective employees (or people it currently intends to hire) made prior to their employment by the Company or any of its Subsidiaries, as the case may be.

3.10 Compliance with Other Instruments. Neither the Company nor any of its Subsidiaries are in violation or default of any provision of its Articles of Incorporation (or equivalent document) or bylaws (or equivalent document) or, to the Company's knowledge, of any provision of any federal or state statute, rule or regulation applicable to the Company or any of its Subsidiaries (excluding Environmental Laws, which are covered by Section 3.15, laws and regulations relating to Company Products, FDA matters and similar laws and regulations, which are covered by Section 3.14 and Section 3.21, laws and regulations relating to Company Benefit Plans, which are covered by Section 3.20, and Tax Law, which is covered by Section 3.24). Neither the Company nor any of its Subsidiaries are in violation or default of any mortgage, indenture, contract, agreement, instrument, judgment, order, writ, decree or contract to which it is a party or by which it is bound that has resulted in or could reasonably be expected to result in a material financial penalty or loss to the Company or would otherwise result in a Material Adverse Effect on the Company. The execution, delivery and performance of this Agreement by the Company and the consummation of the Merger, (i) will not result in any violation or default described in the preceding two sentences, (ii) result in the creation of any mortgage, pledge, lien, charge or encumbrance upon any of the properties or assets of the Company or any of its Subsidiaries, or (iii) result in the suspension, revocation, impairment, forfeiture, or non-renewal of any

material permit, license, authorization or approval applicable to the Principal Business, operations or any of the assets or properties of the Company or any of its Subsidiaries.

3.11 Agreements; Actions.

(a) Except as set forth in Section 3.11(a) of the Company Disclosure Schedule, there are no agreements, understandings or proposed transactions between the Company and any of its officers, directors, Affiliates, or any Affiliate thereof, or between any Subsidiary of the Company and any of its officers, directors or Affiliates.

(b) Section 3.11(b) of the Company Disclosure Schedule sets forth all agreements, understandings, instruments, contracts, proposed transactions, judgments, orders, writs or decrees to which the Company or any of its Subsidiaries is a party or by which it is bound that involve (i) obligations (contingent or otherwise) of, or payments to, the Company or any of its Subsidiaries in excess of $50,000, or that may not be extinguished on thirty (30) days' notice or less (other than open purchase orders and invoices for the purchase or sale of goods or services entered into in the ordinary course of business), (ii) the license, assignment or transfer of any patent, copyright, trade secret or other proprietary right to or from the Company or any of its Subsidiaries (other than licenses to the Company arising from the purchase of commercial "off the shelf' or other standard products), (iii) the manufacture, marketing, sale or distribution of any products of the Company or any of its Subsidiaries in any jurisdiction, or any restrictions on the Company's or any of its Subsidiaries' exclusive rights to develop, manufacture, assemble, distribute, market and sell its products, (iv) indemnification by the Company or any

of its Subsidiaries with respect to infringements of proprietary rights (other than indemnification obligations arising from purchase, sale, marketing, supply, manufacturing, or license agreements or similar agreements entered into in the ordinary course of business), (v) any supply agreements, or (vi) other agreements that are otherwise material to the Principal Business of the Company.

(c) The Company has delivered or has caused to be delivered to the Parent or its counsel (including in connection with the delivery of the Company's compiled response to the Parent's due diligence request list, which compiled response was delivered to the Parent and its counsel at the offices of the Company's counsel by making such compiled response available for Parent and its counsel to review and remove from such offices) correct and complete copies of each contract, agreement or other arrangement listed in Section 3.11 of the Company Disclosure Schedule, as such contracts, agreements and arrangements are amended to date. Each such contract, agreement or other arrangement is a valid, binding and enforceable obligation of the Company or any of its Subsidiaries, as applicable, and, to the knowledge of the Company, of the other party or parties thereto, and is in full force and effect. Except as set forth in Section 3.11(c) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries nor, to the knowledge of the Company, the other party or parties thereto, is in breach or non-compliance, or, to the knowledge of the Company, is considered to be in breach or non-compliance by the other party thereto, of any term of any such contract, agreement or other arrangement, except for breach or non-compliance that has not and could not be reasonably expected to result in a Material Adverse Effect on the Company or

result in provide any other party thereto with the right to impose a material financial penalty on the Company. Except as set forth in Section 3.11(c) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries has received notice of any default or threat thereof with respect to any such contract, agreement or other arrangement and neither the Company nor any of its Subsidiaries has a reasonable basis for suspecting that any such default exists or will be forthcoming. Subject to obtaining any necessary consents by the other party or parties to any such contract, agreement or other arrangement (as further set forth in Section 3.11(c) of the Company Disclosure Schedule), no contract, agreement or other arrangement listed in Section 3.11 of the Company Disclosure Schedule includes or incorporates any provision the effect of which would be to enlarge or accelerate any obligations of the Company or any of its Subsidiaries or give additional rights to any other party thereto, or terminate or lapse by reason of, the transactions contemplated by this Agreement.

(d) For the purposes of Section 3.11(b), all liabilities, agreements, understandings, instruments, contracts and proposed transactions involving the same person (including persons the Company or any of its Subsidiaries has reason to believe are affiliated therewith) shall be aggregated for the purpose of meeting the individual minimum dollar amounts of such subsections.

3.12 Related-Party Transactions. No employee, officer, or director of or consultant to the Company or any of its Subsidiaries, as the case may be, or member of his or her immediate family is indebted to the Company or any of its Subsidiaries, nor is the Company or any of its Subsidiaries indebted (or committed

to make loans or extend or guarantee credit) to any of them other than (a) for payment of salary or fees (in the case of consultants) for services rendered, (b) reimbursement for reasonable expenses incurred on behalf of the Company or any of its Subsidiaries, and (c) for other standard employee benefits made generally available to all employees (including stock options outstanding under any stock option plan approved by the Company Board or the board of directors of any of the Company's Subsidiaries, as the case may be). To the knowledge of the Company, none of such persons has any direct or indirect ownership interest in any firm or corporation with which the Company or any of its Subsidiaries is affiliated or with which the Company or any of its Subsidiaries has a business relationship, or any firm or corporation that competes with the Company or any of its Subsidiaries, except that employees, officers or directors of the Company or any of its Subsidiaries and members of their immediate families may own stock in publicly-traded companies that may compete with the Company or any of its Subsidiaries. No member of the immediate family of any officer or director of the Company is directly or indirectly interested in any material contract with the Company. No member of the immediate family of any officer or director of any Subsidiary of the Company is directly or indirectly interested in any material contract with such Subsidiary. Except as may be disclosed in the Financial Statements, neither the Company nor any of its Subsidiaries is a guarantor or indemnitor of any Indebtedness of any other person.

3.13 Changes. Except as reflected in the Financial Statements provided to the Parent, since the end of the latest completed fiscal year of the Company, there has not been:

(a) Any change in the assets, liabilities, financial condition or operations of the Company or any of its Subsidiaries from that reflected in the Financial Statements, other than changes in the ordinary course of business consistent with past practice, none of which individually or in the aggregate has resulted in or could reasonably be expected to result in a Material Adverse Effect on the Company;

(b) Any resignation or termination of any executive officer of the Company or of any of its Subsidiaries;

(c) Any material change, except in the ordinary course of business consistent with past practice, in the contingent obligations of the Company or any of its Subsidiaries by way of guaranty, endorsement, indemnity, warranty or otherwise;

(d) Any damage, destruction or loss, whether or not covered by insurance, which has resulted in or could reasonably be expected to result in a Material Adverse Effect on the Company;

(e) Any waiver by the Company or any of its Subsidiaries of a right or of a debt owed to it (i) by a director, officer or employee or the Company or any Subsidiary of the Company or (ii) in excess of $100,000;

(f) Any direct or indirect loans made by the Company to any shareholder, employee, officer or director of the Company, or a Subsidiary of the Company to any shareholder, employee, officer or director of such Subsidiary, other than advances made in the ordinary course of business consistent with past practice;

(g) Any material change in any compensation arrangement or agreement with any employee, officer, director or shareholder of the Company or any of its Subsidiaries;

(h) Any declaration or payment of any dividend or other distribution of the assets of the Company or any of its Subsidiaries, or any repurchase of any shares of outstanding capital stock of the Company;

(i) Any labor organization activity;

(j) Any Indebtedness, obligation or liability incurred, assumed or guaranteed by the Company or any of its Subsidiaries, except those for immaterial amounts and for current liabilities incurred in the ordinary course of business consistent with past practice;

(k) Any sale, assignment, transfer or license of any patents, trademarks, copyrights, trade secrets or other intangible assets of the Company or any of its Subsidiaries;

(l) Any change in any material agreement to which the Company or any of its Subsidiaries is a party or by which it is bound which has resulted in or could reasonably be expected to result in a Material Adverse Effect on the Company;

(m) Any change in the manner, method or policies employed by the Company or its Subsidiaries in the collection of its accounts receivable; or

(n) Any other event or condition of any character that, either individually or cumulatively, has resulted in or could reasonably be expected to result in a Material Adverse Effect on the Company.

3.14 Compliance with Laws; Permits. Neither the Company nor any of its Subsidiaries is in violation of any applicable statute, rule, regulation, order, judgment, decree, writ or restriction of any domestic or foreign government or any instrumentality or agency thereof in respect of the Company Products, the conduct of its business or the ownership of its properties, including, without limitation, the Health Insurance Portability and Accountability Act of 1996, 104 P.L. 191, Subtitle F, and regulations from time to time promulgated thereunder ("HIPAA") and all other laws, statutes, rules or regulations related to the delivery of health care or health care services or the payment for health care or health care services, including any laws relating to Medicare fraud and abuse or similar state laws and regulations relating to reimbursement for medical procedures. The Company and each of its Subsidiaries has all franchises, permits, licenses and any similar authority (the "Permits") necessary for the conduct of its business as now being conducted by it. No suspension or cancellation of any of the Permits is pending or, to the knowledge of the Company, threatened.

3.15 Environmental, Zoning and Safety Laws. Except as set forth in Section 3.15 of the Company Disclosure Schedule, (a) neither the activities carried on by the Company or any of its Subsidiaries at the facilities, offices or properties leased by the Company or any of its Subsidiaries, as the case may be, nor, to the knowledge of the Company, the premises occupied by the Company or any of its Subsidiaries, are in violation of any Environmental Laws, or any other zoning, health or safety law or regulation, the violation of which has resulted in or could reasonably be expected to result in a Material Adverse Effect on the Company; (b) neither the Company nor any of its

Subsidiaries nor, to the knowledge of the Company, any owner of any real property currently occupied by the Company or any of its Subsidiaries, has received written notice from any Governmental Authority that it is in violation, or alleged violation, of, or has any liability or threatened liability under, any Environmental Laws; (c) none of the properties currently or formerly owned, leased or operated by the Company or any of its Subsidiaries (including, without limitation, soils and surface and ground waters) are contaminated with any Hazardous Substance, except to the extent as would not be reasonably likely to result in material liability to the Company or any of its Subsidiaries; (d) neither the Company nor any of its Subsidiaries is liable for any off-site contamination by Hazardous Substances, except to the extent as would not be reasonably likely to result in material liability to the Company or any of its Subsidiaries; (e) the Company and each of its Subsidiaries has all material Environmental Permits necessary for the conduct of its business as now being conducted by it; (g) the Company and each of its Subsidiaries has always been and is in compliance in all material respects with its Environmental Permits; and (h) neither the execution of this Agreement nor the consummation of the transactions contemplated hereby will require the Company or any Subsidiary to perform any investigation, remediation or other action with respect to Hazardous Substances, or to provide any notice to or consent of Governmental Authorities or third parties, pursuant to any applicable Environmental Law or Environmental Permit.

3.16 Manufacturing and Marketing Rights. Neither the Company nor any of its Subsidiaries has granted rights to manufacture, produce, assemble, license, market, or sell its products to any other person

and is not bound by any agreement that affects the Company's, or any of its Subsidiaries', exclusive right to develop, manufacture, assemble, distribute, market or sell its products.

3.17 Disclosure. Neither this Agreement (including all the exhibits and schedules hereto), nor any other statements or certificates made or delivered in connection herewith or therewith, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements herein or therein not misleading in light of the circumstances under which they were made.

3.18 First Offer Rights. Except as set forth in Section 3.18 of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries has granted or agreed to grant any right of first offer with respect to any acquisition of all or substantially all of the capital stock or assets of the Company to any person. Notwithstanding anything to the contrary in this Agreement or the Company Disclosure Schedule, the execution and delivery by the Company of this Agreement and the consummation of the transactions contemplated hereby have not resulted, and will not result, in a violation or breach of any agreements identified in Section 3.18 of the Company Disclosure Schedule.

3.19 Insurance. The Company and each of its Subsidiaries has in full force and effect fire and casualty insurance policies, with extended coverage, sufficient in amount (subject to reasonable deductibles) to allow the Company or such Subsidiary to replace any of its properties that might be damaged or destroyed. The Company and each of its Subsidiaries has in full force and effect insurance, including but not limited to products liability, commercial general and

excess liability and errors and omissions insurance, in the amounts set forth in Section 3.19 of the Company Disclosure Schedule. Neither the Company nor any of the Company's Subsidiaries is in default with respect to its obligations under any insurance policy maintained by it, and neither the Company nor any of the Company's Subsidiaries has been denied insurance coverage.

3.20 Employee Benefit Plans.

(a) Identification of Plans. Except as disclosed in Section 3.20(a) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries currently maintains or contributes to, or has any outstanding liability to or in respect of or obligation under, any pension, profit-sharing, deferred compensation, bonus, stock option, employment, share appreciation right, severance, group or individual health, dental, medical, life insurance, survivor benefit, or similar plan, policy, arrangement or agreement, whether formal or informal, written or oral, for the benefit of any current or former director, officer or employee of or consultant to the Company or any of its Subsidiaries, as applicable. Each of the arrangements set forth in Section 3.20(a) of the Company Disclosure Schedule is herein referred to as an "Employee Benefit Plan".

(b) Delivery of Documents. The Company has heretofore delivered to Parent or its counsel true, correct and complete copies of each Employee Benefit Plan and, with respect to each such Employee Benefit Plan, true, correct and complete copies of (i) any associated trust, custodial, insurance or service agreements, (ii) any annual report, actuarial report, or disclosure materials (including specifically any summary plan descriptions) submitted to any gov-

ernmental agency or distributed to participants or beneficiaries thereunder in the current or any of the three (3) preceding calendar years, and (iii) the most recently received IRS determination letters, if any, and any governmental advisory opinions, rulings, compliance statements, closing agreements or similar materials specific to such Employee Benefit Plan.

(c) Compliance with Terms and Law. Each Employee Benefit Plan is and has heretofore been maintained and operated in material compliance with the terms of such Employee Benefit Plan and in material compliance with the requirements prescribed (whether as a matter of substantive law or as necessary to secure favorable tax treatment) by any and all applicable statutes, governmental or court orders, or governmental rules or regulations in effect from time to time, including ERISA and the Code, and applicable to such Employee Benefit Plan. Each Employee Benefit Plan which is intended to qualify under Section 401(a) of the Code and each trust or other entity intended to qualify as a "voluntary employee benefit association" within the meaning of Section 501(c)(9) of the Code and associated with any Employee Benefit Plan is expressly identified as such in Section 3.20(c) of the Company Disclosure Schedule and has been determined to be so qualified by the IRS (or, in the case of a 401(a) plan based upon a master and prototype or volume submitter form, the sponsor of such form has received a current advisory opinion as to the form upon which the Company is entitled to rely under applicable IRS procedures) and, to the knowledge of the Company, nothing has occurred as to each which has resulted or is likely to result in the revocation of such qualification determination or which requires or could require action under the

compliance resolution programs of the IRS to preserve such qualification.

(d) Absence of Certain Events and Arrangements. Except as set forth in Section 3.20(d) of the Company Disclosure Schedule:

(i) there is no pending or, to the knowledge of the Company, threatened legal action, proceeding or investigation, other than routine claims for benefits, concerning any Employee Benefit Plan or, to the knowledge of the Company, any fiduciary or service provider thereof and, to the knowledge of the Company, there is no basis for any such legal action or proceeding;

(ii) no liability (contingent or otherwise) to the PBGC or any multi-employer plan has been incurred by the Company or any of its ERISA Affiliates or Subsidiaries (other than insurance premiums satisfied in due course);

(iii) no reportable event, or event or condition which presents a material risk of termination by the PBGC, has occurred with respect to any Employee Benefit Plan, or any retirement plan of an ERISA Affiliate or Subsidiary of the Company, which is subject to Title IV of ERISA;

(iv) no Employee Benefit Plan nor any party in interest with respect thereof has, to the knowledge of the Company, engaged in a prohibited transaction which could subject the Company or any of its Subsidiaries directly or indirectly to liability under Section 409 or 502(i) of ERISA or Section 4975 of the Code;

(iv) no Employee Benefit Plan provides health benefits subsequent to termination of employ-

ment to employees or their beneficiaries except to the extent required by applicable state laws and Title I, Part 6 of ERISA;

(v) neither the Company nor any of its Subsidiaries has announced its intention to modify or terminate any Employee Benefit Plan or adopt any arrangement or program which, once established, would come within the definition of an Employee Benefit Plan; and

(vi) neither the Company nor any of its Subsidiaries has undertaken to maintain any Employee Benefit Plan for any period of time and each such Employee Benefit Plan is terminable at the sole discretion of the sponsor thereof, subject only to such constraints as may be imposed by applicable law and the ordinary costs of termination and cancellation of the applicable contracts.

(e) Funding of Certain Plans. With respect to each Employee Benefit Plan for which a separate fund of assets is or is required to be maintained, full and timely payment has been made of all amounts required of the Company or any of its Subsidiaries, as the case may be, under the terms of each such Employee Benefit Plan or applicable law, as applied through the Closing Date, the consummation of the Merger or a short-form merger, and no accumulated funding deficiency (as defined in Section 302 of ERISA and Section 412 of the Code), whether or not waived, exists with respect to any such Employee Benefit Plan. The current value of the assets of each such Employee Benefit Plan, as of the end of the most recently ended plan year of that Employee Benefit Plan, equals or exceeds the current value of all accrued benefits liabilities under that Employee Benefit Plan.

(f) Effect of Transactions. The execution of this Agreement and the consummation of the transactions contemplated by this Agreement, including the Merger, will not, by themselves or in combination in any other event (regardless of whether that other event has or will occur), result in any payment (whether of severance pay or otherwise) becoming due from or under any Employee Benefit Plan (including any employment agreement) to any current or former director, officer or employee of or consultant to the Company or any of its Subsidiaries or result in the vesting, acceleration of payment or increases in the amount of any benefit payable to or in respect of any such current or former director, officer or employee of or consultant to the Company.

(g) Multi-employer Plans. No Employee Benefit Plan is a multi-employer plan.

(h) Definitions. For purposes of this Section, "multi-employer plan", "party in interest", "current value", "reportable event" and "benefit liability" have the same meaning assigned such terms under Sections 3(37), 4043(b) or 4001(a) of ERISA, and "ERISA Affiliate" means any entity which under Section 414(b), (c), (m) or (o) of the Code is treated as a single employer with the Company, determined, however, without regard to this Agreement.

3.21 FDA and Regulatory Matters; Clinical Trials.

(a) With respect to the Company Products, (i) (A) the Company and each of its Subsidiaries has obtained all necessary and applicable approvals, clearances, authorizations, licenses and registrations required by United States or foreign governments or government agencies, including, without limitation, the CE Mark, to permit the design, development, pre-

clinical and clinical testing, manufacture, labeling, sale, distribution and promotion of the Company Products in jurisdictions where it currently conducts such activities (the "Activities to Date") with respect to each Company Product (collectively, the "Company Licenses"); (B) the Company and each of its Subsidiaries, as the case may be, is in compliance in all material respects with all terms and conditions of each Company License and with all applicable Laws pertaining to the Activities to Date with respect to each Company Product which is not required to be the subject of a Company License; (C) the Company and each of its Subsidiaries, as the case may be, is in compliance with all applicable Laws regarding registration, license, certification for each site at which a Company Product is manufactured, labeled, sold, or distributed; and (D) to the extent that any Company Product has been exported from the United States, the Company or, as applicable, a Subsidiary of the Company exporting such Company Product, has exported such Company Product in compliance in all material respects with applicable Law; (ii) all manufacturing operations performed by or on behalf of the Company or its Subsidiaries have been and are being conducted in all material respects in compliance with the Quality Systems regulations of the FDA and, to the extent applicable to the Company or any of its Subsidiaries, counterpart regulations in the European Union and all other countries where compliance is required; (iii) all non-clinical laboratory studies of Company Products under development, sponsored by the Company or any of its Subsidiaries and intended to be used to support regulatory clearance or approval, have been and are being conducted in compliance with the FDA's Good Laboratory Practice for Non-Clinical Studies regulations (21 CFR Part 58) in the United

States and, to the extent applicable to the Company or any of its Subsidiaries, counterpart regulations in the European Union and all other countries; and (iv) the Company and each of its Subsidiaries is in compliance in all material respects with all applicable reporting requirements for all Company Licenses or plant registrations described in clause (i) above, including, but not limited to, applicable adverse event reporting requirements in the United States and outside of the United States under applicable Law.

(b) The Company and each of its Subsidiaries is in compliance in all material respects with all FDA and non-United States equivalent agencies and similar state and local Laws applicable to the maintenance, compilation and filing of reports, including medical device reports, with regard to the Company Products. Section 3.21(b) of the Company Disclosure Schedule sets forth a list of all applicable adverse event reports related to the Company Products, including any Medical Device Reports (as defined in 21 CFR 803). Set forth on Section 3.21(b) of the Company Disclosure Schedule are complaint review and analysis reports of the Company and each of its Subsidiaries through the date hereof, including information regarding complaints, categorized by product and root cause analysis of closed complaints, which reports are correct in all material respects.

(c) Except as set forth in Section 3.21(c) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries has received any written notice or other written communication from the FDA or any other Governmental Authority (i) contesting the pre-market clearance or approval of, the uses of or the labeling and promotion of any of the Products, or

(ii) otherwise alleging any violation of any Laws by the Company or any of its Subsidiaries.

(d) There have been no recalls, field notifications or seizures ordered or adverse regulatory actions taken (or, to the knowledge of the Company, threatened) by the FDA or any other Governmental Authority with respect to any of the Company Products, including any facilities where any Company Products are produced, processed, packaged or stored and neither the Company nor any of its Subsidiaries has within the last three (3) years, either voluntarily or at the request of any Governmental Authority, initiated or participated in a recall of any Company Product.

(e) The Company and each of its Subsidiaries have conducted all of their clinical trials with reasonable care and in accordance with all applicable Laws and the stated protocols for such clinical trials.

(f) All filings with and submissions to the FDA and any similar regulatory entity in any other jurisdiction made by the Company or any of its Subsidiaries with regard to the Company Products, whether oral, written or electronically delivered, were true, accurate and complete in all material respects as of the date made, and, to the extent required to be updated, have been updated to be true, accurate and complete in all material respects as of the date of such update, and to the knowledge of the Company such filings, submissions and updates comply with all regulations of the FDA or such similar regulatory entity regarding material misstatements and omissions to state material facts.

3.22 Brokers; Expenses. The Company and its Subsidiaries have not incurred, nor will they incur,

any liability for brokerage or finders' fees or agents' commissions or investment bankers' fees or any similar charges in connection with this Agreement or the consummation of the transactions contemplated hereby, other than the investment bankers' fees payable to Piper Jaffray that will be described in the Transaction Cost Certificate.

3.23 Consents. Except for approvals contemplated by this Agreement, including without limitation, (i) the Shareholder Approval, (ii) approvals and consents, which, if not secured, would not result in a material liability to the Company or its Subsidiaries and would not result in a Material Adverse Effect on the Company, and (iii) the other consents and approvals set forth in Section 3.23 of the Company Disclosure Schedule, no permit, approval, authorization or consent of any person (excluding governmental authorities) is required in connection with the execution, delivery and performance by the Company of this Agreement or the consummation of the transactions contemplated hereby, including the consummation of the Merger.

3.24 Taxes.

(a) Filing of Tax Returns and Payment of Taxes. The Company and each of its Subsidiaries has timely filed all material Tax Returns required to be filed by it, each such Tax Return has been prepared in compliance with all applicable laws and regulations, and all such Tax Returns are true, correct and complete in all respects. All Taxes that have become due and payable by the Company or any of its Subsidiaries (whether or not shown on any Tax Return) have been paid. Neither the Company nor any Subsidiary is or will be liable for any additional Taxes in respect of any Taxable period, or any portion

thereof, ending on or before the date of the unaudited consolidated financial statements forming part of the Financial Statements included in the Company Disclosure Schedule in an amount that exceeds the corresponding reserve therefor, as reflected in such Financial Statements. Any Taxes of the Company or any of its Subsidiaries arising after such date and at or before the Effective Time have been or will be incurred in the ordinary course of the business of the Company or the applicable Subsidiary. The Company has made available to the Parent or its counsel true, correct and complete copies of all Tax Returns with respect to income Taxes filed by or with respect to the Company and/or any of its Subsidiaries with respect to Taxable periods ended on or after December 31, 1999 (the "Recent Tax Returns"), and has made available to the Parent or its counsel all relevant documents and information with respect thereto, including without limitation work papers, records, examination reports, and statements of deficiencies proposed, assessed against or agreed to by the Company or any of its Subsidiaries.

(b) Deficiencies. No deficiency or adjustment in respect of Taxes has been proposed, asserted or assessed by any Taxation Authority against the Company or any of its Subsidiaries. There are no outstanding refund claims with respect to any Tax or Tax Return of the Company or any of its Subsidiaries.

(c) Liens. There are no liens for Taxes (other than Taxes not yet due and payable) on any of the assets of the Company or any of its Subsidiaries.

(d) Extensions to Statute of Limitations for Assessment of Taxes. Neither the Company nor any Subsidiary has consented to extend the time in which

any Tax may be assessed or collected by any Taxation Authority.

(e) Extensions of the Time for Filing Tax Returns. Neither the Company nor any Subsidiary has requested or been granted an extension of the time for filing any Tax Return that has not yet been filed.

(f) Pending Proceedings. There is no action, suit, Taxation Authority proceeding, or audit with respect to any Tax now in progress, pending or, to the knowledge of the Company, threatened against or with respect to the Company or any of its Subsidiaries.

(g) No Failures to File Tax Returns. No claim has ever been made by a Taxation Authority in a jurisdiction where the Company or any of its Subsidiaries does not pay Tax or file Tax Returns that the Company or any of its Subsidiaries that does not pay Tax or file Tax Returns in such jurisdiction is or may be subject to Taxes assessed by such jurisdiction.

(h) Tax Attributes, Etc. The Company has made available to Parent a report prepared by Ernst & Young, LLP regarding the impact of Sections 382 and 383 on the Company's net operating loss and credit carryforwards. The Company has reviewed such report and has no knowledge that any fact provided to Ernst & Young LLP by the Company in connection therewith is incorrect in any material respect.

(i) Elections. All elections with respect to Taxes affecting the Company that were not made in the Recent Tax Returns are described in Section 3.24(i) of the Company Disclosure Schedule.

(j) Membership in Affiliated Groups, Liability for Taxes of Other Persons, Etc. Neither the Company nor any of its Subsidiaries has ever been a member of

any affiliated group of corporations (as defined in Section 1504(a) of the Code), other than a group having the Company as the common parent. Neither the Company nor any of its Subsidiaries has ever filed or been included in a combined, consolidated or unitary Tax Return, other than a return filed for a group having the Company as the common parent. Neither the Company nor any of its Subsidiaries is a party to or bound by any Tax sharing or allocation agreement. Neither the Company nor any of its Subsidiaries is presently liable or has any potential liability for Taxes of any person other than the Company and its Subsidiaries (i) under Treasury Regulations Section 1.1502-6 (or comparable provision of state, local or foreign law), (ii) as transferee or successor, or (iii) by contract or indemnity or otherwise.

(k) Adjustments under Section 481. Neither the Company nor any of its Subsidiaries will be required, as a result of a change in method of accounting for any period ending on or before or including the Effective Time, to include any adjustment under Section 481(c) of the Code (or any similar or corresponding provision or requirement under any other Tax Law) in Taxable income for any period ending on or after the Effective Time.

(l) Withholding Taxes. The Company and each of its Subsidiaries has, to the knowledge of the Company, timely withheld and timely paid all Taxes which are required to have been withheld and paid by it in connection with amounts paid or owing to any employee, independent contractor, creditor or other person.

(m) U.S. Real Property Holding Corporation. Neither the Company nor any of its Subsidiaries is or

has been a United States real property holding corporation within the meaning of Code Section 897(c)(2), during the applicable period specified in Code Section 897(c)(1)(A)(ii).

(n) Safe Harbor Lease Property. None of the property owned or used by the Company or any of its Subsidiaries is subject to a Tax benefit transfer lease executed in accordance with Section 168(0(8) of the Internal Revenue Code of 1954, as amended by the Economic Recovery Tax Act of 1981.

(o) Tax-Exempt Use Property. None of the property owned by the Company or any of its Subsidiaries is "tax-exempt use property" within the meaning of Section 168(h) of the Code.

(p) Security for Tax-Exempt Obligations. None of the assets of the Company or any of its Subsidiaries directly or indirectly secures any Indebtedness, the interest on which is tax-exempt under Section 103(a) of the Code, and neither the Company nor any Subsidiary is directly or indirectly an obligor or a guarantor with respect to any such Indebtedness.

(q) Parachute Payments, Etc. Neither the Company nor any Subsidiary has made any payments, is obligated to make any payments, or is a party to any agreement that under certain circumstances could obligate it to make any payments to an employee or independent contractor in connection with the transactions contemplated by this Agreement, that are not or would not be deductible under Section 280G of the Code. Neither the Company nor any Subsidiary has made any payments or is obligated to make any payments that are not or would not be deductible under Section 162(m) of the Code.

(r) Rulings. The Company has made available to the Parent or its counsel copies of all rulings (if any) issued to the Company by any Taxation Authority, and copies of all outstanding requests for rulings that have been submitted by the Company to any Taxation Authority.

(s) Divisive Transactions. Neither the Company nor any Subsidiary has ever been either a "distributing corporation" or a "controlled corporation" in connection with a distribution of stock qualifying for tax-free treatment, in whole or in part, pursuant to Section 355 of the Code.

(t) Operations Outside the United States. Neither the Company nor any of its Subsidiaries is subject to Tax in any jurisdiction in which it does not file Tax Returns.

3.25 Employees. The Company has no collective bargaining agreements with any of its employees. There is no labor union organizing activity pending or, to the Company's knowledge, threatened with respect to the Company or any of its Subsidiaries. To the Company's knowledge, no employee of the Company or its Subsidiaries, nor any consultant with whom the Company or any of its Subsidiaries has contracted, is in violation of any term of any employment contract, proprietary information agreement or any other agreement relating to the right of any such individual to be employed by, or to contract with, the Company and its Subsidiaries because of the nature of the business to be conducted by the Company; and to the Company's knowledge, the continued employment by the Company and its Subsidiaries of its present employees, and the performance of the Company's contracts with its independent contractors, will not result in any such violation. Neither the Company nor

any of its Subsidiaries has received any notice alleging that any such violation has occurred. No employee of the Company or any of its Subsidiaries has been granted the right to continued employment by the Company.

3.26 Obligations of Management. To the knowledge of the Company, each officer of the Company and its Subsidiaries is currently devoting one hundred percent (100%) of his or her business time to the conduct of the business of the Company. To the knowledge of the Company, no officer of the Company or any of its Subsidiaries is planning to work less than full time at the Company or any of its Subsidiaries in the future.

3.27 Title to Properties and Assets; Liens, Etc. The Company and each of its Subsidiaries has good and valid title to all of its properties and assets, including the properties and assets reflected in the most recent balance sheet included in the Financial Statements, and good title to its leasehold estates, in each case subject to no mortgage, pledge, lien, lease, encumbrance or charge, other than (a) those resulting from Taxes which have not yet become delinquent, (b) minor liens and encumbrances not materially impair the operations of the Company, and (c) those that have otherwise arisen in the ordinary course of business. All facilities, machinery, equipment, fixtures, vehicles and other properties owned, leased or used by the Company and its Subsidiaries are reasonably fit and usable for the purposes for which they are being used.

## ARTICLE 4
## REPRESENTATIONS AND WARRANTIES OF PARENT AND MERGER SUB

Parent and Merger Sub, jointly and severally, hereby represent and warrant to the Company as of the Agreement Date, and as of the Closing Date, as follows, subject in each case to such exceptions as are specifically contemplated by this Agreement:

4.1 Organization, Good Standing and Qualification. Parent is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Merger Sub is a corporation duly organized, validly existing and in good standing under the laws of the State of California. Each of Parent and Merger Sub has all requisite corporate power and authority to own and operate its properties and assets, to execute and deliver this Agreement, to carry out the provisions of this Agreement and the Escrow Agreement and to perform its obligations under, and carry out the provisions of, this Agreement and the Escrow Agreement, and to carry on its principal business as presently conducted and as presently proposed to be conducted. Parent is duly qualified to transact business and is in good standing in each jurisdiction where such qualification is required and in which failure to so qualify would result in or could be reasonably expected to result in a Material Adverse Effect on Parent.

4.2 Authorization; Binding Obligations; Governmental Consents.

(a) All corporate actions on the part of Parent and Merger Sub, and their respective officers, directors and shareholders necessary for the authorization of this Agreement and the Escrow Agreement and the

performance of all obligations of Parent and Merger Sub hereunder and thereunder have been taken. This Agreement is and, once executed and delivered by Parent in accordance with the terms hereof, the Escrow Agreement will be, the valid and binding obligations of Parent and Merger Sub, enforceable against such parties in accordance with their respective terms, except as such enforcement may be limited by (i) the effect of bankruptcy, insolvency, reorganization, receivership, conservatorship, arrangement, moratorium or other laws affecting or relating to the rights of creditors generally, or (ii) the rules governing the availability of specific performance, injunctive relief or other equitable remedies and general principles of equity, regardless of whether considered in a proceeding in law or equity.

(b) No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority on the part of Parent or Merger Sub is required in connection with the consummation by Parent or Merger Sub of the transactions contemplated by this Agreement and the Escrow Agreement except for (i) the filing of the Merger Document with the California Secretary of State; (ii) such filings as may be required under the HSR Act or any applicable state or foreign antitrust, competition, anti-takeover and similar laws; and (iii) such other consents, authorizations, filings, approvals and registrations which, if not obtained or made, would not result in and could not be reasonably expected to result in a Material Adverse Effect on Parent and would not prevent, or materially alter or delay any of the transactions contemplated by this Agreement.

4.3 Compliance with Other Instruments. The execution, delivery and performance of this Agreement by Parent and Merger Sub and the execution, delivery and performance of the Escrow Agreement by Parent will not (a) violate the charter documents or bylaws of Parent or Merger Sub, (b) breach or result in a violation of any law applicable to Parent or Merger Sub or the transactions contemplated by this Agreement or the Escrow Agreement, or (c) constitute a material breach of the terms, conditions, provisions of, or constitute a default under, any judgment, order, or decree of any court or arbitrator to which Parent or Merger Sub is a party or any material contract of Parent.

4.4 Brokers. Parent and Merger Sub have not incurred, nor will they incur, any liability for brokerage or finders' fees or agents' commissions or investment bankers' fees or any similar charges in connection with this Agreement or the consummation of the transactions contemplated hereby, other than investment bankers' fees payable to Morgan Stanley.

4.5 Financing. Attached as Schedule 4.5 is a true and correct copy of a written commitment letter from Morgan Stanley, dated February 27, 2004 (the "MS Commitment Letter"). The terms set forth in the MS Commitment Letter are satisfactory in all material respects to Parent, subject to the execution of a credit agreement with Morgan Stanley (the "MS Credit Agreement"). Upon consummation of the Debt Financing contemplated by Section 6.13, Parent will possess cash sufficient to pay the respective portions of the Closing Payment Amount it is required to pay at the Closing in accordance with the terms of this Agreement.

## ARTICLE 5
## CONDUCT OF BUSINESS PENDING THE MERGER AND RELATED COVENANTS

5.1 Conduct of Business of the Company. Except as expressly contemplated by this Agreement and except to the extent Parent shall otherwise consent in writing, the Company covenants and agrees that, during the period beginning on the Agreement Date and ending on the earlier of the termination of this Agreement or the Effective Time, (i) the business of the Company shall be conducted only in, and the Company shall not take any action except in the ordinary course of business and in a manner consistent with past practice or as otherwise expressly contemplated by this Agreement; (ii) the Company shall use its best efforts to preserve intact its business organization, (iii) the Company shall use commercially reasonable efforts to keep available the services of the current employees of and consultants to the Company; and (iv) the Company shall use commercially reasonable efforts to preserve the current relationships of the Company with customers, suppliers and other persons with which the Company has significant business relations. Except as expressly contemplated by this Agreement, and without limiting the foregoing, the Company shall not, directly or indirectly do, or propose to do, any of the following without the written consent of the Parent, with it being understood that each of such clauses below shall constitute an independent obligation of the Company, not qualified by any other such clause, and shall be deemed to be cumulative:

(a) Charter Documents. Cause or permit any amendments to its Restated Articles or bylaws;

(b) Dividends; Repurchases; Changes in Capital Stock. Except as otherwise specifically con-

templated in this Agreement, (i) declare or pay any dividends on, or make any other distributions (whether in cash, stock or property) in respect of, any of its capital stock, (ii) issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock, or (iii) repurchase or otherwise acquire, directly or indirectly, any shares of its capital stock (other than pursuant to repurchase rights of the Company that permit the Company to repurchase securities from the holders thereof at the original purchase price therefor in connection with the termination of services of such holder as an employee of or consultant to the Company);

(c) Stock Option Plans, Warrants, Etc. Accelerate, except with respect to grants already outstanding pursuant to the existing terms thereof or as expressly permitted by the Company Option Plan, amend or change the period of exercisability or vesting of options or other rights granted under the Company Option Plan, establish any new or additional stock option plan, amend the Company Option Plan other than to increase the number of shares reserved for issuance thereunder, or grant any options, warrants or other rights to acquire shares of Company Common Stock or Company Preferred Stock, other than options granted under the Company Option Plan;

(d) Material Contracts. Enter into any material contract or commitment, or violate, amend or otherwise modify or waive any of the terms of any agreements, understandings, instruments or contracts which are material to the business of the Company as presently conducted and as the Company currently proposes it be conducted other than (i) contracts that are entered into in the ordinary course

of business, or (ii) contracts which are terminable by the Company upon less than sixty (60) days' notice without penalty or surviving obligations. Any material contract or commitment entered into, or extended, by the Company after the Agreement Date shall provide that the consummation of the transactions contemplated by this Agreement shall not result in a breach or violation of such contract or otherwise require the payment of any fees or expenses in connection therewith, or give the other party the right to accelerate any obligations of the Company thereunder or to cause the termination of such contract.

(e) Issuance of Securities. Issue, deliver or sell or authorize or propose the issuance, delivery or sale of, or purchase or propose the purchase of, any shares of its capital stock or securities or other instruments (including notes or other evidences of Indebtedness) convertible into, or subscriptions, rights, warrants or options to acquire, or other agreements or commitments of any character obligating it to issue any such shares or other convertible instruments or securities, other than (i) shares of Company Common Stock issuable upon exercise of Company Options that are outstanding under the Company Option Plan, (ii) Company Options, or (iii) shares of Company Common Stock or Company Preferred Stock issuable upon exercise or conversion of the derivative securities listed in Section 3.2 of the Company Disclosure Schedule.

(f) Intellectual Property.

(i) Sell, license, assign or transfer any Intellectual Property of the Company to any other person other than the Parent, or encumber any Intellectual Property of the Company;

(ii) License, or otherwise acquire, any Intellectual Property not owned by the Company or the Parent from any third party on terms requiring any royalty payments or imposing other obligations on the Company; or

(iii) Cease to prosecute any current patent applications or other material Intellectual Property or fail to pay any patent or other Intellectual Property maintenance fees;

(g) Marketing or Other Rights. Except as set forth on Schedule 5.1(g) hereto, enter into or amend any agreement pursuant to which any other party is granted manufacturing, marketing or other development or distribution rights of any type or scope with respect to any of the Company's products or technology, or enter into any agreement that would limit the ability of any of the Surviving Corporation, the Parent or any Affiliate of the Parent to operate in a specific area of business or specific geographic area after the closing of the Merger.

(h) Dispositions; Obligations. Except for the sale of the Company's inventory in the ordinary course of business, sell, lease, license or otherwise dispose of or encumber any of its properties or assets which are material, individually or in the aggregate, taken as a whole, or, except for the incurrence of obligations in the ordinary course of business consistent with past practice, otherwise incur material obligations that would become obligations of the Parent upon the consummation of the Merger;

(i) Indebtedness. Incur any Indebtedness for borrowed money or guarantee any such Indebtedness or issue or sell any debt securities or guarantee any debt securities of others;

(j) Insurance. Materially reduce the amount of any material insurance coverage provided by existing insurance policies;

(k) Termination or Waiver. Terminate or waive any right of substantial value, other than in the ordinary course of business;

(l) Employee Benefit Plans; New Hires; Pay Increases. Except as set forth in Schedule 5.1(1), adopt or amend any employee benefit, pay or commit to pay any special bonuses or special remuneration to any employee or director, or, increase the salaries, bonuses or wage rates of its employees, except for increases in the ordinary course of business pursuant to periodic evaluations of employees;

(m) Severance Arrangements. Except as set forth in Schedule 5.1(m) or as otherwise explicitly contemplated by this Agreement, adopt or approve any severance, bonus or benefit acceleration arrangements (whether individually or more broadly) that could be triggered after the Agreement Date, including but not limited to after consummation of the Merger;

(n) Lawsuits. Commence a lawsuit other than (i) for the routine collection of bills, (ii) in such cases where it in good faith determines that failure to commence suit would result in the material impairment of a valuable aspect of its business, provided, that it consults with the Parent prior to the filing of such a suit, or (iii) with respect to this Agreement;

(o) Acquisitions. Acquire or agree to acquire by merging or consolidating with, or by purchasing a substantial portion of the assets of, or by any other manner, any business or any corporation, partnership, association or other business organization or division thereof which are material, individually or in the

aggregate, to the Company's business, taken as a whole;

(p) Taxes. Make or change any material election in respect of Taxes, adopt or request permission of any Taxation Authority to change any accounting method in respect of Taxes, enter into any closing agreement in respect of Taxes, settle any claim or assessment in respect of Taxes, surrender or allow to expire any right to claim a refund of Taxes, consent to any extension or waiver of the limitation period applicable to any claim or assessment in respect of Taxes, or take (or permit any Subsidiary to take) any such actions with respect to any Subsidiary;

(q) Notices. Fail to give any notices and other information required to be given to the employees of the Company, any collective bargaining unit representing any group of employees of the Company, or any applicable government authority for actions to be taken by the Company before the Closing Date under the Worker Adjustment and Retraining Act (the WARN Act), the National Labor Relations Act, the Code, the Consolidated Omnibus Reconciliation Act (COBRA), or other applicable law in connection with the transactions provided for in this Agreement;

(r) Other Transactions. Merge or consolidate with any entity other than the Parent, Merger Sub or an Affiliate of the Parent, or liquidate, dissolve or effect a recapitalization or reorganization in any form of transaction;

(s) Confidentiality Agreements. Hire, any employee or consultant having access to confidential or proprietary information of the Company unless such employee or consultant enters into, or has entered into, a proprietary information and inventions

agreement with the Company in the form of Exhibit C attached hereto or containing substantially similar confidentiality and assignment of inventions provisions, or amend or otherwise modify, or grant a waiver under, any such confidentiality or proprietary information agreement with any such person;

(t) Related Party Transactions. Enter into any transaction with any director, officer, employee, significant shareholder or family member of or consultant to any such person, corporation or other entity of which any such person beneficially owns 10% or more of the equity interests or has 10% or more of the voting power, or Subsidiary or Affiliate of the Company, except as approved by a majority of the disinterested directors of the Company Board on terms and conditions which are fair and reasonable to the Company and no less favorable to the Company as could be obtained from a third party on an arms-length basis;

(u) Principal Business. Materially participate in any business other than the Principal Business;

(v) Accounting; Accounts Receivable and Accounts Payable. Make any change in any method of accounting or accounting practice or policy other than those required by GAAP, or make any change in the Company's practices or procedures relating to collections and accounts payable or adopt any other material changes in their business policies and procedures, or manage the accounts payable of the Company other than in accordance with the Company's past practices;

(w) Other Activities. Knowingly engage in any other activity which could reasonably be expected to impair the ability of the Parent, the Merger Sub or the Company to consummate the Merger;

(x) Subsidiaries. Permit any Subsidiary of the Company to take any action from which the Company would be prohibited pursuant to this Section; or

(y) General. Authorize, commit to, agree to take, or permit to occur any of the foregoing actions.

5.2 Payment of Taxes, Etc. The Company shall, and shall cause each of its Subsidiaries to, timely file all of its material Tax Returns as they become due (taking all timely filed proper extension requests into account), all such Tax Returns to be true, correct and complete, and the Company shall, and shall cause each of its Subsidiaries to, timely pay and discharge as they become due and payable all material Taxes (other than Taxes contested in good faith by the Company or its Subsidiaries in appropriate proceedings), assessments and other governmental charges and levies imposed upon it or its income or any of its property that, if unpaid, may by law become a lien or charge upon its properties.

## ARTICLE 6
## ADDITIONAL AGREEMENTS

6.1 Notices; Consents; Filings. From and after the Agreement Date, the Company shall use its best efforts, at the Company's expense, to obtain the consents described in Section 3.23 of the Company Disclosure Schedule; provided, however that, without limiting the rights of Parent and Merger Sub under Section 7.2(h), the Company shall not be required to pay cash in exchange for such consents except to the extent required or contemplated by the terms of any agreement which requires such a consent. In the event that the Company shall fail to obtain any third party consent necessary for the consummation of the transactions contemplated hereby, the Shareholder Repre-

sentative shall use commercially reasonable efforts, and take any such actions reasonably requested by Parent, to minimize any adverse effect upon the Company, the Surviving Corporation and Parent, their respective Subsidiaries, and their respective businesses resulting, or which could reasonably be expected to result after the Effective Time, from the failure to obtain such consent.

6.2 HSR Act. In the event that Parent, the Company or any shareholder of Parent or the Company reasonably determines that it is required to make pre-merger notification filings (an "Antitrust Filing") under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"), and any corresponding law or regulation of any foreign Governmental Authority (a "Foreign Antitrust Filing") with respect to the Merger and the other transactions contemplated hereby such party shall promptly notify each other party of such requirement and thereafter each of the parties will:

(a) as promptly as is practicable, make its required filings under the HSR Act or any laws mandating a Foreign Antitrust Filing and in connection therewith seek early termination of any applicable waiting periods thereunder;

(b) as promptly as is practicable after receiving any governmental request under the HSR Act or any corresponding law or regulation of any foreign Governmental Authority for additional information, documents, or other materials, use its commercially reasonable best efforts to comply with such request;

(c) cooperate with the other in connection with resolving any governmental inquiry or investigation, whether domestic or foreign, relating to their respec-

tive HSR Act filings, Foreign Antitrust Filings, the Merger or any related inquiry or investigation;

(d) promptly inform the other of any communication with, and any proposed understanding, agreement, or undertaking with any governmental entity, whether domestic or foreign, relating to their respective HSR Act filings, Foreign Antitrust Filings, the Merger or any related inquiry or investigation;

(e) to the extent reasonably practicable, give the other reasonable advance notice of, and the opportunity to participate in (directly or through its representatives), any meeting or conference with any governmental entity, whether domestic or foreign, relating to their respective HSR Act filings, Foreign Antitrust Filings, the Merger or any related inquiry or investigation to the extent allowed by law; and

(f) pay any filing fees required to be paid in connection with such filings, if any, under the HSR Act or in connection with any Foreign Antitrust Filings.

6.3 Further Assurances.

(a) Following the Agreement Date, each of Parent and the Company will:

(i) use its best efforts to take, or cause to be taken, all appropriate action, and to do, or cause to be done, all things necessary, proper or advisable, including such actions as may be necessary, proper or advisable under applicable laws and regulations, to consummate and make effective the Merger and the transactions contemplated hereby, including using its commercially reasonable best efforts to obtain all permits, consents, approvals, authorizations, qualifications and orders of governmental authorities as are necessary for the consummation of the Merger and the

other transactions contemplated hereby and to fulfill the conditions set forth in Article 7; and

(ii) cooperate and use its best efforts to vigorously contest and resist any action, including administrative or judicial action, and to have vacated, lifted, reversed or overturned any decree, judgment, injunction or other order (whether temporary, preliminary or permanent) that is in effect and that restricts, prevents or prohibits consummation of the Merger and the other transactions contemplated hereby, including by vigorously pursuing all available avenues of administrative and judicial appeal.

(b) In case, at any time after the Effective Time, any further action is necessary or desirable to carry out the purposes of this Agreement, the proper officers and directors of each party to this Agreement shall use their commercially reasonable best efforts to take all such action.

(c) Notwithstanding the terms of Sections 6.2 or 6.3(a), nothing in the Agreement, shall require or be construed to require any party hereto, in order to obtain the consent or successful termination of any review of any Governmental Authority regarding the transactions contemplated hereby, to (i) sell or hold separate, or agree to sell or hold separate, before or after the Effective Time, any material assets, businesses or any interests in any assets or businesses, of Parent, the Company or any of their respective affiliates (or to consent to any sale, or agreement to sell, by Parent or the Company, of any assets or businesses, or any interests in any assets or businesses), or any change in or restriction on the operation by Parent or the Company of any assets or businesses, or (ii) enter into any agreement or be bound by any obligation that, in Parent's good faith exercise of reasonable business

judgment, may have a material adverse effect on the benefits to Parent of the transactions contemplated by this Agreement. In the event that any party hereto shall be required, in order to obtain the consent or successful termination of any review under the HSR Act regarding the transactions contemplated hereby, to take any of the actions set forth in part (i) or (ii) of the preceding sentence or if such consent or successful termination has not been obtained within 90 days following the initial pre-merger notification filings of the Parent and the Company with respect to the transactions contemplated hereby have been made under the HSR Act with the U.S. Department of Justice and Federal Trade Commission (the "HSR Filing Date"), Parent shall have the right to abandon its efforts to obtain approval under the HSR Act of the transactions contemplated hereby, notwithstanding Section 6.2 or 6.3(a). In the event that consent or successful termination under the HSR Act regarding the transactions contemplated hereby has not been obtained within 120 days following the HSR Filing Date, the Company shall have the right to abandon its efforts to obtain approval under the HSR Act of the transactions contemplated hereby, notwithstanding Section 6.2 or 6.3(a). If the Parent or Company so elects to abandon its efforts to seek such approval pursuant to one of the preceding two sentences, it shall promptly give notice of such abandonment to the other party.

6.4 Shareholder Approval. As soon as practicable following the Agreement Date, the Company will promptly solicit the approval by written consent of the execution and delivery by the Company of this Agreement, and the consummation of the transactions contemplated hereby, by Company Shareholders holding the requisite number of shares of each class of

the Company's capital stock required to approve the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby (the "Shareholder Approval"). Such solicitation shall be in the form of a proxy statement in a form to be mutually agreed upon by the Parent and the Company. The Company shall take all other action necessary or advisable to secure the vote or consent of shareholders required by California Law, if applicable, to obtain such approval.

6.5 Notice of Developments. Parent, on the one hand, and the Company, on the other hand, shall use reasonable efforts to give prompt written notice to the other party of any material development causing a breach of any of its own representations and warranties in this Agreement.

6.6 Exclusivity.

(a) From and after the Agreement Date until the Effective Time or termination of this Agreement pursuant to Article 8, the Company will not, nor will it authorize or permit any of its officers, directors, affiliates or employees or any investment banker, attorney or other advisor or representative retained by it to, directly or indirectly, (i) solicit, initiate or induce the making, submission or announcement of any Acquisition Proposal, (ii) participate in any discussions or negotiations regarding, or furnish to any person any non-public information with respect to, or take any other action to facilitate any inquiries or the making of any proposal that constitutes or may reasonably be expected to lead to, any Acquisition Proposal, (iii) engage in discussions with any person with respect to any Acquisition Proposal, except as to disclose the existence of these provisions, (iv) endorse or recommend any Acquisition Proposal, or (v) enter

into any letter of intent or similar document or any contract, agreement or commitment contemplating or otherwise relating to any Acquisition Proposal. The Company and its Subsidiaries will, and will cause their respective officers, directors, affiliates, employees, investment bankers, attorneys and other advisors and representatives to, immediately cease any and all existing activities, discussions or negotiations with any parties conducted heretofore with respect to any Acquisition Proposal. Without limiting the foregoing, it is understood that any violation of the restrictions set forth in the preceding two sentences by an officer or director of the Company or any of its Subsidiaries or any investment banker, attorney or other professional advisor of the Company or any of its Subsidiaries shall be deemed to be a breach of this Section 6.6 by the Company.

(b) In addition to the obligations of the Company set forth in Section 6.6(a), the Company as promptly as practicable shall advise Parent in writing of any Acquisition Proposal or of any request for nonpublic information or other inquiry which the Company reasonably believes could lead to an Acquisition Proposal, the material terms and conditions of such Acquisition Proposal (to the extent known), and the identity of the person or group making any such request, inquiry or Acquisition Proposal. The Company agrees to keep Parent informed on a current basis of the status and details (including any material amendments or proposed amendments) of any such request, inquiry or Acquisition Proposal.

6.7 Full Access. At all times from the Agreement Date until the earlier of the Effective Time or termination of this Agreement in accordance with Article 8, the Company will afford to Parent and its authorized

representatives, upon reasonable notice, full access during normal business hours to all properties, books, records, contracts and documents of the Company as Parent and such authorized representatives may reasonably request and a complete opportunity to make such investigations as Parent and such authorized representatives reasonably request, and the Company will furnish or cause to be furnished to Parent and its authorized representatives all such information with respect to the affairs and businesses of the Company as they may reasonably request to the extent allowed by law. All information obtained by Parent pursuant to this Section 6.7 shall be kept confidential in accordance with the Mutual Non-Disclosure Agreement, dated May 15, 2003 (the "Confidentiality Agreement"), between Parent and the Company. No investigation pursuant to this Section 6.7 shall affect any representation or warranty in this Agreement of any party hereto or any condition to the obligations of the parties hereto or thereto.

6.8 Certain Tax Matters. If the Company is obligated to make any payments, or is a party to any agreement that under certain circumstances could obligate it to make any payments, that will not be deductible under Section 280G of the Code if the shareholder approval requirements of Section 280G(b)(5)(B) are not satisfied and if that shareholder approval has not already been obtained, Parent agrees that it shall cooperate and assist the Company in obtaining the requisite shareholder approval described in Section 280G(b)(5)(B) of the Code, and the Company agrees that it shall use commercially reasonably efforts to obtain such shareholder approval promptly after the Agreement Date and in any event prior to the date on which the transactions contemplated by this Agreement are consummated.

6.9 Public Announcements. Prior to the closing of the Merger, the Parent shall not, without having previously informed the Company about the form, content and timing of any such announcement, issue any press release or otherwise make any public statements with respect to this Agreement or the transactions contemplated hereby, except as may be required by (a) law, (b) the SEC, (c) the Securities Act or the Exchange Act, or (d) any listing agreement with the Nasdaq National Stock Market, the National Association of Securities Dealers, Inc. or any national securities exchange to which the Parent is subject. Nothing herein express or implied shall require the Parent to consult with the Company following the closing of the Merger. The Company and the Company Shareholders shall not, without the prior written consent of the Parent, issue any press release or otherwise make any public statements with respect to this Agreement or the transactions contemplated hereby at any time.

6.10 Benefit Plans.

(a) Following the Effective Time, Parent shall arrange for each participant in the Company Benefit Plans (the "Company Participants") (including without limitation all dependents) who becomes a Parent employee (or an employee of any Parent subsidiary or Affiliate) after the Effective Time to be eligible for the same benefits in the aggregate as those received by Parent employees with similar positions and responsibilities, provided, that nothing in this Section 6.10(a) shall be deemed to require Parent to offer any particular Company Participants any particular benefit. Each Company Participant shall, to the extent permitted by law, applicable tax qualification requirements and the existing terms of the applicable

employee benefit plans, and subject to any applicable break in service or similar rule, receive credit for all purposes including, without limitation, for eligibility to participate, matching contributions, and vesting under Parent employee benefit plans for years of service with the Company (and its Subsidiaries and predecessors) prior to the Effective Time. If applicable and permitted by the relevant plan, Parent shall cause any and all pre-existing condition (or actively at work or similar) limitations, eligibility waiting periods and evidence of insurability requirements under any Parent employee benefit plans to be waived with respect to such Company Participants and their eligible dependents and shall provide them with credit for any co-payments, deductibles, and offsets (or similar payments) made during the plan year including the Effective Time for the purposes of satisfying any applicable deductible, out-of-pocket, or similar requirements under any Parent employee benefit plans in which they are eligible to participate after the Effective Time.

(b) Parent agrees that, from and after the Effective Time, the Company employees who become employees of Parent or any of its Subsidiaries or Affiliates may participate in the employee stock purchase plan sponsored by Parent (the "Parent ESPP"), subject to the terms and conditions of the Parent ESPP, and that service with the Company shall be treated as service with Parent or its Subsidiaries for determining eligibility of the Company's employees under the Parent ESPP.

6.11 Non-Competition Agreements. The Company shall use commercially reasonable best efforts to cause each of the Company's executive officers specified in Schedule 6.11 to execute and deliver a non-

competition agreement with Parent in the form attached hereto as Exhibit D-1.

6.12 Employment Agreements. The Company and Parent shall use commercially reasonable best efforts to cause the persons specified on Schedule 6.12 to enter into employment agreements in substantially the form attached hereto as Exhibit D-2. The principal terms of each such employment agreement shall be as specified on Schedule 6.12.

6.13 Debt Financing. Parent shall use its commercially reasonable best efforts to (i) negotiate, execute and deliver the MS Credit Agreement and all ancillary agreements thereto with Morgan Stanley containing terms substantially as set forth in the MS Commitment Letter and (ii) satisfy, or obtain a waiver of, all conditions applicable to Parent and within Parent's reasonable control in the MS Credit Agreement. Parent will keep the Company reasonably informed on a regular ongoing basis of the status of Parent's efforts to borrow an amount of funds at least equal to $250,000,000 pursuant to the MS Credit Agreement or otherwise (the "Debt Financing"). Notwithstanding the foregoing, nothing herein shall be interpreted to require Parent to seek to obtain the Debt Financing on terms that differ in any material respect from those set forth in the MS Commitment Letter. The Company shall provide all cooperation and assistance reasonably requested by Parent in connection with the Debt Financing.

6.14 Certain Antitrust Filings. Prior to the Closing Date or the termination of this Agreement pursuant to Section 8, Parent shall not enter into any agreement that would require Parent to file an Antitrust Filing under the HSR Act with respect any transaction contemplated by such agreement if such

Antitrust Filing would reasonably be expected to result in a material delay in the approval of or in the termination of any applicable waiting period for any Antitrust Filing filed with respect to the Merger and the other transactions contemplated by this Agreement.

6.15 Tail Insurance Coverage. The Company shall elect to purchase the "tail" or "extension" with a duration of at least five years under the product liability and general liability insurance policies in effect as of the Agreement Date and listed in Section 3.19 of the Company Disclosure Schedule to the extent permitted in accordance with the terms thereof.

## ARTICLE 7
## CONDITIONS TO THE MERGER

7.1 Conditions to the Obligations of Each Party. The obligations of the Company, Parent and Merger Sub to consummate the Merger are subject to the satisfaction of each of the following conditions:

(a) no order, stay, decree, judgment or injunction shall have been entered, issued or enforced by any court of competent jurisdiction which prohibits consummation of the Merger, and there shall not be any action taken by any Governmental Authority, or any statute, rule, regulation or order enacted, entered, enforced or deemed applicable to the Merger, which makes the consummation of the Merger illegal or substantially deprives Parent, the Company or the Participating Rights Holders of any of the anticipated benefits of the Merger or the related transactions, taken as a whole;

(b) all actions by or in respect of or filings with any Governmental Authority required to permit the consummation of the Merger in accordance with the

terms hereof, including but not limited to the expiration or early termination of the waiting period under the HSR Act, shall have been obtained (other than those actions or filings which, if not obtained or made prior to the consummation of the Merger, would not result in and could not be reasonably expected to result in a Material Adverse Effect on the Company prior to or after the Effective Time or a Material Adverse Effect on Parent after the Effective Time or be reasonably likely to subject the Company, Parent, Merger Sub, or any of their respective Subsidiaries or any of their respective officers or directors to substantial penalties or criminal liability); and

(c) the Shareholder Approval shall have been obtained.

7.2 Conditions to the Obligations of Parent and Merger Sub. The obligations of Parent and Merger Sub to consummate the Merger are subject to the satisfaction of the following further conditions (any one of which may be waived in whole or part by Parent in its sole discretion by giving written notice to the Company in compliance with Section 10.1 hereof):

(a) (i) the Company shall have performed all of its material obligations hereunder required to be performed by it at or prior to the Effective Time; and (ii) Parent shall have received a certificate dated as of the Closing Date and signed by the Company's President or Chief Executive Officer, certifying to the foregoing effect;

(b) (i) each of the representations and warranties of the Company contained in this Agreement shall have been true and correct (without regard to any qualifications to such representations and warranties as to materiality, Material Adverse Effect

of similar expressions) at the time originally made (as qualified by the Company Disclosure Schedule) and the representations and warranties made as of the Agreement Date shall be true and correct as of the Effective Time (as qualified by the Company Disclosure Schedule delivered on the Agreement Date), except for breaches of such representations and warranties that, individually or in the aggregate, would not and could not reasonably be expected to result in a Material Adverse Effect; and (ii) the Company shall deliver to Parent at the Closing a certificate, dated as of the date of the Closing and signed by the Company's President or Chief Executive Officer, certifying to that effect;

(c) no Material Adverse Effect with respect to the Company shall have occurred or been discovered by Parent since the Agreement Date;

(d) no injunction or other decree shall have been issued by any court of competent jurisdiction prohibiting the sale of the Company Products by the Company or Parent on the basis of any rights held by a third party (including without limitation any rights of any third party in any. Intellectual Property);

(e) Wilson Sonsini Goodrich & Rosati will have issued a legal opinion addressed to Parent in the form attached hereto as Exhibit E;

(f) the Company shall have delivered a properly executed statement, dated as of the Closing Date, in a form reasonably acceptable to Parent conforming to the requirements of Treasury Regulation Section 1.1445-2(c)(3);

(g) the Company shall have delivered to Parent and Merger Sub a certificate that sets forth (i) the information required to be set forth on Section 3.2

of the Company Disclosure Schedule, updated to reflect capitalization as of immediately prior to the Effective Time (giving effect to any conversion of shares of Company Preferred Stock to Company Common Stock that is made contingent upon the Closing), (ii) the Fully-Diluted Common Stock Number and the calculation thereof, and (iii) the aggregate exercise price for all Company Options and Company Warrants outstanding as of the Agreement Date (the "Capitalization Certificate"), which Capitalization Certificate shall be deemed to be representations and warranties of the Company hereunder;

(h) the Company shall have obtained those consents or approvals with respect to the consummation of the Merger of each person listed on Schedule 7.2(h);

(i) any and all rights, warrants, options or other instruments or rights to purchase shares of Company Common Stock or Company Preferred Stock (other than Company Options and Company Warrants, which shall be converted into the right to receive a portion of the Closing Payment Amount in accordance with Section 2.1) outstanding immediately prior to the Closing, whether or not exercisable, whether or not vested, and whether or not performance based, shall have been exercised or terminated

(j) holders of no more than 5.0% of the aggregate outstanding Company Common Stock and Company Preferred Stock (calculated on an as-converted to Company Common Stock basis) as of the Effective Time shall have elected to, or continue to have contingent rights to, exercise dissenters', appraisal or similar rights under California Law with respect to such shares; and

(k) the Company shall have delivered a certification to Parent, in form and substance (other than with respect to any amounts set forth thereon) satisfactory to Parent, setting forth the maximum amount of fees and expenses that each professional advisor engaged by the Company or its Board of Directors in connection with this Agreement or the Company's efforts to consummate an initial public offering of the Company Common Stock, consisting of Piper Jaffray, Wilson Sonsini Goodrich & Rosati and Ernst & Young, will charge with respect to the transactions contemplated hereby or the Company's efforts to consummate an initial public offering of the Company Common Stock (regardless of whether or not such fees and expenses have been billed to, or collected from, the Company) (each a "Transaction Cost Certificate"), and Parent shall have received such written assurances with respect to such amounts from Piper Jaffray and Wilson Sonsini Goodrich & Rosati as it shall reasonably request; and

(l) each holder of Company Warrants shall have executed and delivered a amendment, in form and substance reasonably satisfactory to Parent, to the Company Warrants held by such holder acknowledging such holder will receive the portion of the Closing Payment Amount calculated pursuant Section 2.1(c)(ii) in exchange for such Company Warrants; or, alternatively, for any holders who have not delivered such amendment, the Company Warrants held by such holders shall terminate no later than the Effective Time.

7.3 Conditions to the Obligations of the Company. The obligations of the Company to consummate the Merger are subject to the satisfaction of the following

further conditions (any one of which may be waived in whole or part by the Company):

(a) (i) Parent and Merger Sub shall have performed all of their respective material obligations hereunder required to be performed by them at or prior to the Effective Time; and (ii) the Company shall have received a certificate from each of Parent and Merger Sub, each signed by an executive officer of Parent or Merger Sub, as appropriate, to the foregoing effect;

(b) (i) each of the representations and warranties of the Parent and the Merger Sub contained in this Agreement shall have been true and correct at the time originally made (as qualified by the Parent Disclosure Schedule) and the representations and warranties made as of the Agreement Date shall be true and correct as of the Effective Time (as qualified by the Parent Disclosure Schedule delivered on the Agreement Date), except for breaches of such representations and warranties that, individually or in the aggregate, would not and could not reasonably be expected to result in a Material Adverse Effect; and (ii) the Company shall have received a certificate from each of Parent and Merger Sub, each signed by an executive officer of Parent or Merger Sub, as appropriate, certifying to that effect;

(c) no Material Adverse Effect with respect to the Parent shall have occurred or been discovered by Company since the Agreement Date which could reasonably be expected to result in the Parent being unable to consummate the Merger in accordance with the terms hereof on or before the Final Termination Date; and

(d) Bingham McCutchen LLP will have issued a legal opinion in the form attached hereto as Exhibit F.

ARTICLE 8
TERMINATION.

8.1 Termination. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time, notwithstanding any requisite approval and adoption of this Agreement and the transactions contemplated hereby by the Company Shareholders:

(a) by duly authorized mutual written consent executed by each of Parent, Merger Sub and the Company;

(b) by the Company if the Parent has not consummated the Debt Financing, or otherwise obtained cash in an amount sufficient to pay the aggregate amount payable in respect of the Merger at the Closing, on or before the later of the 30th day following the Agreement Date or the fifth (5th) business day following the date on which the conditions under Sections 7.1 and 7.2(a)(i), (b)(i), (c), (d), (h) and (j) have been satisfied and the Company has certified to the Parent that it could, as of such date, deliver each certificate or other document required from the Company by Sections 7.2(a)(ii), (b)(ii), (f), (g) and (k) (or in the case of Section 7.2(e), that Wilson Sonsini Goodrich & Rosati could deliver the document required by such section) (the "Company Financing Termination Date"), provided, that the right to terminate this Agreement under this Section 8.1(b) shall not be available to the Company if it is not exercised by the Company prior to the end of the day

on the fifth business day following the Financing Termination Date.

(c) by Parent, if the Parent has not consummated the Debt Financing, or otherwise obtained cash in an amount sufficient to pay the aggregate amount payable in respect of the Merger at the Closing, on or before the 30th day following the Agreement Date (the "Parent Financing Termination Date"), provided, that the right to terminate this Agreement under this Section 8.1(b) shall not be available to Parent unless the Debt Financing shall not have been consummated prior to the Financing Termination Date because Morgan Stanley shall have elected not to enter into the MS Credit Agreement or otherwise not consummate the Debt Financing as a result of either of the events described in clauses (b), (c) (as it relates to the Company only), and (d) of the last paragraph of page 2 of the MS Commitment Letter or any similar provision in the MS Credit Agreement.

(d) by Parent, or by the Company, if the Effective Time shall not have occurred before the 90th day following the Agreement Date (the "Final Termination Date"); provided, however, that (i) in the event that one or both of Parent and the Company (or any shareholder thereof) are required or deem it advisable to make an Antitrust Filing under the HSR Act, or under similar foreign statutes or regulations, or seek any other governmental approvals or authorizations as may be reasonably necessary in connection with the closing of the Merger, including any filings or notifications as may be reasonably necessary that are to be made under California Law, the Final Termination Date shall be delayed, without further action of the parties, until the tenth (10th) business day after, with respect to each necessary

approval or authorization, (x) the date on which any applicable waiting periods thereunder have expired or been terminated so that such approval or authorization is no longer required or (y) the date on which the necessary approval and authorization is received, as applicable and (ii) the right to terminate this Agreement under this Section 8.1(d) shall not be available to Parent in the event that the failure of the Effective Time to occur on or before such date arises out of or is related to Parent's failure to fulfill any obligation under this Agreement and the right to terminate this Agreement under this Section 8.1(d) shall not be available to the Company in the event that the failure of the Effective Time to occur on or before such date arises out of or is related to the failure by the Company to fulfill any obligation under this Agreement;

(e) automatically if there shall be any law that makes consummation of the Merger illegal or otherwise prohibited or if any court of competent jurisdiction or Governmental Authority shall have issued an order, decree, ruling or taken any other action restraining, enjoining or otherwise prohibiting the Merger and such order, decree, ruling or other action shall have become final and non-appealable;

(f) by Parent, by giving written notice to the Company at any time prior to the Closing in the event that the Company has given Parent any notice pursuant to Section 6.5 above, if the breach or breaches described in such notice would, individually or in the aggregate, render any condition to the Merger contained in Sections 7.1 or 7.2 hereof impossible of being satisfied;

(g) by the Company, by giving written notice to Parent at any time prior to the Closing in the event

that Parent has given the Company any notice pursuant to Section 6.5 above, if the breach or breaches described in such notice would, individually or in the aggregate, render any condition to the Merger contained in Sections 7.1 or 7.3 hereof impossible of being satisfied; or

(h) automatically, in the event that Parent or Company delivers notice of abandonment of its efforts under the HSR Act in accordance with Section 6.3(c).

8.2 Effect of Termination. Except as provided in Section 8.1 hereof, in the event of the termination of this Agreement pursuant to Section 8.1, this Agreement shall forthwith become void, there shall be no liability under this Agreement on the part of Parent, Merger Sub or the Company or any of their respective officers, directors, or shareholders, and all rights and obligations of any party hereto shall cease, except for liabilities arising from a breach of this Agreement prior to such termination.

## ARTICLE 9
## INDEMNIFICATION

9.1 Indemnification by Parent and the Surviving Corporation.

(a) Subject to the limitations set forth in Section 9.5 hereof, from and after the Effective Time, Parent and the Surviving Corporation, jointly and severally, will indemnify, defend and hold harmless each of the Company Shareholders, the Participating Rights Holders and each of their respective directors, officers, employees, representatives and other Affiliates (each such Indemnified Person a "Rights Holder Indemnitee"), from and against any and all Damages related to or arising out of or in connection with any breach by Parent or Merger Sub of any representation,

warranty, covenant, agreement, obligation, or undertaking made by Parent or Merger Sub in this Agreement (including any schedule or exhibit hereto), or any other agreement, instrument, certificate or other document delivered by or on behalf of Parent or Merger Sub in connection with this Agreement, the Merger, or any of the other transactions contemplated hereby.

(b) At all times after the Effective Time, each Company Shareholder and Participating Rights Holder shall be entitled to rely as third-party beneficiaries on the mutual promises of Parent and Merger Sub pursuant to this Agreement and the Escrow Agreement.

9.2 Indemnification of Parent by Resort to Escrow. Subject to the limitations set forth in Section 9.5 hereof, from and after the Effective Time, Parent, the Surviving Corporation, and each of their respective directors, officers, employees, representatives and other Affiliates (each such Indemnified Person a "Parent Indemnitee") shall be entitled to recover from the Escrowed Funds any and all Damages suffered by such Parent Indemnitee related to or arising out of or in connection with:

(a) any breach by the Company of any representation, warranty, covenant, agreement, obligation or undertaking made by such party in or pursuant to this Agreement, or any other agreement, instrument, certificate or other document delivered by or on behalf of the Company in connection with this Agreement, the Merger, or any of the other transactions contemplated hereby, including but not limited to the Capitalization Certificate;

(b) any actual liability of the Company, the Surviving Corporation or any of its Affiliates for death

or injury to person or property related to or arising out of the complaints described in Schedule 9.2(b) hereto only to the extent such Damages are not covered by insurance obtained by the Company prior to the Effective Time (collectively, "Product Liability Claims");

(c) any payments made by Parent, the Merger Sub or the Surviving Corporation after the Effective Time with respect to any Dissenting Shares to the extent that such payments exceed the portion of the Closing Payment Amount to which the holders of such Dissenting Shares would have been entitled had such Dissenting Shares not been Dissenting Shares, with any claims made pursuant to this Section 9.2(c) being referred to hereafter as the "Appraisal Claims";

(d) any lawsuit filed before the first anniversary of the Closing Date asserting claims or allegations that the development, manufacture, marketing, distribution or sale of the Company Products infringes or violates any patent rights or patents of third parties (collectively "Specified Intellectual Property Claims"); or

(e) any amounts which the Parent is required to pay in respect of fees, expenses and other costs incurred in respect of professional advisors engaged by the Company in connection with this Agreement and the transactions contemplated hereby, or the Company's efforts to consummate an initial public offering of the Company Common Stock (including any fees and expenses of legal counsel, outside auditors and financial advisors retained by the Company or its Board of Directors); but only to the extent that such costs and expenses exceed the aggregate total of the maximum amounts specified in the Transaction Cost Certificate (such aggregate total being the "Aggregate

Maximum Transaction Cost" and such claims collectively constituting the "Transaction Cost Claims").

9.3 Third-Party Claims.

(a) In the event that any Rights Holder Indemnitee desires to make a claim against an Indemnifying Party (which term shall be deemed to include all Indemnifying Parties if more than one) or in the event that any Parent Indemnitee desires to make a claim against the Escrowed Funds in connection with any third-party litigation, arbitration, action, suit, proceeding, claim or demand at any time instituted against or made upon it for which it may seek indemnification hereunder (a "Third-Party Claim"), the Indemnified Person will promptly notify the Indemnification Control Person of such Third-Party Claim and of its claims of indemnification with respect thereto; provided, that failure to promptly give such notice will not relieve the Indemnifying Party of its indemnification obligations under this Section 9.3, except to the extent, if any, that the person or persons represented by the Indemnification Control Person have actually been prejudiced thereby.

(b) The Indemnification Control Person will have the right to assume the defense of the Third-Party Claim with counsel of its choice reasonably satisfactory to the Indemnified Person by written notice to the Indemnified Person within twenty (20) days after the Indemnification Control Person has received notice of the Third-Party Claim; provided, however, that the Indemnification Control Person must conduct the defense of the Third-Party Claim actively and diligently thereafter in order to preserve the rights of the person or persons represented by the Indemnification Control Person in this regard; and provided, further, that the Indemnified Person may

retain separate co-counsel at its sole cost and expense and participate in the defense of the Third-Party Claim.

(c) The Indemnification Control Person will not consent to the entry of any judgment or enter into any settlement with respect to the Third-Party Claim without the prior written consent of the Indemnified Person (which consent will not be unreasonably conditioned, withheld or delayed) unless the judgment or proposed settlement (i) includes an unconditional release of all liability of each Indemnified Person with respect to such Third-Party Claim, and (ii) involves only the payment of money damages that are fully covered by the Indemnifying Party (or fully covered by amounts paid pursuant to Section 9.4 by distribution of amounts to Parent Indemnitees from Escrowed Funds) and does not impose an injunction or other equitable relief upon the Indemnified Person. So long as the Indemnification Control Person has assumed and is conducting the defense of the Third-Party Claim in accordance with Section 9.3(b) above, the Indemnified Person will not consent to the entry of any judgment or enter into any settlement with respect to the Third-Party Claim without the prior written consent of the Indemnification Control Person (which consent will not be unreasonably conditioned, withheld or delayed).

(d) In the event that the Indemnification Control Person fails to assume the defense of the Third-Party Claim in accordance with Section 9.3(b) above, (i) the Indemnified Person may defend against, and consent to the entry of any judgment or enter in to any settlement with respect to, the Third-Party Claim in any manner it reasonably may deem appropriate (and the Indemnified Person need not consult

with, or obtain any consent from, the Indemnification Control Person in connection therewith), and (ii) the Indemnifying Party will remain responsible (or, as applicable, the Parent Indemnitee may claim and recover from the Escrowed Funds) for any Damages the Indemnified Person may suffer as a result of such Third-Party Claim to the extent subject to indemnification under this Article 9.

(e) Notwithstanding the foregoing, Parent and the Surviving Corporation shall be responsible for the prosecution and defense of any claims relating to the Intellectual Property of the Company (collectively, the "Parent-Handled Claims"). Parent and the Surviving Corporation shall pursue in good faith, through counsel of their selection, the prosecution or defense of all Parent-Handled Claims until such time, if any, that Parent shall elect not to pursue indemnification with respect to such Third-Party Claim.

(f) Parent shall, to the extent that Parent and the Surviving Corporation are entitled to indemnification for Damages pursuant to this Article 9 and it could reasonably be expected that Parent may recover a substantial portion of the Damages relating to such Parent-Handled Claim pursuant to this Article 9, (i) provide the Shareholder Representative with access to appropriate employees of Parent and the Surviving Corporation for the purpose of discussing matters relating to Parent-Handled Claims as the Shareholder Representative may from time to time reasonably request, (ii) permit the Shareholder Representative, upon its reasonable request, to participate in the process of any settlement or other resolution of any Parent-Handled Claims pursuant to this Article 9; and (iii) secure the written consent of the Shareholder Representative before settling any Parent-Handled

Claim (which consent shall not be unreasonably withheld, delayed or conditioned).

9.4 Payment of Claims. In the event of any bona fide claim for indemnification hereunder, the Indemnified Person will advise the Indemnification Control Person in writing, advising the Indemnification Control person of the amount of the claim and, with reasonable specificity, the circumstances surrounding the claim. With respect to liquidated claims for Damages, if within thirty (30) days the Indemnification Control Person has neither objected nor contested to such claim in writing, the Indemnifying Party will pay the full amount thereof (or in the case of a claim by an Parent Indemnitee against the Escrowed Funds, such Parent Indemnitee shall recover the full amount thereof from the Escrowed Funds), subject to the limitations set forth in Section 9.5. If the Indemnification Control Person objects to such claim in writing within such thirty-day period, the objection will be resolved pursuant to the procedures in the Escrow Agreement. All recoveries from Escrowed Funds shall be made on a *pro rata* basis from the amounts that would otherwise be released from the Escrowed Funds to the Participating Rights Holders. The parties agree that to the greatest extent possible the payment of any indemnity hereunder shall be treated as an adjustment to the Closing Payment Amount paid by Parent hereunder for Tax purposes. Indemnification obligations of Parent and the Merger Sub shall be satisfied by the Parent in cash. Except in the case of fraud, resort to indemnification pursuant to this Article 9 through claims against the Escrowed Funds shall be the sole remedy of Parent and Merger Sub and any other Parent Indemnitee with respect to any and all Damages related to or arising out of or in connection with

(i) any breach by Company of any representation, warranty, covenant, agreement, obligation or undertaking made by the Company in or pursuant to this Agreement or any other agreement, instrument, certificate or other document delivered by or on behalf of the Company in connection with this Agreement, or (ii) any other claim, for indemnification or otherwise, arising out of or related to the subject matter of this Agreement or any other agreement, instrument, certificate or other document delivered by or on behalf of the Company in connection with this Agreement.

9.5 Limitations of Liability.

(a) Deductible. No Indemnifying Party will be required to indemnify an Indemnified Person and no claim may be made against the Escrowed Funds hereunder until such time as the amount of Damages for which (i) all Parent lndemnitees, on the one hand, or (ii) all Rights Holder Indemnitees, on the other hand, are otherwise entitled to indemnification pursuant to this Agreement exceeds $500,000 in the aggregate for all such Damages, and then only to the extent such aggregate amount exceeds $500,000. No Indemnifying Party will be required to indemnify any Rights Holder Indemnitee hereunder with respect to any claim for Damages unless the amount of Damages for which all Rights Holder Indemnitees are entitled for such claim exceeds $50,000 in the aggregate. No claim may be made against Escrowed Funds by any Parent Indemnitee unless the amount of Damages for which all Parent Indemnitees are entitled from such claim exceeds $50,000 in the aggregate. Notwithstanding anything to the contrary in this Section 9.5, the minimum claim limit and deductible imposed by this Section 9.5(a) shall not apply to any Damages arising out of or in connection with (A) any breach by the

Company of any Special Representations, (B) any Special Claims, or (C) fraud, nor shall any such Damages be counted against the foregoing deductible.

(b) Maximum Recovery.

(i) The parties specifically agree that, notwithstanding any provision of this Agreement to the contrary, the maximum aggregate recovery by all Parent Indemnitees from the Escrowed Funds for indemnification under this Article 9, except in the case of fraud, will not exceed a maximum amount equal to the amount of the Initial Escrow Amount originally deposited into escrow pursuant to the Escrow Agreement. The parties specifically agree that, notwithstanding any provision of this Agreement to the contrary, the maximum recovery of all Rights Holder Indemnitees from the Parent under this Article 9, except in the case of fraud, will not exceed a maximum amount equal to the amount of the Initial Escrow Amount originally deposited into escrow pursuant to the Escrow Agreement.

(ii) As a further limitation, any claims of Parent Indemnitees against the Escrowed Funds for indemnification under this Article 9 with respect to Specified Intellectual Property Claims shall not exceed $10,000,000 in the aggregate for all such Specified Intellectual Property Claims (the "Specified Intellectual Property Claims Cap"), and as a further limitation, shall not exceed $7,000,000 with respect to Specified Intellectual Property Claims related to any single third party (taken together with all of its affiliates and related persons and entities) (the "Specified Intellectual Property Claims Per Claim Cap"). Notwithstanding the foregoing, the Specified Intellectual Property Claims Cap shall be reduced to $7,000,000, until such time (if ever) before the first

anniversary of the Closing Date that a third party specified on Schedule 9.2(d) hereto files a lawsuit that results in a Specified Intellectual Property Claim; after such a claim is filed (if ever), the Specified Intellectual Property Claims Cap shall be increased to $10,000,000, however, the Specified Intellectual Property Claims Per Claim Cap will remain at $7,000,000.

(iii) As a further limitation, with respect to any Product Liability Claims, Parent and the Surviving Corporation must use commercially reasonable efforts to seek reimbursement from applicable insurance policies and first apply insurance proceeds from applicable insurance policies to any Damages related to Product Liability Claims; thereafter, once such insurance proceeds, if any, are exhausted, any Parent Indemnitee may make a claim against the Escrowed Funds for Damages related to Product Liability Claims; provided, however that Parent Indemnitees shall not be entitled to recover an amount with respect to such claims in excess of $5,000,000 in the aggregate (the "Product Liability Claims Cap"). Notwithstanding the foregoing, unless an insurance carrier has paid the Product Liability Claims to the extent of insurance coverage limits or confirmed in writing that it will cover the Known Claims to the extent of insurance coverage limits, without reservations other than customary limited exclusions that do not reference specific facts or circumstances that the applicable carrier has identified as a potential basis for the denial of coverage, after making claims for indemnification that would exceed the Product Liability Claims Cap, any Parent Indemnitee may make a further claim against the Escrowed Funds for Damages related to any Product Liability Claim not defended by an insurance carrier; provided, however that such claims

shall be limited to a portion of the Escrowed Funds (distinct from and in addition to the Product Liability Claims Cap portion) not to exceed an additional $5,000,000 in the aggregate, less any amounts that have been paid by insurance in respect of Product Liability Claims (the "Supplemental Product Liability Claims Cap"). For avoidance of doubt, the purpose of the Supplemental Product Liability Claims Cap portion of the Escrowed Funds is to provide a remedy for the Parent if the Company's existing insurance carriers determine pursuant to applicable insurance policies not to cover the Product Liability Claims to the extent of insurance coverage limits, and it is the intent of the parties that such Supplemental Product Liability Claims Cap will not be available to Parent if insurance coverage for Product Liability Claims is available.

(c) Time Limit. All representations and warranties in this Agreement shall survive the Closing and shall expire on, and no Indemnifying Party will be liable for any Damages hereunder and no claim may be made against the Escrowed Funds with respect to a breach of such representations and warranties unless a written claim for indemnification is given by the Indemnified Person to the Indemnification Control Person with respect thereto prior to, the first anniversary of the Closing Date (the "Claim Deadline"). The right to make claims for indemnification, shall expire as of the Claim Deadline, except with respect to claims (i) that have been duly noticed before Claim Deadline and (ii) for which a reserve from the Escrowed Funds has been duly established, each of (i) and (ii) in accordance with this Agreement and the Escrow Agreement, as applicable, provided, that notwithstanding the foregoing, the right of Parent to make claims for indemnification with respect to a Product

Liability Claim shall survive until the sixtieth (60th) day following the final resolution, including but not limited to by way of final settlement agreement of all of the parties or issuance of an order of a court having jurisdiction over the matter which is final and not subject to further court proceedings or appeal, of the matter underlying such Product Liability Claim.

(d) No Liability of Company Shareholders, Participating Rights Holders or Shareholder Representative. Notwithstanding anything to the contrary in this Agreement and for purposes of clarification, except in the case of fraud, the liability of the Participating Rights Holders, including indemnification obligations, under this Agreement shall be limited to the Escrowed Funds; and, once amounts held pursuant to the Escrow Agreement are released to the Participating Rights Holders pursuant to the terms of the Escrow Agreement, Parent, the Surviving Corporation and any Affiliates thereof and any other Parent Indemnitees shall have no further claim to the amount thereof from the Participating Rights Holders, except in the case of fraud. Without limiting the ability of the Parent to recover from the Escrowed Funds in accordance with this Article 9, and except in the case of fraud, nothing in this Agreement shall cause the Shareholder Representative or Participating Rights Holders to become personally liable for any indemnification claim pursuant to the provisions of this Article 9.

9.6 Right to Bring Action; No Contribution. Notwithstanding anything in this Article 9 or elsewhere in this Agreement to the contrary, only the Shareholder Representative shall have the right, power and authority to commence any action, suit or proceeding, including any arbitration proceeding, by

and on behalf of any or all Participating Rights Holders against Parent or the Surviving Corporation or any other Indemnified Person in connection with the Agreement and the Escrow Agreement and the transactions contemplated herebyand thereby, and in no event shall any Participating Rights Holder himself, herself or itself have the right to commence any action, suit or proceeding, including any arbitration proceeding, against Parent or the Surviving Corporation, or any other Indemnified Person in such connection. By virtue of the adoption of this Agreement and the approval of the Merger by the Company Shareholders, each Participating Rights Holder (regardless of whether or not such Participating Rights Holder votes in favor of the adoption of the Agreement and the approval of the Merger, whether at a meeting or by written consent in lieu thereof) shall be deemed to have waived, and shall be deemed to have acknowledged and agreed that such Participating Rights Holder shall not have and shall not exercise or assert (or attempt to exercise or assert), any right of contribution, right of indemnity or other right or remedy against Surviving Corporation in connection with any indemnification obligation or any other liability to which he may become subject under or in connection with this Agreement.

## ARTICLE 10

## GENERAL PROVISIONS

10.1 Notices. All notices, claims and demands hereunder, and all other communications which are required to be given in writing pursuant to this Agreement, shall be in writing and shall be given (and shall be deemed to have been duly given upon receipt) by delivery in person or facsimile (received at the facsimile machine to which it is transmitted prior

to 5 p.m., local time, on a business day for the party to which it is sent, or if received after 5 p.m., local time, as of the next business day) or by registered or certified mail (postage prepaid, return receipt requested) to the respective parties at the following addresses (or at such other address for a party as shall be specified in a notice given in accordance with this Section 10.1):

if to Parent or Merger Sub:

Cytyc Corporation
85 Swanson Road
Boxborough, MA 01719
Attention: Vice President — Corporate Development
Facsimile: (978) 266-3008

with a copy to:

Bingham McCutchen LLP
150 Federal Street
Boston, Massachusetts 02110
Attention: Johan V. Brigham, Esq.
Facsimile: (617) 951-8736

if to the Company:

Novacept, Inc.
1047 Elwell Court
Palo Alto, California 94303 Attention: President
Facsimile: (650) 335-2613

with a copy to:

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
Attention: Christopher D. Mitchell, Esq.
Facsimile: (650)-493-6811

and if to the Shareholder Representative:

David Clapper
860 Hobart Street
Menlo Park, CA 94025
Facsimile: (650)-493-6811 (c/o Chris Mitchell)

and:

Edward Unkart
6 Valley Oak
Portola Valley, CA 94028
Facsimile: (650)-493-6811 (c/o Chris Mitchell)

with a copy to:

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
Attention: Christopher D. Mitchell, Esq.
Facsimile: (650) 493-6811

10.2 Certain Definitions. For purposes of this Agreement, the term:

"Acquisition Proposal" means any bona fide offer or proposal (other than an offer or proposal by Parent) relating to any Acquisition Transaction.

"Acquisition Transaction" means (a) any transaction or series of related transactions other than the transactions contemplated by this Agreement involving the purchase of all or any significant portion of the capital stock or assets of the Company, (b) any agreement to enter into a business combination with the Company, (c) any agreement made, other than in the ordinary course of business, with regard to the Intellectual Property owned or licensed by the Company, and (d) any other extraordinary business transaction involving or otherwise relating to the Company or any Intellectual Property owned or licensed by the Company.

"Affiliate" means, with respect to any person, any person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such person. Until the consummation of the Merger, the Company shall not be deemed for any purposes of this Agreement to be an Affiliate of the Parent.

"Closing Payment Amount" means the amount of (i) $325,000,000, plus (ii) the aggregate exercise price of all Company Options and Company Warrants outstanding and unexercised immediately prior to the Effective Time; and minus (iii) the Aggregate Maximum Transaction Cost.

"Code" means the Internal Revenue Code of 1986, as amended.

"Company Licensed Intellectual Property" means all Intellectual Property licensed to the Company or any of its Subsidiaries by any third party.

"Company Owned Intellectual Property" means all Intellectual Property owned by the Company or any of its Subsidiaries.

"Company Products" means the Company's NovaSure impedance controlled endometrial ablation system in its current configuration, together with all enhancements thereto currently under development.

"Company Warrant" means each unexercised right, warrant or option to purchase Company Common Stock or Company Preferred Stock listed in Section 3.2(f) of the Company Disclosure Schedule or the Capitalization Certificate.

"Conversion Rate", with respect to any series of Company Preferred Stock, means at any point in time the number of shares of Company Common Stock into

which each share of such Company Preferred Stock may be converted pursuant to the then effective Restated Articles.

"Damages" means all damages, losses, costs, and expenses incurred or suffered, or that are reasonably likely to be incurred or suffered, by a party with respect to or relating to an event, circumstance or state of facts. Damages shall specifically include court costs and the reasonable fees and expenses of legal counsel arising out of or relating to any direct or third-party claims, demands, actions, causes of action, suits, litigations, arbitrations or liabilities.

"Environmental Law" means any judgment, decree, order, law license, rule or regulation pertaining to environmental matters, including those arising under any federal, state or local statute, regulation, ordinance, order or decree relating to the environment or exposure to a Hazardous Substance.

"Environmental Permit" means all material permits, licenses and other authorizations required under any Environmental Law.

"Escrowed Funds" means the amounts delivered to the Escrow Agent pursuant to the provisions of Section 1.5 hereof less any such amounts distributed to the Participating Rights Holders or to any Parent Indemnitee by the Escrow Agent in accordance with this Agreement or the Escrow Agreement.

"Exchange Act" means the Securities Exchange Act of 1934, as amended.

"FDA" means the United States Food and Drug Administration.

"Financial Statements" means (a) the audited consolidated financial statements (including balance

sheet, income statement and statement of cash flows) as of and for the year ended December 31, 2003, and with respect to representations made as of the Closing Date also means (b) the unaudited consolidated financial statements (including balance sheet, income statement and statement of cash flows) as of the end of the most recently completed fiscal quarter prior to the Closing Date, and for the portion of the current fiscal year ended on such date, each of which the Company has made available to the Parent or its counsel and included in the Company Disclosure Schedule.

"Fully-Diluted Common Stock Number" means (i) the number of shares of Company Common Stock outstanding immediately prior to the Effective Time (including Dissenting Shares and any shares of Company Stock that would be issued upon conversion of any shares of Company Preferred Stock that have elected to be, or are required to be, converted into Company Common Stock as of immediately prior to the Effective Time in connection with the Merger), plus (ii) the maximum number of shares of Company Common Stock issuable upon exercise of unexercised Company Options and Company Warrants outstanding immediately prior to the Effective Time, and minus (iii) any shares of Company Common Stock, Company Preferred Stock, Company Options or Company Warrants (all calculated similarly as above) held by the Company or any Subsidiary of the Company or by Parent or any Affiliate of Parent. For the purposes of this calculation, the number of shares of Company Common Stock issuable upon exercise of any Company Warrants exercisable for Company Preferred Stock shall be deemed to be such number of shares of Company Preferred Stock multiplied by the

conversion ratio for the applicable series of Company Preferred Stock.

"GAAP" means United States generally accepted accounting principles consistently applied.

"Governmental Authority" (whether such term is capitalized or not) means any United States (federal, state or local) or foreign government, or governmental, regulatory or administrative authority, agency or commission.

"Hazardous Substance" means (a) those substances defined in or regulated under the following federal statutes and their state counterparts and all regulations thereunder: the Hazardous Materials Transportation Act, the Resource Conservation and Recovery Act, the Comprehensive Environmental Response, Compensation and Liability Act, the Clean Water Act, the Safe Drinking Water Act, the Atomic Energy Act, the Federal Insecticide, Fungicide, and Rodenticide Act and the Clean Air Act; (b) petroleum and petroleum products, including crude oil and any fractions thereof; (c) natural gas, synthetic gas, and any mixtures thereof; (d) polychlorinated biphenyls, asbestos and radon; and (e) any substance, material or waste regulated by any federal, state, local or foreign Governmental Authority pursuant to any Environmental Laws.

"Indebtedness" means, as applied to any person, (a) all indebtedness for borrowed money, whether current or funded, or secured or unsecured, (b) all indebtedness for the deferred purchase price of property or services represented by a note or other security, (c) all indebtedness created or arising under any conditional sale or other title retention agreement with respect to property acquired (even though the

rights and remedies of the seller or lender under such agreement in the event of default are limited to repossession or sale of such property), (d) all indebtedness secured by a purchase money mortgage or other lien to secure all or part of the purchase price of property subject to such mortgage or lien, (e) all obligations under leases which shall have been or must be, in accordance with GAAP, recorded as capital leases in respect of which such person is liable as lessee, (f) any liability in respect of banker's acceptances or letters of credit, and (g) all indebtedness referred to in clauses (a), (b), (c), (d), (e) or (f) above which is directly or indirectly guaranteed by or which such person has agreed (contingently or otherwise) to purchase or otherwise acquire or in respect of which it has otherwise assured a creditor against loss.

"Indemnification Control Person" means (i) in the event of a claim by a Rights Holder Indemnitee, the Parent or (ii) in the event of a claim made by a Parent Indemnitee against the Escrowed Funds, the Shareholder Representative.

"Indemnifying Party" means any person against whom indemnification may be sought pursuant to the provisions of Article 9.

"Indemnified Person" means any person entitled to seek indemnification pursuant to the provisions of Article 9.

"Intellectual Property" means intellectual property or proprietary rights of any description including (a) rights in any patent, patent application (including any provisionals, continuations, divisions, continuations-in-part, extensions, renewals, reissues, revivals and reexaminations, any national phase PCT applications,

any PCT international applications, and all foreign counterparts), copyright, industrial design, URL, domain name, trademark, service mark, logo, trade dress or trade name, (b) related registrations and applications for registration, (c) trade secrets, moral rights or publicity rights, and (d) inventions, discoveries, or improvements, modification, know-how, technique, methodology, writing, work of authorship, design or data, whether or not patented, patentable, copyrightable or reduced to practice, including any inventions, discoveries, improvements, modification, know-how, technique, methodology, writing, work of authorship, design or data embodied or disclosed in any: (i) computer source code (human-readable format) and object code (machine-readable format); (ii) specifications; (iii) manufacturing, assembly, test, installation, service and inspection instructions and procedures; (iv) engineering, programming, service and maintenance notes and logs; (v) technical, operating and service and maintenance manuals and data; (vi) hardware reference manuals; and (vii) user documentation, help files or training materials.

"knowledge" of the Company or any Subsidiary whether or not capitalized means the actual knowledge of David Clapper, Edward Unkart, Russ Sampson, Eugene Skalnyi and Donald Nathe.

"Material Adverse Effect" means with respect to the Company or Parent, as the case may be, any change or effect that, when taken individually or together with all other adverse changes or effects, materially adversely effects the business, results of operations and financial condition of the Company or Parent, as the case may be, together with their respective Subsidiaries, taken as a whole; provided, however that any event or occurrence resulting from the announce-

ment or pendency of the Merger, this Agreement and the transactions contemplated hereby shall not be deemed to result in a Material Adverse Effect; provided, further, however that any event or occurrence resulting from (i) changes in general economic or political conditions, (ii) changes in law, regulation or policy or (iii) changes in the healthcare industry generally, the medical device industry generally or the market for products and procedures for the treatment of excessive menstrual bleeding in particular shall not be deemed to result in a Material Adverse Effect, unless in any such instance such change described in (i), (ii) or (iii) above impacts the Company in a materially disproportionate manner relative to a preponderance of other entities impacted by such change.

"PBGC" means the Pension Benefit Guaranty Corporation.

"Participating Rights Holders" means those persons (other than the holders of Dissenting Shares, the Company, Parent or any Subsidiary of the Company or Parent) who, immediately prior to the Effective Time of the Merger, were holders of shares of Company Common Stock, Company Preferred Stock, Company Options or Company Warrants and whose interests therein, as the result of the Merger, are converted into rights to receive a portion of the Closing Payment Amount.

"Per Share Common Closing Payment" means the amount equal to the quotient obtained by dividing (x) the amount of the Closing Payment Amount minus the Preferred Closing Payment Amount, and minus the Representative Reimbursement Amount, by (y) the Fully-Diluted Common Stock Number.

"Per Share Preferred Closing Payment" means, with respect to each share of any series of Company Preferred Stock outstanding immediately prior to the Effective Time (other than any shares of Company Preferred Stock held by Parent and any shares of Company Preferred Stock converted into Common Stock immediately prior to the Effective Time in connection with the Merger), the portion of the Closing Payment Amount allocable to such share, in preference to any share of Company Common Stock or other series of Preferred Stock, pursuant to the Company's Restated Articles as in effect immediately prior to the Effective Time.

"Preferred Closing Payment Amount" means an amount equal to the sum of all Per Share Preferred Closing Payments for all series of Company Preferred Stock.

"Principal Business" means the design, development, manufacture, marketing and sale of the Company Products.

"Restated Articles" means the Amended and Restated Articles of Incorporation of the Company.

"SEC" means the United States Securities and Exchange Commission.

"Securities" means all shares of Company Common Stock and Company Preferred Stock, all outstanding options, warrants, convertible notes, rights of conversion and other rights to acquire capital stock of the Company, and all shares issuable upon exercise or conversion of the Company Preferred Stock, options, warrants, convertible notes, rights of conversion and other rights to acquire stock of the Company, outstanding from time to time, whether or not then currently vested, exercisable or convertible.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Securityholder" means any holder of Securities.

"Shareholder Representative" means the individual appointed to serve as such under Section 2.5.

"Special Claims" means any Tax Claims, Appraisal Claims, Product Liability Claims and Transaction Cost Claims.

"Special Representations" means any representations or warranties relating to Section 3.2 of this Agreement or representations or warranties contained in the Capitalization Certificate.

"Subsidiary or Subsidiaries" (whether or not capitalized) of any person means any corporation, partnership, limited liability company, association, trust, joint venture or other legal entity of which such person (either above or through or together with any other Subsidiary), owns, directly or indirectly, more than 50% of the stock or other equity interests the holders of which are generally entitled to vote for the election of the board of directors or other governing body of such corporation or other legal entity.

"Tax" or "Taxes" (and with correlative meaning, "Taxable" and "Taxing") means any United States federal, state or local, or non-United States, income, gross receipts, franchise, estimated, alternative minimum, add-on minimum, sales, use, transfer, registration, value added, excise, natural resources, severance, stamp, withholding, occupation, premium, windfall profit, environmental, customs, duties, real property, personal property, capital stock, net worth, intangibles, social security, unemployment, disability,

payroll, license, employee or other tax or similar levy, of any kind whatsoever, including any interest, penalties or additions to tax in respect of the foregoing.

"Taxation Authority" means any Governmental Authority having any responsibility for (a) the determination, assessment or collection or payment of any Tax, or (b) the administration, implementation or enforcement of or compliance with any law relating to any Tax.

"Tax Claims" means a claim resulting from any breach of any representation or warranty in Section 3.24 of this Agreement or any covenant in Sections 5.1(p), 5.2, or 6.8 of this Agreement;

"Tax Return" means any return, declaration, report, claim for refund, information return or other document (including any related or supporting estimates, elections, schedules, statements or information) filed or required to be filed in connection with the determination, assessment or collection of any Tax or the administration of any laws, regulations or administrative requirements relating to any Tax.

The following table sets forth certain other defined terms and the Section of the Agreement in which the meaning of each such term appears:

| | Section(s) |
|---|---|
| "Activities to Date" | 3.21(a) |
| "Agreement" | Preamble |
| "Aggregate Maximum Transaction Cost" | 9.2(e) |
| "Agreement Date" | Preamble |
| "Antitrust Filing" | 6.2 |
| "Appraisal Claims" | 9.2(c) |

| | Section(s) |
|---|---|
| "California Law" | Preamble |
| "Capitalization Certificate" | 7.2(i) |
| "Certificates" | 2.2(a)(i) |
| "Claim Deadline" | 9.5(c) |
| "Closing" | 1.1(b) |
| "Closing Date" | 1.1(b) |
| "Company" | Preamble |
| "Company Board" | Preamble |
| "Company Common Stock"- | Preamble |
| "Company Disclosure Schedule" | Article 3 |
| "Company Financing Termination Date" | 8.1(b) |
| "Company Licenses" | 3.21(a) |
| "Company Option" | 2.1(c) |
| "Company Option Plan" | 2.1(c) |
| "Company Participants" | 6.10(a) |
| "Company Preferred Stock" | Preamble |
| "Company Shareholders" | Preamble |
| "Company Warrant" | 2.1(c)(ii) |
| "Confidentiality Agreement" | 6.7 |
| "Debt Financing" | 6.13 |
| "Derivative Instruments" | 2.2(a)(i) |
| "Dissenting Shares" | 2.4(a) |
| "Effective Time" | 1.1(b) |
| "Employee Benefit Plan" | 3.20(a) |

| | Section(s) |
|---|---|
| "Escrow Agent" | 1.5(b) |
| "Escrow Agreement" | 1.5(b) |
| "Final Termination Date" | 8.1(d) |
| "Foreign Antitrust Filing" | 6.2 |
| "HIPPA" | 3.14 |
| "HSR Act" | 6.2 |
| "HSR Filing Date" | 6.3(c) |
| "Initial Escrow Amount" | 1.5(b) |
| "Joint Representative" | 2.5(a) |
| "Merger" | Preamble |
| "Merger Document" | 1.1(b) |
| "Merger Sub" | Preamble |
| "MS Commitment Letter" | 4.5 |
| "MS Credit Agreement" | 4.5 |
| "Notified Party" | 3.9(g) |
| "Option Shares" | 2.1(c) |
| "Parent" | Preamble |
| "Parent ESPP" | 6.10(b) |
| "Parent Financing Termination Date" | 8.1(c) |
| "Parent-Handled Claims" | 9.3(e) |
| "Parent Indemnitee" | 9.2 |
| "Permits" | 3.14 |
| "Product Liability Claims" | 9.2(b) |
| "Product Liablity Claims Cap" | 9.5(b)(iii) |

| | Section(s) |
|---|---|
| "Recent Tax Returns" | 3.24(a) |
| "Representative Reimbursement Amount" | 1.5(c) |
| "Rights Holder Indenmitee" | 9.1(a) |
| "Shareholder Approval" | 6.4 |
| "Specified Intellectual Property Claims" | 9.2(d) |
| "Specified Intellectual Property Claims Cap" | 9.5(b)(ii) |
| "Specified Intellectual Property Claims Per Claim Cap" | 9.5(b)(ii) |
| "SR Expenses" | 2.5(c) |
| "Surviving Corporation" | 1.1 |
| "Surviving Corporation Charter" | 1.3(a) |
| "Third-Party Claim" | 9.3(a) |
| "Transaction Cost Certificate" | 7.2(k) |
| "Transaction Cost Claims" | 9.2(e) |
| "Warrant Shares" | 2.1(c)(ii) |

10.3 Severability. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any rule of applicable law, or public policy, all other conditions and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the Merger is not affected in any manner materially adverse to any party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that

the Merger be consummated as originally contemplated to the fullest extent possible.

10.4 Entire Agreement; Assignment. This Agreement, together with the Confidentiality Agreement and, when executed and delivered by the parties thereto, the Escrow Agreement, constitutes the entire agreement among the parties with respect to the subject matter hereof and thereof and supersedes all prior agreements and undertakings, both written and oral, among the parties, or any of them, with respect to the subject matter hereof and thereof. This Agreement shall not be assigned by operation of law or otherwise, except that (a) Parent and Merger Sub may assign all or any of their rights and obligations hereunder to any Affiliate of Parent; provided, that no such assignment to an Affiliate shall relieve the assigning party of its obligations hereunder, and (b) after the Effective Time, Parent may assign all of its rights and obligations hereunder to a person that acquires all of the capital stock, or substantially all of the assets, of the division or business unit of Parent responsible for the business of the Company; provided, that such person assumes this Agreement, in writing, and agrees to be bound by and to comply with all of the terms and conditions hereof.

10.5 Parties in Interest. This Agreement shall be binding upon and inure solely to the benefit of each party hereto and nothing in this Agreement, express or implied is intended to or shall confer upon any other person any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

10.6 Specific Performance. The parties hereto agree that irreparable damage would occur in the event that any provision of this Agreement was not performed in accordance with the terms hereof and

that the parties shall be entitled to specific performance of the terms hereof, in addition to any other remedy at law or equity.

10.7 Governing Law. This Agreement shall be governed by, and construed in accordance with the laws of the State of California applicable to contracts executed in and to be performed in that state.

10.8 Consent to Jurisdiction.

(a) EACH OF PARENT, THE COMPANY AND MERGER SUB HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE COURTS OF CALIFORNIA AND TO THE JURISDICTION OF THE UNITED STATES DISTRICT COURT FOR NORTHERN DISTRICT OF CALIFORNIA, FOR THE PURPOSE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND EACH OF PARENT, THE COMPANY AND MERGER SUB HEREBY IRREVOCABLY AGREES THAT ALL CLAIMS IN RESPECT TO SUCH ACTION OR PROCEEDING MAY BE HEARD AND DETERMINED EXCLUSIVELY IN ANY CALIFORNIA STATE OR FEDERAL COURT SITTING IN THE CITY OF SAN FRANCISCO. EACH OF PARENT, THE COMPANY AND MERGER SUB AGREES THAT A FINAL JUDGMENT IN ANY ACTION OR, PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON THE JUDGMENT OR IN ANY OTHER MANNER PROVIDED BY LAW.

(b) EACH OF PARENT, THE COMPANY AND MERGER SUB IRREVOCABLY CONSENTS TO THE SERVICE OF THE SUMMONS AND COMPLAINT AND ANY OTHER PROCESS IN ANY

OTHER ACTION OR PROCEEDING RELATING TO THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, ON BEHALF OF ITSELF OR ITS PROPERTY, BY THE PERSONAL DELIVERY OF COPIES OF SUCH PROCESS TO SUCH PARTY. NOTHING IN THIS SECTION 10.8 SHALL AFFECT THE RIGHT OF ANY PARTY TO SERVE LEGAL PROCESS IN ANY OTHER MANNER PERMITTED BY LAW.

10.9 Headings; Interpretation. The descriptive headings contained in this Agreement are included for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement. Whenever the word "include," "includes," or "including" appears in this Agreement, it shall be deemed in each instance to be followed by the words "without limitation."

10.10 Counterparts. This Agreement may be executed and delivered (including by facsimile transmission) in one or more counterparts, and by the different parties hereto in separate counterparts, each of which when executed and delivered shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

10.11 Fees and Expenses. Except for claims for Damages pursuant to Article 9 and as provided in Section 2.5(c) hereof and as such fees and expenses are incorporated in the definitions of "Closing Payment Amount" and "Aggregate Maximum Transaction Cost", each party hereto shall be responsible for all fees and expenses (including the fees and expenses of legal counsel and financial advisors engaged by such parties) incurred by such party in connection with the preparation and negotiation of this Agreement, and the consummation of the transactions contemplated

hereby, including, in the case of the Company, any fees and expenses incurred by the Company in any related or alternative transactions, including but not limited to the preparation and filing of the Company's registration statement on Form S-1 filed with the SEC on January 12, 2004 and any amendments thereto.

10.12 Amendment. This Agreement may be amended prior to the Effective Time only by an instrument in writing, duly authorized by the Company Board, executed by Parent or its designee, the Merger Sub, the Company and the Shareholder Representative. This Agreement may be amended subsequent to the Effective Time only by an instrument in writing executed by Parent, the Surviving Corporation and the Shareholder Representative, after authorization by written consent the Participating Rights Holders entitled to a majority in amount of the Escrowed Funds then in the possession of the Escrow Agent.

10.13 Waiver. At any time prior to the Effective Time, Parent and the Company may agree to (a) extend the time for the performance of any obligation or other act of the other (including, in the case of Parent, the Merger Sub) party hereto, (b) waive any inaccuracy in the representations and warranties of the other contained herein or in any document delivered pursuant hereto, and (c) waive compliance by the other, as the case may be, with any agreement or condition contained herein. Any such extension or waiver shall be valid if set forth in an instrument in writing signed by the party or parties to be bound thereby.

* * *

*[The remainder of the page is intentionally left blank.]*

* * *

IN WITNESS WHEREOF, Parent, Merger Sub, the Company and, for the limited purposes of agreeing to perform the duties specified in Section 2.5, the Shareholder Representative, have duly executed this Agreement and Plan of Merger as an instrument under seal as of the date first above written.

CYTYC CORPORATION

By: /s/ Patrick J. Sullivan
Name: Patrick J. Sullivan
Title: President

RADIO ACQUISITION CORP.

By: /s/ Patrick J. Sullivan
Name: Patrick J. Sullivan
Title: President

NOVACEPT

By: /s/ David M. Clapper
Name: David Clapper
Title: President

SHAREHOLDER REPRESENTATIVE

for the limited purposes of agreeing to perform the duties expressly delegated to the "Shareholder Representative" hereunder

/s/ David M. Clapper
Name: David Clapper, Joint Representative

/s/ Edward Unkart
Name: Edward Unkart, Joint Representative

From: mare@minervasurgical.com
Sent: Sunday, July 18, 2010 5:42 PM
To: Michael Regan
Subject: Fw: Resend: Questions for budget purposes regarding endometrialablation trials

Mike

Interesting. We're getting better response from FDA than from our own advisory board.

Talk to you tomorrow.

Mary

Sent via BlackBerry by AT&T

From: "Pollard, Cohn M." <Collin.Pollard@fda.hhs.gov> Date: Sun, 18 Jul 2010 16:57:22 -0700
To: Mary Edwards<marye@minervasurgical.com>
Subject: RE: Resend: Questions for budget purposes regarding endometrial ablation trials

I'm sorry. I was away last week on vacation. I had hoped my last e-mail to you would help, but I will find some time to talk to you tomorrow, even if it's late in the day.

Colin

From: Mary Edwards [mailto:marye@minervasurgical.com]
Sent: Monday, July 12, 2010 7:51 PM
To: Pollard, Colin M.
Subject: RE: Resend: Questions for budget purposes regarding endometrial ablation trials

Colin:

I'm under huge fire because I warvs not able to get answers after almost 6 weeks. [I know it's crazy for you; but not getting any internal sympathy]. We have a board meeting on the 20th and fundraising will be dependent on the regulatory plan. I'm really hoping that we could touch base for just a couple minutes on the Monday when you return. I fully understand that some of the below might sound new — but they really are not new questions.

1. We are still going to use resection/rollerball as the control arm.
2. We are not changing any of the other endpoints hence the non-inferiority margin of 20%.
3. The Minerva device is almost dead identical to NovaSure except using plasma energy (RF).
4. The 6 months question is straight out of the guidance document which states PMA can be filed with 6 months data. I thought that had changed to filing the PMA with full 12 month data, but just needed to confirm.
5. There was rumors in the investment community that because of the switch to AH instead of PBLAC that the patient numbers have gone up (rumor has it at approximately 600 patients).

6. Lastly, you had committed to me for some feedback regarding the number of follow-ups for AH. (all I need is whether it will be 3,6 and 12 or 3 and 6— plus baseline, of course).

From: Thomas Pendlebury
To: Dave Clapper; Eugene Skalnyi; Jon Wangsness; Michael Regan; Dominique Filloux
Sent: 8/15/2015 4:27:31 PM
Subject: FW: JMIG article about Minerva endometrial ablation
Attachments: ATT00001.htm: JMIG Article.pdf

Dave, Eugene,

This (his e-mail below) is from Dr. Tom Fromuth, Lancaster, PA. I will be talking with him next week to get details on # cases and date.

Tom

Dr. Deborah Willwerth named CEO at Heart of Lancaster

By Larry Portzline, (February 23, 2013 at 11:07 AM

Dr. Deborah Willwerth has been named chief executive officer of Heart of Lancaster Regional Medical Center, according to a news release from the hospital today.

Dr. Deborah Willwerth
Dr. Deborah Willwerth - (Photo/Submitted)

From: Thomas Fromuth <tfromie@comcast.net>
Date: Friday, August 14, 2015 at 7:24 AM
To: Deborah Willwerth <deborah.Willwerth@hma.com>
Subject: Fwd: JMIG article about Minerva endometrial ablation

Deborah,

Attached is the article about Minerva, the newest endometrial ablation technique to be FDA approved. It is based on the technology of Novasure, the most

common type of ablation procedure we do at Heart. It augments the technology to improve the overall effectiveness and amenorrhea rate while maintaining the same safety profile. I would really like for Heart to be the first in the area to use this newest technology. As I mentioned it is a new start up company so will not be a member of the CHS purchasing group.

I have tried over the last few months to work through our system to get it in at least for a trial. I have had no success; not sure why. Please help me to get some of the devices purchased at least as a trial. I have the support of many of my physicians who also would like to try it. If you approve of and can help with getting the devices I can ask the surgery desk to put several ablations on one day with as many physicians as we can. The inventor of the device has offered to come in and train all of us. I worked with him in the past when he developed the Novasure and together we brought Novasure to Lancaster.

I appreciate in advance anything you can do to help Thank you.

drtomfromuth

Begin forwarded message:

From: Thomas Pendlebury <thomas.pendlebury@minervasurgical.com>
Subject: JMIG article
Date: August 12, 2015 at 10:16:44 AM EDT
To: Thomas Fromuth <tfromie@comcast.net>

From: Csaba Truckai
To: Callahan, Amanda
CC: Csaba Truckai
Sent: 12/19/2014 10:51:07 AM
Subject: RE: Patent declaration

Dear Mandy:

Following up on my email sent December 2, 2014 reference to US Patent Application No. 13/003,011, I have now reviewed the Declaration that you attached to your letter of November 21, 2014, and I cannot in good faith sign it. The Declaration states that "I believe that I am the original inventor or an original joint inventor of a claimed invention in the application." I have reviewed the claims in the application that you provided, and I do not believe that those claims define any invention. The use of mechanical spreaders for indicating the width of a uterus was well known at the time that we tiled the application describing uterine measurement. I was aware of such devices, and I incorporated such features into the device design described in the application that you sent. At no time have I ever considered the use of the mechanical indicator mechanism disclosed and for the first time now claimed in the application to be an invention.

Thus, I cannot sign the Declaration. Best regards,

Csaba Truckai

-----Original Message-----

From: Callahan, Amanda
[mailto:Amanda.Callahan@hologic.com]
Sent: Monday, December 03, 2014 2:12 PM
To: Csaba Truckai
Subject: RE: Patent declaration

Good evening Csaba – thanks very much for getting back to me so quickly. Next week is perfect; safe journeys home!

All the best, Mandy

Mandy Callahan
IP Paralegal
O: 503-263-3492
F: 50M-263-2959
Amanda.Callahan@hologic.com

Hologic, Inc. 250 Campus Drive
Marlborough, MA 01752

-----Original Message-----

From: Csaba Truckai
[mailto:csabat@hermesinnovations.com]
Sent: Tuesday, December 02, 2014 2:34 PM
To: Callahan, Amanda
Subject: Patent declaration

Dear Amanda,

I am in Europe till late next week (pending Lufthansa strike). My wife told me that I need to sign the declaration for a patent. I hope next week is not to late for returning the document.

Best,

Csaba

Sent from my iPhone

*Inadequate physician training and inexperience related to Minerva Device use has the potential to lead to use error. Although you specify in your label that physicians using the Minerva Endometrial Ablation System should have sufficient training in performing hysteroscopic procedures and be familiar with the Operator's Manual, including the trouble shooting section, experience with one device type does not necessarily translate into mastery with another. In order to optimize patient safety and new provider use, please clarify whether you have implemented any specific training practices when introducing your product to physician groups for initial clinical use.*

Since the start of Minerva Endometrial Ablation System commercialization the Minerva Surgical has not developed and/or implemented any specific training practices when introducing our product to physician groups for initial clinical use. In large this was and continues to be based on the fact that adequacy of Physician Training with any device and mastery of any surgical procedure is fundamentally controlled, monitored and verified by the Credentialing Departments of each medical institution/facility. They operate using their own Standards and methods in assessing the degree of such adequacy and overall proficiency. Pre-requisites and requirements used by different institution vary and we are not aware of mechanisms for credentialing of such "industry sponsored training" modules.

Most importantly, endometrial ablation in general and independently of the method used is not novel and quite uniform with respect to patient selection criteria. When it comes to the steps of Minerva procedure, it is important to appreciate that the Minerva system was specifically designed to virtually mimic the steps of the NovaSure procedure, endometrial ablation procedure

most commonly used in the United States today. As a result, during our almost 16 months of commercialization we observed a seamless transition from NovaSure and adoption of Minerva.

Lastly, we would like to state that Minerva Surgical as a company never received requests for formal training from medical institutions and/or individual physicians.

Outlook E-mail

From: O'Neill, Tom
Sent: 8/18/2015 7:20:56 AN
To: Parachek, Whitney; GSS Division Sales Management Team
Cc: GSS Division Sales RBD Team; Mascari, Adam; Hunter, Mark; Sharma, Val; Sheffer, Danielle; Compton, Eric; McMahon, Bob
Subject: RE: Minerva Hiring

Team,

Great message by both Whit and Brian!

While you don't know me yet, I have past experience in a "star- up" company. The best thing we can do is to not let them get a footing in ANY market. This will put tremendous financial pressure on their entire organization and we will stop them in there tracks. Their entire company/business model is set up to eventually sell to a PE or to a strategic. In short, Minerva is all about driving to a sale of the company. WE on the other hand are in it for the long term. We are focused on long term commitment to our customers and to women's health long term.

I have also heard from some of you that they are hiring some of ex Hologic reps who are very good. While I don't know these individuals, I do know that you as a collective group are closing an amazing year. You have 12+ year old products and you are growing near double digits this past quarter. To that end, they may have some very good ex Hologic reps hut the CLEAR FACT IS THAT YOU ARE BETTER!

Take it personally. Don't let them off the ground. Don't let them have even one case. We will win as a team!

Tom

From: Parachek, Whitney
Sent: Friday, August 14, 2015 6:50 AM
To: GSS Division Sales Management Team
Cc: GSS Division Sales RBD Team; Mascari, Adam; Hunter, Mark; O'Neill, Tom; Sharma, Vai; Sheffer, Danielle
Subject: Re: Minerva Hiring

This is fantastic guidance and leadership from Brian! It's specific, actionable, and in complete alignment with the strategies we've discussed. Please read and replicate this message to your teams TODAY. We need ALL hands on deck to insulate our business, isolate this distraction, and demonstrate our story of

commitment and partnership to our customers. .

His analogy of "ankle biting vs. hemorrhaging" is right on! We may lose a case but we will not lose an account. TMs must understand their priority NS accounts and have a plan in place to defend them. As a management team, we need to be inspecting our position in these accounts and exploring options to lock down our business.

This is our call to action! These next 3 months are critical! We cannot allow them any traction. With over 200 people sharing our value messagee will not be beat! Thank you, Brian!

Game On!
Whitney

Sent from my iPhone

CA TEAM –

As you can see from Dan's email below Minerva is ramping up their sales force with a sales training class taking place this week and In September.

As discussed on our call I want each of you to work with a sense of urgency and belief that you will have a new competitor in your territory tomorrow. As we invest in our clinical competitive knowledge let's make sure upfront you know those "Beachhead" accounts you can't afford to allow any access whatsoever. The goal is to drive your competition to those inconsequential accounts where case conversion/ankle biting is not going to lead to absolute hemorrhaging of your business. I have attached a MS Infiltration report that is sorted by stack ranking of NS sales. I have highlighted in green each of your top accounts. The top forty accounts of this list comprise of approximately 64% of our Novasure sales in the past four quarters. My expectation is that you similarly know and have a plan for those top accounts that drive the majority of your NS sales. We need to defend and prepare to wage war in these accounts. Think of your defense of these accounts as building a moat around your castle. The more successful we are upfront of this defense the better positioned we are to execute on the year we all expect to have in 2016. Think "#1 District in the Country" and "COE".

So how do we execute from an activity perspective in these key accounts today:

- Sell the whole HOI.X story / value proposition
- Maximize the TM/CS partnership
- Senior Management account visit
- DrivelT promotion

- Leverage our entire product portfolio
- Implement multi product agreements with market share commitments
- Ramp up frequency and reach of calls to the key practices and physicians that are the volume driver of these key acounts...(you can be sure the competitor will be knocking on these doors)
- Quality clinical calls to the entire office...MD, APC, Biller, Surgery Scheduler
- Raise the level of visibility of the great solutions that NS is by painting the office with NS marketing collateral....at a minimum patient education (English & Spanish) and poster clings
- Consultative approach... engage your customers / practices on how you can assist to grow their procedures
- Via a Business review help them understand the reimbursement picture / what their plans reimburse / leverage the economic calculator
- Super User Dinners // APC & Surgery Scheduler Dinners
- Leverage your territory physician advocates

The first 90-180 days are going to be absolutely critical in keeping the competition at bay. Our best opportunity at denying them the ability to capture attention and Initiate trials Is going to be right out of the gate. As busy as we are with Myosure...competing for new accounts, securing contractual commitments and selling MS/AQcapital we can't lose sight of how important the work upfront is to defend the Novasure business we have developed over the past 10 plus years. TM's please take a look at your Novasure stack ranking and

email me back by the close of business Wednesday, Aug 195h with your top five accounts and the total amount of sales each had over the last four successive quarters. We will be discussing these accounts and the key physicians that drive the volume in the corning weeks.

Thanks,

Brian Logan | District Sales Manager, California District
Mobile: 559-244-9305 | brian.logan@hologic.com
Hologic, Inc. | 250 Campus Drive, Marlborough, MA 01752

<image001.jpg>

From: Eby, Daniel
Sent: Wednesday, August 12, 2015 7:04 AM
To: Logan, Brian
Cc: Surg Mgrs West Region
Subject: Re: Minerva hires

Team

Thanks for the updates here. There is a new hire training taking place this week, so they will be in the field next. There is another training taking place place 9/16.

They are going to be active and coming after our business. Let's be sure to keep communication high in these areas where they are being placed.

Thanks-

Dan Eby
616-450-5792

<Top NS Customers.xls>
<image001.jpg>

Outlook E-mail

From: O'Neill, Tom
Sent: 10/2/2015 8:46:36 AM
To: Parachek, Whitney; Fruhan, Bill; Evantash, Edward
Subject: RE: Minerva

Thank you. Let's plan on reviewing the plan and the costs by next Friday. Does that work?

From: Parachek, Whitney
Sent: Friday, October02, 2015 7:57 AM
To: O'Neill, Tom; Fruhan, Bill; Evantash, Edward
Subject: RE: Minerva

Tom,

Sorry for the delayed response. I planned to respond to this during our 1:1 but we did not get to it.

We have an outline of aggressive ideas for a "scorched earth" strategy that I will forward. These will he vetted and prioritized with the Minerva Task Force later this afternoon. I met with Adam Jay this week and clarified his priorities in his interiMinerva defense" role. He will be attending the Task Force meeting and will work closely with me and the team to outline next steps.

Edward, Bill, and I met to discuss expediting Regional education/training summits and are outlining the roll out. Our goal is to pilot our first program in early December in California and estimate the cost to be @ $90,000. We'e also engaged Anne to discuss a "turn key" office strategy to include social selling and co-op marketing to implement with our customers to drive partnership, growth and insulation. We strongly believe med/ed (both large and small programs) and marketing

will be our key to solidifying our message, our customers, and our business.

Once vetted and prioritized we will present to you recommended strategies and budgets.

Thanks,
Whitney

From: O'Neill, Tom
Sent: Wednesday, September 30, 2015 9:32 AM
To: Fruhan, Bill; Evantash, Edward; Parachek, Whitney
Subject: Minerva

Where are we with the Minerva defense program we discussed last week at dinner?

Thanks, Tom

Strategy Planning Meeting Key Themes and Take Aways

NovaSure key issues:

1. Lost market share
2. IP expiring in 2016
3. Key competitors entering GEA market in 2015
4. Quality complaints are up considerably

NovaSure Sales Flattening- ANALYZE AND DEPLOY PROPER SIZE AND SKILL SALESFORCE

- DTC appears to be having a positive effect in the marketplace.
- Economy, more specifically patient deductibles, have stopped the short term growth of the GEA market. (Can we help pay deductibles????)
- Effect of DTC also muted by some declining share. Share loss due to both competitive ramping up of sales and GSP decreased time per product with launch of MyoSure.
- The contraindication is hurting. Rather than our reps using it to leverage Adiana we have been outsold. If we are contraindicated for use with Essure so should every other thermal energy product. I would like to see a study launched immediately to show the thermal effects of other products used in conjunction with the Essure coil. This should be combined with an analysis of the MAUDE database.
- Marketing to launch a customer satisfaction survey
- Marketing to launch patient pathway survey- where are we losing them these days and why

- Brodeur to provide the public with information about robotic complications and costs

NovaSure Gen 4- ACCELERATE OUR TIME TO MARKET

- AEGEA and Minerva are for real and they aren't going to just go away. They are well capitalized with very viable product platforms.
- We can buy them before they get through clinicals
  - Pros- Could become next generation NS
  - Cons- Likely expensive and where does it stop
- R&D/BD subcommittee to determine strategy here
- Current thinking on Gen 4: Smaller diameter catheter. This is right thought process but not enough. NovaSure is successful because it is quick, simple, safe, successful. We need to focus on more quick and more simple. Workflow and patient comfort key concepts.
- We are out of time and need to solve this problem. We have been working on feasibility for a year and our concept is not complete.
- Our Gen 4 team must focus their efforts on laying minefields around our products to:
  - A. Prevent more entrants into this field
  - B. Protect our current portfolio
- What Gen 4 isn't- A rush to copy the small features of a new entrant that will simply move to a price strategy in the event they offer no new features. We need to "move the cheese" and we need to move it quickly. While we are inventing the next smartphone we also need to invent an IPAD.

Adiana key issues:

1. Regulatory hurdles on RO and 2.0
2. Patency rates
3. 2015 revenue decreased massively due to efficacy labeling
4. Instant occlusion is the holy grail

Concomitant Use: NEW PRE-IDE REQUEST FOR THIS CHANGED PROTOCOL

- Current $6M strategy costly, too long, and not aggressive enough. Sales/Marketing says it will help- need to quantify how much. How do we avoid class labeling change?
- Attempt to eliminate the HSG requirement- can fall back to current clinical if this path fails.

2.0- CHANGE ACCESS STUDY PROTOCOL IN ANTICIPATION OF FDA REQUEST FOR CLINICAL?

- It is now possible that the 2.0 catheter will need some form of clinical beyond the access study. Potential cost for delay is $24M+ lost business.
- Need regulatory/Marketing/R&D caucus and decision on this
- Requirements should be issued to team for IP submissions. We must focus on protecting our edge here

APACS

- Delay tied to RO. Continue enrolling dots.

RO

- Not yet understood how RO will affect the patency rate. Initial in-growth data appears positive.

Sales

- Remains a complicated sale with excess sales time spent on getting people back after a negative event (expectation setting???)

MyoSure Key Issues

1. Patent Suit
2. Definition of polyp device
3. Office reimbursement strategy (why?)

- Work around for lawsuit is now #1 priority
- Speed to market of a polyp device can be accomplished with a hybrid ATEC/MyoSure product. We don't have to invent the IPAD here. COGS= $70.
- We are nowhere on the polyp device and haven't determined what it is yet. We need a PDD ASAP so we can get started on designing this product. Nicole to complete.
- Is it worth bringing this device into the office? Will it be supported? Where will this market be in 3 years? Where will our reps be? Can we get reimbursement increased here?

THS Key Issues

1. Transfer price very high- sales commitment high as well
2. 2012 less of an office focus

- We are selling these products and not just placing them. This needs to add revenue and cash to the GSP income statement.
- Need to incorporate into rep comp to see any focus from sales force.

General themes/comments

- We are spending too much time in the office (I'm not sure I agree with this- smaller territories may fix this)
- We have a negative reputation- especially regarding price flexibility
- Strength of new hires (Hunter/Farmer)

Tactical notes

- Key account development (more Mayo's)
- Heightened presence in residency programs
- We must focus our tactical or the message becomes diluted with the reps

Doc code: Oath
Document Description: Oath or declaration filed

PTO/AIA/02 (07-13)
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# SUBSTITUTE STATEMENT IN LIEU OF AN OATH OR DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (35 U.S.C. 115(d) AND 37 CFR 1.64)

| Title of Invention | MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION |
|---|---|

This statement is directed to:

☐ The attached application,

OR

☒ United States application or PCT international application number 13/962,178 filed on August 8, 2013.

**LEGAL NAME of inventor to whom this substitute statement applies:**

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Csaba Truckai

Residence (except for a deceased or legally incapacitated inventor):

| City | State | Country |
|---|---|---|
| Saratoga | CA | US |

Mailing Address (except for a deceased or legally incapacitated inventor):

19566 Arden Court

| City | State | Zip | Country |
|---|---|---|---|
| Saratoga | CA | 95070 | US |

I believe the above-named inventor or joint inventor to be the original inventor or an original joint inventor of a claimed invention in the application.

The above-identified application was made or authorized to be made by me.

I hereby acknowledge that any willful false statement made in this statement is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

Relationship to the inventor to whom this substitute statement applies:

- ☐ Legal Representative (for deceased or legally incapacitated inventor only),
- ☒ Assignee,
- ☐ Person to whom the inventor is under an obligation to assign,
- ☐ Person who otherwise shows a sufficient proprietary interest in the matter (petition under 37 CFR 1.46 is required), or
- ☐ Joint Inventor.

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# SUBSTITUTE STATEMENT

Circumstances permitting execution of this substitute statement:

- ☐ Inventor is deceased,
- ☐ Inventor is under legal incapacity,
- ☐ Inventor cannot be found or reached after diligent effort, or
- ■ Inventor has refused to execute the oath or declaration under 37 CFR 1.63.

If there are joint inventors, please check the appropriate box below:

- ■ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) naming the entire inventive entity has been or is currently submitted.

OR

- ☐ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) has not been submitted. Thus, a Substitute Statement Supplemental Sheet (PTO/AIA/11 or equivalent) naming the entire inventive entity and providing inventor information is attached. See 37 CFR 1.64(b).

## WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

**PERSON EXECUTING THIS SUBSTITUTE STATEMENT:**

Name: Lindsay G. McGuinness | Date (Optional): 4/21/2015

Signature: Lindsay G McGuinness

**APPLICANT NAME AND TITLE OF PERSON EXECUTING THIS SUBSTITUTE STATEMENT:**

If the applicant is a juristic entity, list the applicant name and the title of the signer:

Applicant Name: Cytyc Surgical Products

Title of Person Executing This Substitute Statement: VP, Deputy General Counsel & Chief IP Counsel

The signer, whose title is supplied above, is authorized to act on behalf of the applicant.

**Residence of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent):**

City Marlborough | State MA | Country US

**Mailing Address of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent)**

250 Campus Drive

City Marlborough | State MA | Zip 01752 | Country US

Note: Use an additional PTO/AIA/02 form for each inventor who is deceased, legally incapacitated, cannot be found or reached after diligent effort, or has refused to execute the oath or declaration under 37 CFR 1.63.

# SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

## I. GENERAL INFORMATION

| | |
|---|---|
| Device Generic Name: | Thermal (Radiofrequency Ionized Argon Gas) Endometrial Ablation Device |
| Device Trade Name: | MinervaTm Endometrial Ablation System |
| Device Procode: | MNB |
| Applicant's Name and Address: | Minerva Surgical, Inc.<br>101 Saginaw Drive<br>Redwood City, CA 94063 |
| Date(s) of Panel Recommendation: | None |
| Premarket Approval Application (PMA) Number: | P140013 |
| Date of FDA Notice of Approval: | July 27, 2105 |
| Priority Review: | No |

## II. INDICATIONS FOR USE

The Minerva Endometrial Ablation System is indicated to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive menstrual bleeding) due to benign causes for whom childbearing is complete.

III. CONTRAINDICATIONS

The Minerva Endometrial Ablation System is contraindicated for use in the following:

- A patient who is pregnant or who wants to become pregnant in the future. PREGNANCIES FOLLOWING ABLATION CAN BE DANGEROUS FOR BOTH MOTHER AND FETUS.
- A patient with known or suspected (uterine cancer) or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia.
- A patient with any anatomic condition (e.g., history of previous classical cesarean section or transmural myomectomy, including hysteroscopic and/or laparoscopic myomectomy performed immediately prior to the Minerva procedure) or pathologic condition (e.g., requiring long-term medical therapy) that could lead to weakening of the myometrium.

* * *

2. Effectiveness Results

The analysis of effectiveness was based on the 110 evaluable subjects at the 12-month time point. Key effectiveness outcomes are presented in Table 4 and Table 5.

Based on the success rate of 91.8% with a 95% confidence interval (CI) of (85.0%, 96.2%) observed in the Minerva ITT population, the null hypothesis was rejected at the significance level of 5%, and the 12-month follow-up success rate observed with the Minerva Endometrial Ablation System was demon-

strated to be statistically significantly greater than the OPC of 66% (p-value <0.0001).

This analysis did not compare the success rate of the Minerva Endometrial Ablation Device to the individual success rates of the five approved endometrial ablation devices used to set the OPC.

Table 2 summarizes the effectiveness outcomes from the single arm study.

Table 2 Effectiveness outcomes from single arm study

| | MINERVA™ N (% OF 110) |
|---|---|
| Number of successful patients (diary score < 75) | 101 |
| Study success rate (% patients with PBLAC score < 75) — Non-Proportional (Traditional) Method[1] | 91.8% |
| Study success rate (% patients with PBLAC score < 75) — Proportional Method | 87.3% |
| Number of patients reporting amenorrhea (PBLAC score=0) | 73 |
| Amenorrhoea rate (% patients with PBLC score = 0) | 66 4% |

[1] The success rate compared to the OPC. See discussion of non-proportion (traditional) versus proportional method below.

When using the PBLAC scoring method, subjects in the single arm study compared the appearances of their catamenial products (pads and tampons) to a set of pictures/icons. To calibrate these icons with the blood volume absorbed by catamenial products used in this study, expired diluted human blood was applied in 0.5 ml increments to the catamenial products to determine the minimum and maximum amount of blood needed to produce each icon on the PBLAC (i.e., heavy, moderate and light staining). This yielded a range of volumes for each icon. The process was repeated five times by the same investigator, yielding 15 scores for each pad/tampon. The mean volume was determined for each icon for each pad/tampon. The applicant used the mean volumes for the icons for one brand of pads as the baseline for the PBLAC scores. The scores for the icons for the other brands of pads were then calibrated using an "adjustment factor." The purpose of this adjustment factor is to account for the variability across pads. This method is referred to as the non-proportional or traditional method.

To evaluate whether the PBLAC instrument could be appropriately applied in the study, two investigators and ten female observers were randomly assigned catamenial products with known amounts of expired diluted blood applied. The

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# SUMMARY OF SAFETY AND EFFECTIVENESS DATA:

## NovaSure™ Impedance Controlled Endometrial Ablation System

## I. GENERAL INFORMATION

| | |
|---|---|
| DEVICE GENERIC NAME: | Thermal (Radio-Frequency) Endometrial Ablation Device |
| DEVICE TRADE NAME: | NovaSureTM Impedance Controlled Endometrial Ablation System |
| APPLICANT'S NAME AND ADDRESS: | Novacept, Inc.<br>1047 Elwell Court<br>Palo Alto, CA 94303 |
| PREMARKET APPROVAL APPLICATION (PMA) NUMBER: | P010013 |
| DATE OF PANEL RECOMMENDATION: | N/A |

## II. INDICATIONS FOR USE

The NovaSure™ System is intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.

## III. CONTRAINDICATIONS

Use of the NovaSure™ Impedance Controlled Endometrial Ablation System (hereafter referred to as the NovaSure™ System) is contraindicated for patients with the following conditions:

- A patient who is pregnant or who wants to become pregnant in the future. Pregnancies following ablation can be dangerous for both mother and fetus.
- A patient with known or suspected endometrial carcinoma (uterine cancer) or premalignant change of the endometrium, such as unresolved adenomatous hyperplasia.
- A patient with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean section or transmural myomectomy.

* * *

These issues were addressed with minor modifications made during the incorporation of the Cavity Integrity Assessment system into the device.

- Patient Accountability

A total of 265 subjects were enrolled in the study. Table 2C identifies the numbers of patients at key points of the study.

TABLE 2C. PATIENT ACCOUNTABILITY

| NUMBER OF PATIENTS | NOVASURE™ | LOOP RESECTION PLUS ROLLERBALL |
|---|---|---|
| Entered into study | 175 | 90 |
| Aborted procedures—uterine size or shape* | 4 | 0 |
| Aborted procedures—uterine perforation* | 0 | 2 |
| Treated | 171 | 88 |
| Failed — required additional treatment* | 4 | 2 |
| Hysterectomy performed* | 2 | 2 |
| Lost to follow-up* | 2 | 2 |
| Hodgkin's disease diagnosed post treatment* | 1 | 0 |
| 6-Month Follow-up | 162 | 82 |
| Hysterectomy performed* | 1 | 0 |
| Pelvic pain — administered leuprolide* | 1 | 0 |
| Lost to follow-up* | 4 | 0 |
| 12-Month Follow-up | 156 | 82 |

* Discontinued patients

- Efficacy at One Year: Diary Scores

Patient success was based on a reduction in diary score from >150 pre-treatment to <75 at one year. Effectiveness rates were based on the Intent-to-Treat population.

TABLE 3— EFFECTIVENESS*:
DIARY SCORES AT 1 YEAR

| | NOVASURE™ n(% OF 175) | LOOP RESECTION PLUS ROLLERBALL n (% of 90) |
|---|---|---|
| Number of successful patients (diary score<75) | 136 | 67 |
| Study success rate (% patients with score <75) | 77.7% | 74.4% |
| Number of patients with amenorrhea (score=0) | 63 | 29 |
| Amenorrhea rate (% patients with score=0) | 36.0% | 32.2% |

* * *