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 I

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

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TABLE OF CONTENTS

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:

U.S. DISTRICT COURT
DISTRICT OF DELAWARE (WILMINGTON)

———

Civil Docket For Case #: 1:15-cv-01031-JFB-SRF

———

HOLOGIC, INC. ET AL

v.

MINERVA SURGICAL, INC.

———

RELEVANT DOCKET ENTRIES

DATE	NO.	DOCKET TEXT
11/06/2015	1	COMPLAINT filed with Jury Demand against Minerva Surgical, Inc. - Magistrate Consent Notice to Pltf. (Filing fee $ 400, receipt number 1823358.) - filed by Hologic, Inc., Cytyc Surgical Products, LLC. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C)(cna) (Additional attachment(s) added on 11/10/2015: # 4 Exhibit D) (sar). (Entered: 11/06/2015)
		* * *
02/05/2016	70	SECOND AMENDED COMPLAINT against Minerva Surgical, Inc.- filed by Hologic, Inc., Cytyc Surgical Products, LLC. (Attachments: # 1 part 2, # 2 part 3, # 3 part 4)(fms) (Entered: 02/05/2016)
		* * *

DATE	NO.	DOCKET TEXT
03/11/2016	85	REDACTED VERSION of 83 Answer to Amended Complaint,, Counterclaim, by Minerva Surgical, Inc.. (Schladweiler, Benjamin) (Entered: 03/11/2016)
		* * *
06/02/2016	127	MEMORANDUM ORDER denying 9 MOTION for Preliminary Injunction filed by Cytyc Surgical Products, LLC, Hologic, Inc. Signed by Judge Sue L. Robinson on 6/2/2016. (nmfn) (Entered: 06/02/2016)
		* * *
04/24/2017	227	MEMORANDUM ORDER re: claim construction. Signed by Judge Sue L. Robinson on 4/24/2017. (nmfn) (Entered: 04/24/2017)
		* * *
01/05/2018	277	MOTION for Partial Summary Judgment - filed by Minerva Surgical, Inc.. (Attachments: # 1 Text of Proposed Order)(Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	278	[SEALED] OPENING BRIEF in Support re 277 MOTION for Partial Summary Judgment filed by Minerva Surgical, Inc..Answering Brief/Response due date per Local Rules is 1/19/2018. (Attachments: # 1 Appendix) (Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
		* * *

DATE	NO.	DOCKET TEXT
01/05/2018	281	[SEALED] DECLARATION Volume I of V of Olivia M. Kim re 277 MOTION for Partial Summary Judgment, 279 MOTION to Preclude, 275 MOTION to Dismiss by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibits 3-5, # 4 Exhibits 6-8, # 5 Exhibits 9-14, # 6 Exhibits 15-34, # 7 Exhibits 35-40, # 8 Exhibits 41-43)(Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	282	[SEALED] DECLARATION Volume II of V re 281 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibits 46-54)(Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	283	[SEALED] Exhibit Volume III of V re 281 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibits 57-60, # 2 Exhibit 61, # 3 Exhibits 62-73, # 4 Exhibits 74-88)(Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	284	[SEALED] EXHIBIT Volume IV of V re 281 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 100, # 2 Exhibit 101 - Parts 1-10, # 3 Exhibits 101 - Part 11 and Exhibit 112, # 4 Exhibits 113-120, # 5 Exhibits 121-126, # 6 Exhibits 127-137)(Schladweiler, Benjamin) Modified

DATE	NO.	DOCKET TEXT
		on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	285	[SEALED] EXHIBIT Volume V of V re 281 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 142, # 2 Exhibit 143 - Parts 1-5, # 3 Exhibits 144-145, # 4 Exhibits 146-147, # 5 Exhibits 148-150, # 6 Exhibits 151-153, # 7 Exhibit 154, # 8 Exhibit 155, # 9 Exhibits 156-161)(Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	286	NOTICE of filing the following Non-Paper material(s) in multi media format: CD containing Exhibits 17, 18, 20, 21, 23, 25, 27, 29, 31, 32, 33, 156, 157, and 158 to the Declaration of Olivia M. Kim in Support of Defendant Minerva's Motion to Dismiss, Motion for Partial Summary Judgment and Daubert Motion. Original Non-paper material(s) to be filed with the Clerk's Office. Notice filed by Benjamin J. Schladweiler on behalf of Minerva Surgical, Inc. (Schladweiler, Benjamin) (Entered: 01/05/2018)
01/05/2018	287	MOTION for Summary Judgment of No Invalidity - filed by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Text of Proposed Order)(Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)

DATE	NO.	DOCKET TEXT
01/05/2018	288	MOTION for Summary Judgment of Infringement - filed by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Text of Proposed Order)(Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	289	MOTION for Summary Judgment of Assignor Estoppel - filed by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Text of Proposed Order)(Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
		* * *
01/05/2018	291	[SEALED] OPENING BRIEF in Support re 290 MOTION to Preclude, 289 MOTION for Summary Judgment, 287 MOTION for Summary Judgment, 288 MOTION for Summary Judgment filed by Cytyc Surgical Products, LLC, Hologic, Inc..Answering Brief/Response due date per Local Rules is 1/19/2018. (Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	292	[SEALED] DECLARATION of Marc A. Cohn (Volume 1 of 2) re 290 MOTION to Preclude, 289 MOTION for Summary Judgment, 287 MOTION for Summary Judgment, 288 MOTION for Summary Judgment by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 1 - 20, # 2 Exhibit 21 -

DATE	NO.	DOCKET TEXT
		45)(Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	293	[SEALED] DECLARATION (Volume 2 of 2) re 290 MOTION to Preclude, 287 MOTION for Summary Judgment, 289 MOTION for Summary Judgment, 288 MOTION for Summary Judgment by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 46 - 61, # 2 Exhibit 62 - 65, # 3 Exhibit 66 - 73, # 4 Exhibit 74 - 90, # 5 Exhibit 91 - 122)(Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	294	[SEALED] DECLARATION of Karl R. Leinsing, MSME, PE re 290 MOTION to Preclude, 289 MOTION for Summary Judgment, 287 MOTION for Summary Judgment, 288 MOTION for Summary Judgment by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	295	NOTICE of of Filing of Multimedia Format by Cytyc Surgical Products, LLC, Hologic, Inc. re 293 Declaration,, (Pascale, Karen) (Entered: 01/05/2018)
01/08/2018	296	MULTI MEDIA DOCUMENT filed by Cytyc Surgical Products, LLC, Hologic, Inc. in the form of a CD Rom. (Media on file in Clerk's Office). (crb) (Entered: 01/08/2018)

DATE	NO.	DOCKET TEXT
01/09/2018	297	MULTI MEDIA DOCUMENT filed by Minerva Surgical, Inc. in the form of a CD ROM (Exhibits 17, 18, 20, 21, 23, 25, 27, 29, 31, 32, 33, 156, 157, 158). (Media on file in Clerk's Office). (crb) (Entered: 01/09/2018)
		* * *
01/16/2018	300	REDACTED VERSION of 278 Opening Brief in Support, by Minerva Surgical, Inc.. (Attachments: # 1 Appendix)(Schladweiler, Benjamin) (Entered: 01/16/2018)
		* * *
01/16/2018	302	REDACTED VERSION of 281 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibits 3-5, # 4 Exhibits 6-8, # 5 Exhibits 9-14, # 6 Exhibits 15-34, # 7 Exhibits 35-40, # 8 Exhibits 41-43)(Schladweiler, Benjamin) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	303	REDACTED VERSION of 282 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibits 46-54) (Schladweiler, Benjamin) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	305	REDACTED VERSION of 284 Exhibit to a Document by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 100, # 2 Exhibit 101 - Parts 1-10, # 3 Exhibits 101 - Part 11 and Exhibit 112, # 4 Exhibits 113-120, # 5

DATE	NO.	DOCKET TEXT
		Exhibits 121-126, # 6 Exhibits 127-137)(Schladweiler, Benjamin) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	306	REDACTED VERSION of 291 Opening Brief in Support by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	307	REDACTED VERSION of 292 Declaration by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit s 1 through 45)(Pascale, Karen) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	308	REDACTED VERSION of 293 Declaration by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit s 46 through 122)(Pascale, Karen) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	309	REDACTED VERSION of 294 Declaration by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	310	REDACTED VERSION of 285 Exhibit to a Document by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 142, # 2 Exhibit 143 - Parts 1-5, # 3 Exhibits 144-145, # 4 Exhibits 146-147, # 5 Exhibits 148-150, # 6 Exhibits 151-153, # 7 Exhibit 154, # 8 Exhibit 155, # 9 Exhibits 156-161)(Schladweiler,

DATE	NO.	DOCKET TEXT
		Benjamin) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
		* * *
01/17/2018	311	REDACTED VERSION of 283 Exhibit to a Document by Minerva Surgical, Inc.. (Attachments: # 1 Exhibits 57-60, # 2 Exhibit 61, # 3 Exhibits 62-73, # 4 Exhibits 74-88)(Schladweiler, Benjamin) Modified on 1/17/2018 (lih). (Entered: 01/17/2018)
		* * *
02/14/2018	320	[SEALED] ANSWERING BRIEF in Opposition re 290 MOTION to Preclude, 287 MOTION for Summary Judgment, 289 MOTION for Summary Judgment, 288 MOTION for Summary Judgment filed by Minerva Surgical, Inc..Reply Brief due date per Local Rules is 2/21/2018. (Attachments: # 1 Supplemental Appendix A, # 2 Exhibit 1, # 3 Exhibit 2)(Schladweiler, Benjamin) Modified on 2/16/2018 (lih). (Main Document 320 replaced on 4/16/2018) (lih). (Entered: 02/14/2018)
02/14/2018	321	[SEALED] DECLARATION of Olivia M. Kim re 320 Answering Brief in Opposition by Minerva Surgical, Inc.. (Attachments: # 1 Vol. I of II (Exs. 162-197), # 2 Vol. II of II (Exs. 198-204))(Schladweiler, Benjamin) Modified on 2/16/2018 (lih). (Entered: 02/14/2018)

DATE	NO.	DOCKET TEXT
02/14/2018	322	NOTICE of filing the following Non-Paper material(s) in multi media format: (CD containing Exhibits 181, 182, 183, and 184 to Declaration of Olivia M. Kim in Support of Defendant Minerva's Opposition to Plaintiffs' Motions for Summary Judgment of Infringement, Assignor Estoppel, and No Invalidity and Motion to Exclude Expert Testimony). Original Non-paper material(s) to be filed with the Clerk's Office. Notice filed by Benjamin J. Schladweiler on behalf of Minerva Surgical, Inc. (Schladweiler, Benjamin) (Entered: 02/14/2018)
		* * *
02/14/2018	324	[SEALED] ANSWERING BRIEF in Opposition re 277 MOTION for Partial Summary Judgment, 279 MOTION to Preclude filed by Cytyc Surgical Products, LLC, Hologic, Inc..Reply Brief due date per Local Rules is 2/21/2018. (Pascale, Karen) Modified on 2/16/2018 (lih). (Entered: 02/14/2018)
02/14/2018	325	[SEALED] DECLARATION of Marc A. Cohn re 324 Answering Brief in Opposition,, 323 Answering Brief in Opposition by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 123-150, # 2 Exhibit 151 - 160, # 3 Exhibit 161 -

DATE	NO.	DOCKET TEXT
		170, # 4 Exhibit 171 - 180, # 5 Exhibit 181 - 190, # 6 Exhibit 191 - 202)(Pascale, Karen) Modified on 2/16/2018 (lih). (Entered: 02/14/2018)
02/14/2018	326	MULTI MEDIA DOCUMENT filed by Minerva Surgical, Inc. in the form of a CD Rom. Filing related to 322 Notice of Filing Multi Media Materials. (Media on file in Clerk's Office). (lih) (Entered: 02/16/2018)
		* * *
02/21/2018	329	REDACTED VERSION of 324 Answering Brief in Opposition by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) Modified on 2/22/2018 (lih). (Entered: 02/21/2018)
02/21/2018	330	REDACTED VERSION of 325 Declaration by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 123 - 202)(Pascale, Karen) Modified on 2/22/2018 (lih). (Entered: 02/21/2018)
02/21/2018	331	REDACTED VERSION of 320 Answering Brief in Opposition, by Minerva Surgical, Inc.. (Attachments: # 1 Supplemental Appendix A, # 2 Exhibit 1, # 3 Exhibit 2)(Schladweiler, Benjamin) (Entered: 02/21/2018)
02/21/2018	332	REDACTED VERSION of 321 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Vol. I of II (Exs. 162-197), # 2 Vol. II of II (Exs. 198-

DATE	NO.	DOCKET TEXT
		204))(Schladweiler, Benjamin) Modified on 2/22/2018 (lih). (Entered: 02/21/2018)
		* * *
03/28/2018	341	[SEALED] REPLY BRIEF re 277 MOTION for Partial Summary Judgment filed by Minerva Surgical, Inc.. (Attachments: # 1 Second Supplemental Appendix A) (Schladweiler, Benjamin) Modified on 3/29/2018 (lih). (Entered: 03/28/2018)
		* * *
03/28/2018	343	[SEALED] DECLARATION of Olivia M. Kim re 342 Reply Brief, 340 Reply Brief, 341 Reply Brief by Minerva Surgical, Inc.. (Attachments: # 1 Exhibits 205-209)(Schladweiler, Benjamin) Modified on 3/29/2018 (lih). (Entered: 03/28/2018)
03/28/2018	344	[SEALED] REPLY BRIEF re 290 MOTION to Preclude , 289 MOTION for Summary Judgment , 287 MOTION for Summary Judgment, 288 MOTION for Summary Judgment filed by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) Modified on 3/29/2018 (lih). (Entered: 03/28/2018)
03/28/2018	345	[SEALED] DECLARATION of Marc A. Cohn re 344 Reply Brief, by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 203 - 210)(Pascale, Karen) Modified on 3/29/2018 (lih). (Entered: 03/28/2018)

DATE	NO.	DOCKET TEXT
		* * *
04/04/2018	351	REDACTED VERSION of 344 Reply Brief, by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) (Entered: 04/04/2018)
04/04/2018	352	REDACTED VERSION of 345 Declaration by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 203 - 210)(Pascale, Karen) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)
		* * *
04/04/2018	354	REQUEST for Oral Argument by Minerva Surgical, Inc. re 277 MOTION for Partial Summary Judgment, 279 MOTION to Preclude, 275 MOTION to Dismiss . (Schladweiler, Benjamin) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)
04/04/2018	355	REDACTED VERSION of 340 Reply Brief by Minerva Surgical, Inc.. (Schladweiler, Benjamin) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)
04/04/2018	356	REDACTED VERSION of 341 Reply Brief by Minerva Surgical, Inc.. (Schladweiler, Benjamin) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)
		* * *
04/04/2018	358	REDACTED VERSION of 343 Declaration by Minerva Surgical, Inc.. (Schladweiler, Benjamin) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)

DATE	NO.	DOCKET TEXT
04/04/2018	359	REQUEST for Oral Argument by Cytyc Surgical Products, LLC, Hologic, Inc. re 290 MOTION to Preclude, 289 MOTION for Summary Judgment, 287 MOTION for Summary Judgment, 288 MOTION for Summary Judgment. (Pascale, Karen) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)
		* * *
06/28/2018	407	MEMORANDUM OPINION Signed by Judge Joseph F. Bataillon on 6/28/2018. (nmf) (Entered: 06/28/2018)
06/28/2018	408	ORDER denying 275 Motion to Dismiss for Lack of Subject Jurisdiction ; denying 277 Motion for Partial Summary Judgment; denying 279 Motion to Preclude; granting 287 Motion for Summary Judgment ; granting 288 Motion for Summary Judgment ; granting 289 Motion for Summary Judgment ; denying 290 Motion to Preclude; denying 317 Motion to Strike ; denying 346 Motion to Strike ; denying 374 Motion to Bifurcate. Signed by Judge Joseph F. Bataillon on 6/28/2018. (nmf) (Entered: 06/28/2018)
		* * *
07/16/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/16/2018. (Court Reporter V. Gunning.) (DAY 1) (nmf) (Entered: 07/17/2018)

DATE	NO.	DOCKET TEXT
07/17/2018	485	Initial Jury Instructions read in Open Court 7/17/2018. (nmf) (Entered: 07/17/2018)
07/17/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/17/2018. (Court Reporter V. Gunning.) (DAY 2) (nmf) (Entered: 07/17/2018)
		* * *
07/18/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/18/2018. (Court Reporter V. Gunning.)(DAY 3) (nmf) (Entered: 07/18/2018)
		* * *
07/19/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/19/2018. (Court Reporter V. Gunning.)(DAY 4) (nmf) (Entered: 07/19/2018)
		* * *
07/20/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/20/2018. (Court Reporter V. Gunning.)(DAY 5) (nmf) (Entered: 07/20/2018)
		* * *
07/23/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/23/2018. (Court Reporter V. Gunning.)(DAY 6) (nmf) (Entered: 07/23/2018)

DATE	NO.	DOCKET TEXT
		* * *
07/24/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/24/2018. (Court Reporter V. Gunning.)(DAY 7) (nmf) (Entered: 07/24/2018)
07/25/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/25/2018. (Court Reporter V. Gunning.)(DAY 8) (nmf) (Entered: 07/25/2018)
		* * *
07/26/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/26/2018. Closing Arguments, Final Instructions, and Deliberations (Court Reporter Valerie Gunning.)(DAY 9) (crb) (Entered: 07/26/2018)
		* * *
07/26/2018	496	Revised Initial Jury Instructions read in Open Court 7/26/2018. (nmf) (Entered: 07/27/2018)
07/26/2018	497	Closing Jury Instructions read in Open Court 7/26/2018. (nmf) (Entered: 07/27/2018)
07/27/2018		Minute Entry for proceedings held before Magistrate Judge Sherry R. Fallon - Jury Trial completed on 7/27/2018. (Court Reporter V. Gunning.)(DAY 10) (Deliberations and Verdict) (nmf) (Entered: 07/27/2018)

DATE	NO.	DOCKET TEXT
07/27/2018	498	[SEALED] JURY VERDICT. (nmf) (Entered: 07/27/2018)
07/27/2018	499	REDACTED VERSION of 498 Jury Verdict. (nmf) (Entered: 07/27/2018)

* * *

08/08/2018	507	Official Transcript of jury trial held on July 16, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	508	Official Transcript of jury trial held on July 17, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018.

DATE	NO.	DOCKET TEXT
		Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	509	Official Transcript of jury trial held on July 19, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	510	Official Transcript of jury trial held on July 20, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	511	Official Transcript of jury trial held on July 23, 2018 before Judge Bataillon.

DATE	NO.	DOCKET TEXT
		Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	512	Official Transcript of jury trial held on July 24, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	513	Official Transcript of jury trial held on July 18, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or

DATE	NO.	DOCKET TEXT
		purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	514	Official Transcript of jury trial held on July 25, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	515	Official Transcript of jury trial held on July 26, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained

DATE	NO.	DOCKET TEXT
		through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	516	Official Transcript of jury trial held on July 27, 2018 before Judge Fallon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
		* * *
08/13/2018	520	JUDGMENT FOLLOWING JURY VERDICT: 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. Signed by Judge Joseph F. Bataillon on

DATE	NO.	DOCKET TEXT
		8/13/2018. (nmf) (Entered: 08/13/2018)
		* * *
05/02/2019	616	MEMORANDUM AND ORDER: Defendant's renewed motion for judgment as a matter of law (D.I. 521) is DENIED. Defendant's motion for a new trial (D.I. 523) is DENIED. Defendant's motion for an injunction under the Deceptive Trade Practices Act (D.I. 525) is DENIED. Plaintiffs' motion for attorney fees (D.I. 528) is DENIED. Plaintiffs' motion for enhanced damages (D.I. 530) is DENIED. Plaintiffs' motion (D.I. 532) for a permanent injunction and accounting is DENIED as moot. Plaintiffs' motion for an accounting, supplemental damages, ongoing royalties, prejudgment interest, and post–judgment interest (D.I. 534) is GRANTED in part and DENIED in part as set forth in this order. The parties shall each submit a proposed final judgment to the Court within three weeks of the date of this order (*see Order for details). Signed by Judge Joseph F. Bataillon on 5/1/2019. (ceg) (Entered: 05/02/2019)
		* * *
06/03/2019	621	FINAL JUDGMENT: Judgment is entered in favor of plaintiffs/ counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC,

DATE	NO.	DOCKET TEXT
		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. 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. 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 Minervas counter-claims. Defendant/counterclaimant Minerva's counterclaims are hereby dismissed (*see Order for further details)(*CASE CLOSED). Signed by Judge Joseph F. Bataillon on 5/31/2019. (ceg) (Entered: 06/03/2019)
		* * *
06/28/2019	625	NOTICE OF CROSS APPEAL to the Federal Circuit of 621 Judgment,,,, 227 Memorandum and Order, 407 Memorandum Opinion, 520 Judgment, 408 Order on Motion to Dismiss/Lack of Subject Jurisdiction,, Order on Motion for Partial Summary Judgment,, Order on Motion to Preclude,, Order

DATE	NO.	DOCKET TEXT
		on Motion for Summary Judgment,,,,,,,, Order on Motion to Strike,,,, Order on Motion to Bifurcate, 616 Memorandum and Order,,, . Cross Appeal filed by Minerva Surgical, Inc.. (Schladweiler, Benjamin) (Entered: 06/28/2019)
07/02/2019	626	NOTICE of Docketing Record on Appeal from USCA for the Federal Circuit re 625 Notice of Cross Appeal filed by Minerva Surgical, Inc. USCA Case Number 19-2081. (nmg) (Entered: 07/02/2019)
		* * *
07/22/2020	634	ORDER of USCA. Decision of USCA: The petitions for panel rehearing are denied. The petitions for rehearing en banc are denied. (kmd) (Entered: 07/29/2020)
07/29/2020	635	MANDATE of USCA as to 625 Notice of Cross Appeal, filed by Minerva Surgical, Inc., 622 Notice of Appeal (Federal Circuit), filed by Cytyc Surgical Products, LLC, Hologic, Inc. USCA Decision: Affirmed-in-Part, Vacated-in-Part, and Remanded. (Attachments: # 1 Opinion, # 2 Judgment)(kmd) (Entered: 07/29/2020)

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 19-2081

HOLOGIC, INC., CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs - Appellants

v.

MINERVA SURGICAL, INC.,
Defendant - Cross-Appellant

DOCKET ENTRIES

DATE	NO.	DOCKET TEXT
06/21/2019	1	Appeal docketed. Received: 06/18/2019. [615979] Entry of Appearance due 07/05/2019. Certificate of Interest is due on 07/05/2019. Docketing Statement due 07/05/2019. Appellant's brief is due 08/20/2019. [TAM] [Entered: 06/21/2019 09:48 AM]
06/21/2019	2	Entry of appearance for Matthew M. Wolf as principal counsel for Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Service: 06/21/2019 by email. [616034] [19-2054] [Matthew Wolf] [Entered: 06/21/2019 01:00 PM]
06/21/2019	3	Certificate of Interest for Appellants Hologic, Inc. and Cytyc Surgical Products, LLC. Service: 06/21/2019 by email. [616035] [19-2054] [Matthew Wolf] [Entered: 06/21/2019 01:03 PM]

DATE	NO.	DOCKET TEXT
06/21/2019	4	MOTION of Appellants Cytyc Surgical Products, LLC and Hologic, Inc. to expedite briefing schedule [Consent: opposed]. Service: 06/21/2019 by email. [616037] [19-2054] [Matthew Wolf] [Entered: 06/21/2019 01:08 PM]
06/21/2019	5	Entry of appearance for Jennifer A. Sklenar as of counsel for Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Service: 06/21/2019 by email. [616038] [19-2054] [Jennifer Sklenar] [Entered: 06/21/2019 01:10 PM]
06/21/2019	6	Entry of appearance for Marc A. Cohn as of counsel for Appellants Hologic, Inc. and Cytyc Surgical Products, LLC. Service: 06/21/2019 by email. [616039] [19-2054] [Marc Cohn] [Entered: 06/21/2019 01:13 PM]
06/21/2019	7	ORDER filed. Any opposition to the motion [4] is due no later than June 28, 2019. Any reply in support of the motion is due no later than July 1, 2019. Service: 06/21/2019 by clerk. [616093] [LMS] [Entered: 06/21/2019 03:08 PM]
06/28/2019	8	Entry of appearance for Robert N. Hochman as principal counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617823] [19-2054] [Robert Hochman] [Entered: 06/28/2019 02:36 PM]

DATE	NO.	DOCKET TEXT
06/28/2019	9	Entry of appearance for Caroline A. Wong as of counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617824] [19-2054] [Caroline Wong] [Entered: 06/28/2019 02:39 PM]
06/28/2019	10	Entry of appearance for Jillian Sheridan Stonecipher as of counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617825] [19-2054] [Jillian Stonecipher] [Entered: 06/28/2019 02:41 PM]
06/28/2019	11	Entry of appearance for Vera M. Elson as of counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617852] [19-2054] [Vera Elson] [Entered: 06/28/2019 03:23 PM]
06/28/2019	12	Entry of appearance for Edward G. Poplawski as of counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617859] [19-2054] [Edward Poplawski] [Entered: 06/28/2019 03:36 PM]
06/28/2019	13	Entry of appearance for Olivia M. Kim as of counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617861] [19-2054] [Olivia Kim] [Entered: 06/28/2019 03:41 PM]
06/28/2019	14	Certificate of Interest for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617865] [19-2054] [Robert Hochman] [Entered:

DATE	NO.	DOCKET TEXT
		06/28/2019 03:47 PM]
06/28/2019	15	Docketing Statement for the Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617868] [19-2054] [Robert Hochman] [Entered: 06/28/2019 03:48 PM]
06/28/2019	1	RESPONSE of Appellee Minerva Surgical, Inc. to the motion [4] filed by Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Service: 06/28/2019 by email. [617872] [19-2054] [Robert Hochman] [Entered: 06/28/2019 03:52 PM]
07/01/2019	17	REPLY of Appellants Hologic, Inc. and Cytyc Surgical Products, LLC to response [16]. Service: 07/01/2019 by email. [618214] [19-2054] [Matthew Wolf] [Entered: 07/01/2019 02:07 PM]
07/02/2019	18	Note to file: The following cases are associated:19-2054 (Lead) with 19-2081 (Cross-Appeal). FURTHER ENTRIES WILL BE ADDED TO THE LEAD APPEAL ONLY. [618504] [19-2054, 19-2081] [TAM] [Entered: 07/02/2019 10:58 AM]
07/02/2019	19	Official caption revised to reflect Cross-Appeal. The official caption is reflected on the electronic docket under the listing of the parties and counsel. Service as of thAs date by the Clerk of Court. [618509] [TAM] [Entered: 07/02/2019 11:01 AM]

DATE	NO.	DOCKET TEXT
07/03/2019	20	Docketing Statement for the Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Service: 07/03/2019 by email. [618906] [19-2054] [Matthew Wolf] [Entered: 07/03/2019 12:45 PM]
07/03/2019	21	ORDER filed. The motion [4] is granted to the extent that Hologic's opening brief is due no later than July 15, 2019; Minerva's principal-and-response brief is due no later than August 26, 2019; Hologic's response-and-reply brief is due no later than September 9, 2019; Minerva's reply brief is due no later than September 23, 2019; the joint appendix is due no later than September 30, 2019; and the case will be placed on the December 2019 oral argument calendar. Service: 07/03/2019 by clerk. [618968] [LMS] [Entered: 07/03/2019 02:35 PM]
07/15/2019	22	FILED from Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Title: CONFIDENTIAL OPENING BRIEF. Service: 07/15/2019 by email. [621120] [19-2054] This document is non-compliant. See Doc No.[24] [Matthew Wolf] [Entered: 07/15/2019 05:31 PM]
07/15/2019	23	FILED from Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Title: OPENING BRIEF. Service:

DATE	NO.	DOCKET TEXT
		07/15/2019 by email. [621121] [19-2054] This document is non-compliant. See Doc No.[24] [Matthew Wolf] [Entered: 07/15/2019 05:34 PM]
07/25/2019	24	NOTICE OF NON-COMPLIANCE: The submissions of Appellants Cytyc Surgical Products, LLC and Hologic, Inc., Confidential and Non-Confidential Opening Briefs [22], [23], are not in compliance with the rules of this court (see attached). Compliant documents due on 08/01/2019. Service as of this date by the Clerk of Court. [623538] [TAM] [Entered: 07/25/2019 02:44 PM]
07/31/2019	25	MODIFIED ENTRY: CORRECTED OPENING BRIEF FILED for Appellants Cytyc Surgical Products, LLC and Hologic, Inc. Number of Pages: 71. Service: 07/31/2019 by email. [625030] --[Edited 08/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 07/31/2019 04:53 PM]
07/31/2019	26	MODIFIED ENTRY: CORRECTED CONFIDENTIAL OPENING BRIEF FILED for Appellants Cytyc Surgical Products, LLC and Hologic, Inc. Number of Pages: 71. Service: 07/31/2019 by email. [625031]--[Edited 08/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 07/31/2019 04:55 PM]

DATE	NO.	DOCKET TEXT
08/26/2019	27	MODIFIED ENTRY: RESPONSE BRIEF FILED for Cross-Appellant Minerva Surgical, Inc. Number of Pages: 95. Service: 08/26/2019 by email. Unless ordered otherwise, any responsive deadline runs from the date of service of this brief. See Fed. Cir. R. 31. [631081] --[Edited 09/04/2019 by TAM - compliance review complete] [Robert Hochman] [Entered: 08/26/2019 04:01 PM]
09/09/2019	28	FILED from Appellants Cytyc Surgical Products, LLC, Hologic, Inc. and Cross-Appellant Minerva Surgical, Inc.. Title: CONFIDENTIAL REPLY BRIEF. Service: 09/09/2019 by email. [634161] [19-2054] This document is non-compliant. See Doc No.[30] [Matthew Wolf] [Entered: 09/09/2019 07:01 PM]
09/09/2019	29	FILED from Appellants Cytyc Surgical Products, LLC, Hologic, Inc. and Cross-Appellant Minerva Surgical, Inc.. Title: REPLY BRIEF. Service: 09/09/2019 by email. [634163] [19-2054] This document is non-compliant. See Doc No.[30] [Matthew Wolf] [Entered: 09/09/2019 07:04 PM]
09/20/2019	30	NOTICE OF NON-COMPLIANCE: The submissions of Appellants Cytyc Surgical Products, LLC and Hologic, Inc., Confidential and Non-Confidential Reply Brief [28], [29], are

DATE	NO.	DOCKET TEXT
		not in compliance with the rules of this court (see attached). Compliant documents due on 09/27/2019. The deadline for any responsive filing runs from service of the original version. Service as of this date by the Clerk of Court. [636949] [TAM] [Entered: 09/20/2019 09:10 AM]
09/23/2019	31	MODIFIED ENTRY: CORRECTED REPLY BRIEF FILED for Appellants Cytyc Surgical Products, LLC and Hologic, Inc. Number of Pages: 64. Service: 09/23/2019 by email. [637486] --[Edited 10/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 09/23/2019 03:04 PM]
09/23/2019	32	MODIFIED ENTRY: CORRECTED CONFIDENTIAL REPLY BRIEF FILED for Appellants Cytyc Surgical Products, LLC and Hologic, Inc. Number of Pages: 64. Service: 09/23/2019 by email. [637487]--[Edited 10/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 09/23/2019 03:07 PM]
09/23/2019	33	MODIFIED ENTRY: REPLY BRIEF FILED for Cross-Appellant Minerva Surgical, Inc. Number of Pages: 39. Service: 09/23/2019 by email. Unless ordered otherwise, any responsive deadline runs from the date of service of this brief. See Fed. Cir. R. 31.

DATE	NO.	DOCKET TEXT
		[637577] --[Edited 10/01/2019 by TAM - compliance review complete] [Robert Hochman] [Entered: 09/23/2019 04:44 PM]
09/30/2019	34	MODIFIED ENTRY: APPENDIX FILED for Cytyc Surgical Products, LLC, Hologic, Inc. and Minerva Surgical, Inc.. Number of Pages: 1091. Service: 09/30/2019 by email. [639243] --[Edited 10/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 09/30/2019 10:06 PM]
09/30/2019	35	MODIFIED ENTRY: CONFIDENTIAL APPENDIX FILED for Cytyc Surgical Products, LLC, Hologic, Inc. and Minerva Surgical, Inc.. Number of Pages: 1523. Service: 09/30/2019 by email. [639244]--[Edited 10/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 09/30/2019 10:10 PM]
09/30/2019	36	Joint Statement of Compliance with Fed. Cir. R. 33 for Appellants Hologic, Inc., Cytyc Surgical Products, LLC and Cross-Appellant Minerva Surgical, Inc.. Service: 09/30/2019 by email. [639245] [19-2054] [Matthew Wolf] [Entered: 09/30/2019 10:13 PM]
09/30/2019	37	Certificate of Compliance with Fed. Cir. R. 11(d) (Trial Court) for Appellants Hologic, Inc. and Cytyc Surgical Products, LLC. Service:

DATE	NO.	DOCKET TEXT
		09/30/2019 by email. [639246] [19-2054] [Matthew Wolf] [Entered: 09/30/2019 10:14 PM]
09/30/2019	38	Certificate of Compliance with Fed. Cir. R. 11(d) (Trial Court) for Cross-Appellant Minerva Surgical, Inc.. Service: 09/30/2019 by email. [639247] [19-2054] [Robert Hochman] [Entered: 09/30/2019 10:14 PM]
09/30/2019	39	Notice from Appellants Hologic, Inc. and Cytyc Surgical Products, LLC Notice of Intent to File Supplemental Appendix of Video Recordings on CD-ROM. Service: 09/30/2019 by email. [639248] [19-2054] [Matthew Wolf] [Entered: 09/30/2019 10:20 PM]
09/30/2019	40	Supplementary Video Media Appendix received on CD-ROM from Cytyc Surgical Products, LLC and Hologic, Inc. Number of copies: 4. [639425] [JCP] [Entered: 10/01/2019 03:26 PM]
10/01/2019	41	Outstanding paper copies of all briefs and appendices must be submitted within five business days from the date of issuance of this notice. See Fed. Cir. R. 25(c)(1). [639455] [TAM] [Entered: 10/01/2019 04:08 PM]
10/01/2019	42	Notice to Advise of Scheduling Conflicts. Arguing counsel must advise of, and show good cause for, any scheduling conflicts during the upcoming court session months listed

DATE	NO.	DOCKET TEXT
		in the attached notice. The Response to Notice to Advise of Scheduling Conflicts can be found here. The Oral Argument Guide can be found here. [639462] [TAM] [Entered: 10/01/2019 04:14 PM]
10/04/2019	43	6 paper copies of the Corrected Confidential Opening Brief [26] received from Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. [640315] [CJF] [Entered: 10/04/2019 12:54 PM]
10/04/2019	44	6 paper copies of the Corrected Confidential Reply Brief [32] received from Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. [640318] [CJF] [Entered: 10/04/2019 12:55 PM]
10/04/2019	45	6 paper copies of the Confidential Appendix Brief (Vol. I - IV) [35] received from Appellants Cytyc Surgical Products, LLC, Hologic, Inc. and Cross-Appellant Minerva Surgical, Inc.. [640319] [CJF] [Entered: 10/04/2019 12:55 PM]
10/04/2019	46	Notice from Appellants Hologic, Inc. and Cytyc Surgical Products, LLC regarding conflicts with oral argument. Service: 10/04/2019 by email. [640326] [19-2054] [Matthew Wolf] [Entered: 10/04/2019 01:06 PM]
10/04/2019	47	The following conflict dates submitted by Attorney Matthew Wolf for

DATE	NO.	DOCKET TEXT
		Appellants Hologic, Inc. and Cytyc Surgical Products, LLC have been accepted by the court: 01/08/2020, 01/09/2020, 01/10/2020, 02/03/2020, 02/04/2020, 02/05/2020, 02/06/2020, 02/07/2020, 04/09/2020, 04/10/2020. [640340] [JAB] [Entered: 10/04/2019 01:28 PM]
10/08/2019	48	Notice from Cross-Appellant Minerva Surgical, Inc. regarding conflicts with oral argument. Service: 10/08/2019 by email. [641158] [19-2054] [Robert Hochman] [Entered: 10/08/2019 04:41 PM]
10/08/2019	49	6 paper copies of the Reply Brief [33] received from Cross-Appellant Minerva Surgical, Inc.. [641185] [CJF] [Entered: 10/09/2019 07:36 AM]
10/08/2019	50	6 paper copies of the Opening Response Brief [27] received from Cross-Appellant Minerva Surgical, Inc.. [641186] [CJF] [Entered: 10/09/2019 07:37 AM]
10/09/2019	51	The following conflict dates submitted by Attorney Robert N. Hochman for Cross-Appellant Minerva Surgical, Inc. have been accepted by the court: 12/02/2019, 12/03/2019. [641206] [JAB] [Entered: 10/09/2019 08:58 AM]
10/21/2019	52	NOTICE OF ORAL ARGUMENT. Panel: 1912I. Case scheduled December 4, 2019 10:00 a.m. at the United States Court of Appeals for the

DATE	NO.	DOCKET TEXT
		Federal Circuit (Howard T. Markey National Courts Building, 717 Madison Place, NW Washington, DC 20439), Courtroom 203. Response to Notice of Oral Argument due: 11/15/2019. Please review the attached Notice. The response to notice of oral argument form can be found here. The Oral Argument Guide can be found here. [643499] [JAB] [Entered: 10/21/2019 02:19 PM]
11/07/2019	53	Response to notice of oral argument from the Cross-Appellant Minerva Surgical, Inc.. [647742] [19-2054] [Robert Hochman] [Entered: 11/07/2019 01:09 PM]
11/15/2019	54	Response to notice of oral argument from the Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. [649584] [19-2054] [Matthew Wolf] [Entered: 11/15/2019 10:05 AM]
12/04/2019	55	Submitted after ORAL ARGUMENT by Matthew Wolf for Hologic, Inc. and Cytyc Surgical Products, LLC and Robert N. Hochman for Minerva Surgical, Inc. Panel: Judge: Wallach , Judge: Clevenger , Judge: Stoll. [653886] [JCP] [Entered: 12/04/2019 10:25 AM]
04/22/2020	56	OPINION filed for the court by Wallach, Circuit Judge; Clevenger, Circuit Judge and Stoll, Circuit Judge. Precedential Opinion. [689037]

DATE	NO.	DOCKET TEXT
		[19-2054, 19-2081] [JAB] [Entered: 04/22/2020 10:03 AM]
04/22/2020	57	JUDGMENT. AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED. Terminated on the merits after oral argument. COSTS: No Costs. Mandate to issue in due course. For information regarding costs, petitions for rehearing, and petitions for writs of certiorari click here. [689039] [19-2054, 19-2081] [JAB] [Entered: 04/22/2020 10:04 AM]
05/22/2020	58	Petition for panel rehearing, for en banc rehearing filed by Cross-Appellant Minerva Surgical, Inc.. Service: 05/22/2020 by email. [696559] [19-2054] [Robert Hochman] [Entered: 05/22/2020 12:52 PM]
05/22/2020	59	Petition for en banc rehearing filed by Appellants Hologic, Inc. and Cytyc Surgical Products, LLC. Service: 05/22/2020 by email. [696694] [19-2054] [Matthew Wolf] [Entered: 05/22/2020 05:17 PM]
05/27/2020	60	18 paper copies of the combined petition for panel rehearing and rehearing en banc [58] received from Minerva Surgical, Inc. [697254] [MJL] [Entered: 05/27/2020 03:07 PM]
06/04/2020	61	The court invites a response from Appellants Cytyc Surgical Products, LLC and Hologic, Inc. to the petition for panel rehearing, for en banc

DATE	NO.	DOCKET TEXT
		rehearing filed by Cross-Appellant in 19-2054; and invites a response from Cross-Appellant Minerva Surgical, Inc. to the petition for en banc rehearing filed by Appellants in 19-2054. The responses are due on or before 06/18/2020. [699240] [JAB] [Entered: 06/04/2020 01:22 PM]
06/05/2020	62	Entry of appearance for Mark A. Lemley as principal counsel for Amici Curiae 26 Intellectual Property Professors in Support of Granting the Petition for En Banc Review. Service: 06/05/2020 by email. [699573] [19-2054] [Mark Lemley] [Entered: 06/05/2020 01:13 PM]
06/05/2020	63	FILED from Amici Curiae 26 Intellectual Property Professors in Support of Granting the Petition for En Banc Review Title: AMICUS CURIAE BRIEF. Service: 06/05/2020 by email. [699576] [19-2054] This document is non-compliant. See Doc. No. [65]. [Mark Lemley] [Entered: 06/05/2020 01:18 PM]
06/05/2020	64	Certificate of Interest for Amici Curiae 26 Intellectual Property Professors in Support of Granting the Petition for En Banc Review. Service: 06/05/2020 by email. [699583] [19-2054] [Mark Lemley] [Entered: 06/05/2020 01:20 PM]

DATE	NO.	DOCKET TEXT
06/08/2020	65	NOTICE OF NON-COMPLIANCE: The submission of Movant 26 Intellectual Property Professors, Amicus Curiae Brief [63], is not in compliance with the rules of this court (see attached). Compliant document due on 06/15/2020. Service as of this date by the Clerk of Court. [699801] [JAB] [Entered: 06/08/2020 12:22 PM]
06/09/2020	66	MOTION of 26 Intellectual Property Professors in Support of Granting the Petition for En Banc Review for leave to file amicus brief in support of Neither party. The brief is in support of granting the Petition for En Banc Review. on petition [59], petition [58], petition [58] [Consent: unopposed]. Service: 06/09/2020 by email. [700194] [19-2054] [Mark Lemley] [Entered: 06/09/2020 05:48 PM]
06/10/2020	67	ORDER filed granting motion leave to file amicus brief on en banc or rehearing petition [66]. By: Merits Panel (Per Curiam). Service as of this date by the Clerk of Court. [700292] [JAB] [Entered: 06/10/2020 11:46 AM]
06/10/2020	68	CORRECTED AMICUS BRIEF FILED on Petition for 26 Intellectual Property Professors. Pages: 13. Service: 06/09/2020 by email. [700293] [JAB] [Entered: 06/10/2020 11:50 AM]
06/18/2020	69	RESPONSE of Cross-Appellant Minerva Surgical, Inc. to the petition

DATE	NO.	DOCKET TEXT
		[59] filed by Appellants Hologic, Inc. and Cytyc Surgical Products, LLC. Service: 06/18/2020 by email. [702319] [19-2054] [Robert Hochman] [Entered: 06/18/2020 06:47 PM]
06/18/2020	70	RESPONSE of Appellants Cytyc Surgical Products, LLC and Hologic, Inc. to the petition for panel rehearing [58] filed by Cross-Appellant Minerva Surgical, Inc., petition for en banc rehearing [58] filed by Cross-Appellant Minerva Surgical, Inc.. Service: 06/18/2020 by email. [702326] [19-2054] [Matthew Wolf] [Entered: 06/18/2020 09:15 PM]
06/23/2020	71	18 paper copies of the response [69] received from Minerva Surgical, Inc. [703102] [MJL] [Entered: 06/23/2020 02:18 PM]
07/22/2020	72	ORDER filed denying [59] petition for en banc rehearing filed by Hologic, Inc. and Cytyc Surgical Products, LLC, denying [58] petition for panel rehearing, for en banc rehearing filed by Minerva Surgical, Inc. By: En Banc (Per Curiam). Service as of this date by the Clerk of Court. [709185] [JAB] [Entered: 07/22/2020 11:15 AM]
07/29/2020	73	Mandate issued to the United States District Court for the District of Delaware. Service as of this date by the Clerk of Court. [710906] [19-2054,

DATE	NO.	DOCKET TEXT
		19-2081] [JAB] [Entered: 07/29/2020 10:01 AM]
10/08/2020	74	Petition for writ of certiorari filed on 09/30/2020, and placed on the docket 10/06/2020, in the U.S. Supreme Court. No.: 20-440, Minerva Surgical, Inc. v. Hologic, Inc., et al. [727549] [JAB] [Entered: 10/08/2020 08:29 AM]
11/13/2020	75	Petition for writ of certiorari filed on 11/05/2020, and placed on the docket 11/10/2020, in the U.S. Supreme Court. No.: 20-631, Hologic, Inc., et al. v. Minerva Surgical, Inc. [735330] [MJL] [Entered: 11/13/2020 10:54 AM]
01/11/2021	76	The petition for writ of certiorari, No. 20-631, filed on 11/05/2020, was Denied on 01/11/2021. [748430] [JAB] [Entered: 01/11/2021 02:50 PM]
01/11/2021	77	The petition for writ of certiorari, No. 20-440, filed on 09/30/2020, was Granted on 01/08/2021. [748441] [JAB] [Entered: 01/11/2021 03:01 PM]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No.: 1:15-cv-01031-SLR

HOLOGIC, INC., a Delaware corporation; and CYTYC SURGICAL PRODUCTS, LLC, a Delaware corporation,

Plaintiffs,

v.

MINERVA SURGICAL, INC., a Delaware corporation,

Defendant.

DECLARATION OF DR. EDWARD EVANTASH
IN SUPPORT OF HOLOGIC, INC.'S
MOTION FOR A PRELIMINARY INJUNCTION

FILED UNDER SEAL

I, Edward Evantash, state and declare as follows:

1. I am over the age of 21 and am competent to make this declaration. I am employed by Hologic, Inc. and I have worked at Hologic for over six years. My current title at Hologic is Vice President of Medical Affairs. I provide this declaration in support of Hologic's motion for a preliminary injunction. If called as a witness, I could and would testify competently to the information contained herein.

2. My practice and expertise is in Obstetrics and Gynecology, the medical field for which I did my medical residency and training in the early 1990s. Over the past 6 years, I have worked at Hologic, including as a Medical Director and Vice President of

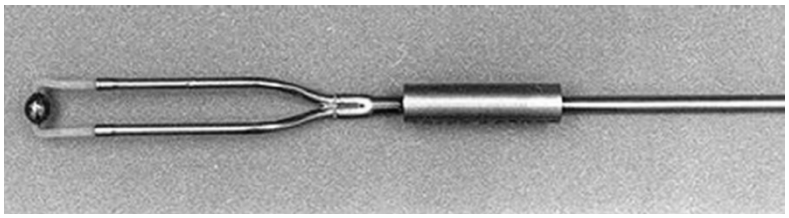
Medical Affairs. Prior to Hologic, I worked at Tufts University as a Director at the Center for Abnormal Uterine Bleeding. I worked at Tufts University for 15 years. Over the past two decades, a focus in my professional work has been clinical research and practice in addressing abnormal uterine bleeding in women, a medical condition known as menorrhagia.

3. Physicians have employed a number of techniques to address the problem of abnormal uterine bleeding in women. For example, many women have decided to undergo a hysterectomy, a surgery which removes a woman's uterus. In the 1990s, however, endometrial ablation gained in popularity as an alternative to hysterectomy. Endometrial ablation is a surgical procedure that destroys the endometrial lining of the uterus, but otherwise does not remove or destroy the remainder of the uterus.

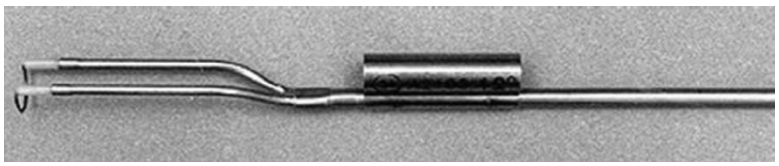
4. In the 1990s, physicians performed endometrial ablation using first generation techniques, including (1) the burning of endometrial tissue with an electrosurgical metal rollerball; and (2) endometrial resection with a metal wire loop electrode. Electricity was conducted from the metal instrument and applied to the endometrial tissue, which would be cauterized through heat and thus destroyed.

5. The rollerball technique used energy for heating the tissue to a temperature between 60 to 90ºC. The uterine lining is destroyed by contact with the heated ball that the physician must roll slowly over the surface of the endometrial lining, burning it away. The physician must be skilled to roll the small-sized, heated ball systematically across the various sections of the uterus to burn the endometrial lining throughout. A physician would perform the rollerball proce-

dure under direct visualization with a hysteroscope. Here is a photograph of a rollerball instrument:

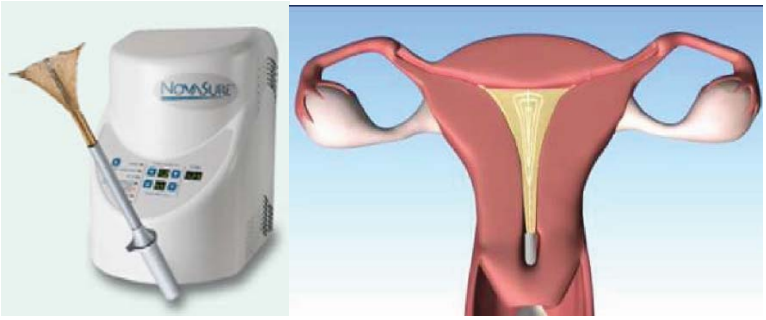


6. Another first generation method was endometrial resection with a metal wire loop. Using the metal wire loop, the physician would systematically strip off the lining of the uterus. The physician would resect or strip away the uterine lining with the wire loop under direct visualization of a hysteroscope. Similar to the rollerball, the physician must be skilled to manually strip away the uterine lining, bit by bit, using a small wire loop throughout the cavity of the uterus. Here is a photograph of an instrument using the wire loop:



7. With the introduction of the NovaSure endometrial ablation system (the "NovaSure system"), endometrial ablation came a long way from the first generation techniques that were employed in the 1990s to address abnormal uterine bleeding without hysterectomy. The NovaSure system became the leading system in a second generation of devices, known for global endometrial ablation. With global endometrial ablation, the NovaSure system treated all areas of the endometrial cavity simultaneously, with minimal hand manipulation. With the NovaSure system, the physician did not need move a small heated ball or a small wire loop manually in a systemic and tedious

procedure that would burn or strip away bit by bit the endometrial lining of the uterus. The rollerball and wire loop techniques presented serious risks to the patient because of the possibility of electrocuting nearby organs. By contrast, the NovaSure system employed an elongated device with an expandable applicator head that conformed to the shape of the uterus to treat the entire endometrial cavity simultaneously in two minutes or less. On the left is a photograph of an early NovaSure system using a mesh applicator head, and on the right, is an illustration of a NovaSure mesh application treating the entire cavity at once.



8. With first generation techniques, physicians needed to distend the uterus with a non-conducting fluid under pressure. This distention required careful control of the fluid pressure to avoid forcing the potentially toxic fluid into the bloodstream via the vessels in the uterine wall (known as intravasation) or into the abdominal cavity via the fallopian tubes. Using the NovaSure system eliminates the need for a non-conducting fluid inside the uterus, thus avoiding the risk of intravasation.

9. Further, the NovaSure system has provided a computerized and sensor-based integrity test to monitor for any perforations (i.e., holes) of the uterus before

administering treatment. Prior to the NovaSure system, a physician had to rely on a manual, visual inspection to identify any perforations in the uterus before the ablation treatment because these perforations could allow steam or hot fluids to escape the uterus and cause serious organ injury to the patient. Physicians would inspect for perforations visually using a tool called a hysteroscope which, when inserted transcervically, allowed a physician to view the inside of the uterus. But, the physician sometimes could not see small perforations with this procedure because the view from a hysteroscope could be limited and/or the uterus had irregularities. In short, spotting perforations with the prior techniques required a high-level of physician skill, and had to be performed in the controlled setting of an operating room.

10. In addition, the NovaSure uses feedback from the tissue itself to customize each ablation. This is because the total amount of energy delivered depends on the impedance (i.e., electrical resistance) of the tissue in contact with the applicator head. In other words, the energy delivery occurs where it is needed most, i.e., deeper tissues receive more energy, and this helps to control the amount of energy delivery during treatment.

11. During the ablation procedure, the energy delivery causes steam and hot moisture to develop inside the uterine cavity. To avoid this moisture from building up inside the cavity, NovaSure provides "moisture transport" functionality that removes the moisture from the cavity.

12. With the above technical advances, including the treatment of all areas of the endometrial cavity simultaneously, the NovaSure system revolutionized the procedure of endometrial ablation as a safer

alternative to first generation techniques for treating abnormal uterine bleeding. Further, as a practical matter, the NovaSure procedure could be performed in a physician's office in five minutes. The first generation techniques required the use of an operating room at a surgery center, where the surgeon would take about 30 to 50 minutes to burn or strip away the portions of the endometrial lining. Because the NovaSure procedure could be performed in a physician's office, such procedures could be less expensive, less intimidating, and substantially more convenient and comfortable for the patient.

13. The NovaSure system continues to provide a sensor-based, computerized integrity test of the uterus before any treatment can occur. The purpose of the integrity test is to assess whether any perforations (i.e., holes) of the uterus are present. Serious injury can occur if perforations are present in the uterus during treatment because hot steam or fluids generated during treatment can escape through the small perforations to damage nearby organs. The NovaSure system originally implemented its computerized integrity test because the clinical data made clear that endometrial ablation should not be performed if the uterus had any perforation, even a small one. Thus, perforation detection has been critically important. Therefore, if a perforation is present in the uterus, the NovaSure system will not start the treatment. NovaSure tests for perforations by sealing the uterus and supplying carbon dioxide gas into the uterus, and then measuring whether there is any flow of gas out of the uterus indicating the presence of a hole. This sensor-based, computerized monitoring for perforations is substantially more accurate than the prior technique of a physician conducting a manual, visual inspection with a hysteroscope. Hologic maintains a

post-market quality assurance tracking of all reportable complications through its representatives and by direct communication with health care providers. Based on this information, Hologic estimates the rate of bowel injury with NovaSure endometrial ablation is less than 1 in 10,000 procedures. These safety rates can be attributed to the NovaSure system pioneering the implementation of its uterine integrity test before endometrial ablation treatment can proceed.

14. Because of all the above features, the NovaSure system has become the leading endometrial ablation product in the world, having treated over two million patients over the past decade. Over the past decade, patients have used three generations of the NovaSure endometrial ablation system, including the current handpiece, photographed here:

Given the long track record of the NovaSure system, there have been many prospective, statistical studies that track groups of patients over periods of 12 months, 36 months, and 60 months, for example. Ex. 28[1] ("Ten-year literature review of global endometrial ablation with the NovaSure device"). These studies confirm the efficacy and safety of the NovaSure system. For example, in arguable the most comprehensive, prospective study, the long-term efficacy of the

[1] Exhibit 28 refers to Exhibit 28 of the Declaration of Marc Cohn in support of Holgic's Motion for a Preliminary Injunction.

NovaSure procedure was reported over a 60-month follow-up period. *Id*. at 3 of exhibit (*i.e.*, page 271 of publication). By 60 months post-procedure, this study reported that 75% of patients had amenorrhea (a lack of any bleeding) and only 2% of patients had menorrhagia. *Id*. Given this track record, the NovaSure system has a decades-long, proven record in safety and efficacy for the treatment of menorrhagia.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my personal knowledge.

Executed this 14 day of Dec, 2015 at Marlborough, Mass.

/s/ Edward Evantash
Dr. Edward Evantash

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 15-1031-SLR

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

v.

MINERVA SURGICAL, INC.,
Defendant.

JURY TRIAL DEMANDED
REDACTED PUBLIC VERSION

DEFENDANT MINERVA SURGICAL, INC.'S ANSWER TO HOLOGIC, INC.'S AND CYTYC SURGICAL PRODUCTS, LLC'S SECOND AMENDED COMPLAINT FOR INFRINGEMENT AND COUNTERCLAIMS

Defendant Minerva Surgical, Inc. ("Minerva"), by and through its undersigned attorneys, respectively submits this Answer to the Second Amended Complaint for Patent Infringement ("SAC") (D.I. 70) filed by Plaintiffs Hologic, Inc. ("Hologic") and Cytyc Surgical Products, LLC ("Cytyc") (collectively, "Plaintiffs") and Counterclaims against Plaintiffs, as follows:

NATURE OF THE ACTION

1. Minerva admits that this action involves Plaintiffs' allegations that Minerva infringes U.S. Patent Nos. 6,872,183 ("the '183 patent"), 8,998,898 ("the '898 patent"), 9,095,348 ("the '348 patent), and

9,247,989 ("the '989 patent") (collectively "the Patents-in-Suit").

THE PARTIES

2. Minerva admits only that, upon information and belief, Hologic is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Minerva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 2 of the SAC, and accordingly denies the same.

3. Minerva admits only that, upon information and belief, Cytyc is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Minerva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 3 of the SAC, and accordingly denies the same.

4. Minerva is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the SAC, and accordingly denies the same.

5. Minerva admits that it is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 101 Saginaw Drive, Redwood City, CA, 94063.

JURISDICTION AND VENUE

6. Minerva admits that the SAC purports to set forth a claim for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code. Minerva further admits that the

SAC purports to set forth claims for unfair competition arising under the Lanham Act, 15 U.S.C. § 1051 *et seq.*, and the law of the State of Delaware. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 6 of the SAC.

7. Minerva admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338, and 15 U.S.C. §§ 1121(a) and 1125(a). Minerva also admits that this Court has jurisdiction over the state law claims asserted in the SAC pursuant to 28 U.S.C. § 1367, as the state law claims arise from the same common nucleus of operative facts as the federal claims.

8. Minerva admits that this Court has personal jurisdiction over Minerva as a Delaware corporation. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 8 of the SAC.

9. Minerva admits that venue is proper in this District under §§ 1391 and 1400(b) because Minerva is a Delaware corporation, but denies that this is an appropriate or convenient forum for this dispute. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 9 of the SAC.

BACKGROUND

10. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 10 of the SAC, and accordingly denies the same.

11. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 11 of the SAC, and accordingly denies the same.

12. Minerva is without knowledge or information sufficient to for a belief as to the truth of the

allegations of paragraph 12 of the SAC, and accordingly denies the same.

13. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 13 of the SAC, and accordingly denies the same.

14. Minerva admits that Exhibit A of the SAC purports to be a copy of the Minerva Endometrial Ablation System Operator's manual. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 14 of the SAC.

15. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 15 of the SAC, and accordingly denies the same.

16. Minerva denies all allegations in paragraph 16 of the SAC.

17. Minerva denies all allegations in paragraph 17 of the SAC.

18. Minerva denies all allegations in paragraph 18 of the SAC.

19. Minerva denies all allegations in paragraph 19 of the SAC.

20. Minerva admits that Dr. James Mirabile has a talk radio show on KCMO, 710 AM and 103.7 FM in the Kansas City area and on September 19, 2015 Minerva's Vice President, Eugene Skalnyi, participated in the show to discuss Minerva's Endometrial Ablation System. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 20 of the SAC.

21. Minerva admits that a podcast of the radio show is shared with physicians. Except as expressly

admitted, Minerva denies any and all remaining allegations in paragraph 21 of the SAC.

22. Minerva denies all allegations in paragraph 22 of the SAC.

23. Minerva denies all allegations in paragraph 23 of the SAC.

24. Minerva denies all allegations in paragraph 24 of the SAC.

25. Minerva admits that it provides an Operator's Manual for the Endometrial Ablation System to its physician customers and at the beginning of the Operator's Manual it states "READ ALL INSTRUCTIONS, CAUTIONS AND WARNINGS PRIOR TO USE. FAILURE TO FOLLOW ANY INSTRUCTIONS OR TO HEED ANY WARNINGS OR PRECAUTIONS COULD RESULT IN SERIOUS PATIENT INJURY." Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 25 of the SAC.

COUNT I

(Alleged Infringement of the '183 Patent)

26. Minerva incorporates by reference the above paragraphs of this Answer.

27. Minerva admits that on its face the '183 patent entitled "System and Method for Detecting Perforations in a Body Cavity," was issued on March 29, 2005 to Russel M. Sampson, Mike O'Hara, Csaba Truckai, and Dean T. Miller. Minerva admits that Exhibit B of the SAC purports to be a true and correct copy of the '183 patent. Minerva denies any and all remaining allegations in paragraph 27 of the SAC.

28. Minerva admits only that, upon information and belief, Cytyc claims to have assigned the '183

patent to Hologic on January 15, 2016. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 28 of the SAC, and on that basis, denies them.

29. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 of the SAC, and on that basis, denies them.

30. Minerva admits that it had knowledge of the '183 patent prior to the filing of the original Complaint. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 30 of the SAC.

31. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 31 of the SAC.

32. Minerva denies all allegations in paragraph 32 of the SAC.

33. Minerva denies all allegations in paragraph 33 of the SAC.

34. Minerva denies all allegations in paragraph 34 of the SAC.

35. Minerva denies all allegations in paragraph 35 of the SAC.

36. Minerva denies all allegations in paragraph 36 of the SAC.

COUNT II
(Alleged Infringement of the '898 Patent)

37. Minerva incorporates by reference the above paragraphs of this Answer.

38. Minerva admits that Plaintiffs purport that the '898 patent entitled "Moisture Transport System for

Contact Electrocoagulation," was issued on April 7, 2005 to Csaba Truckai, Russel M. Sampson, Stephanie Squarcia, Alfonso L. Ramirez, Estela Hilario, and David C. Auth. Minerva admits that Exhibit C of the SAC purports to be a true and correct copy of the '898 patent. Minerva denies any and all remaining allegations in paragraph 38 of the SAC.

39. Minerva admits only that, upon information and belief, Cytyc claims it assigned the '898 patent to Hologic on January 15, 2016. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 39 of the SAC, and on that basis, denies them.

40. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40 of the SAC, and on that basis, denies them.

41. Minerva admits that it had knowledge of the '898 patent prior to the filing of the original Complaint. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 41 of the SAC.

42. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 42 of the SAC.

43. Minerva denies all allegations in paragraph 43 of the SAC.

44. Minerva denies all allegations in paragraph 44 of the SAC.

45. Minerva denies all allegations in paragraph 45 of the SAC.

46. Minerva denies all allegations in paragraph 46 of the SAC.

47. Minerva denies all allegations in paragraph 47 of the SAC.

COUNT III
(Alleged Infringement of the '348 Patent)

48. Minerva incorporates by reference the above paragraphs of this Answer.

49. Minerva admits that Plaintiffs purport that the '348 patent entitled "Moisture Transport System for Contact Electrocoagulation," was issued on August 5, 2015 to Csaba Truckai, Russel M. Sampson, Stephanie Squarcia, Alfonso L. Ramirez, and Estela Hilario. Minerva admits that Exhibit D of the SAC purports to be a true and correct copy of the '348 patent. Minerva denies any and all remaining allegations in paragraph 49 of the SAC.

50. Minerva admits only that, upon information and belief, Cytyc claims to have assigned the '348 patent to Hologic on January 15, 2016. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 50 of the SAC, and on that basis, denies them.

51. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 51 of the SAC, and on that basis, denies them.

52. Minerva admits that it had knowledge of the '348 patent prior to the filing of the original Complaint. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 52 of the SAC.

53. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 53 of the SAC.

54. Minerva denies all allegations in paragraph 54 of the SAC.

55. Minerva denies all allegations in paragraph 55 of the SAC.

56. Minerva denies all allegations in paragraph 56 of the SAC.

57. Minerva denies all allegations in paragraph 57 of the SAC.

58. Minerva denies all allegations in paragraph 58 of the SAC.

COUNT IV
(Alleged Unfair Competition Under
15 U.S.C. § 1125(a))

59. Minerva incorporates by reference the above paragraphs of this Answer.

60. Minerva denies all allegations in paragraph 60 of the SAC.

61. Minerva admits that Minerva markets and/or sells its Endometrial Ablation System in the United States and travels in interstate commerce. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 61 of the SAC.

62. Minerva denies all allegations in paragraph 62 of the SAC.

63. Minerva denies all allegations in paragraph 63 of the SAC.

64. Minerva denies all allegations in paragraph 64 of the SAC.

65. Minerva denies all allegations in paragraph 65 of the SAC.

66. Minerva denies all allegations in paragraph 66 of the SAC.

67. Minerva denies all allegations in paragraph 67 of the SAC.

COUNT V
(Alleged Deceptive Trade Practice Under
6 Del. C. § 2532)

68. Minerva incorporates by reference the above paragraphs of this Answer.

69. Minerva denies all allegations in paragraph 69 of the SAC.

70. Minerva denies all allegations in paragraph 70 of the SAC.

71. Minerva denies all allegations in paragraph 71 of the SAC.

72. Minerva denies all allegations in paragraph 72 of the SAC.

73. Minerva denies all allegations in paragraph 73 of the SAC.

74. Minerva denies all allegations in paragraph 74 of the SAC.

75. Minerva denies all allegations in paragraph 75 of the SAC.

76. Minerva denies all allegations in paragraph 76 of the SAC.

77. Minerva denies all allegations in paragraph 77 of the SAC.

COUNT VI
(Alleged Unfair Competition–Delaware Common Law)

78. Minerva incorporates by reference the above paragraphs of this Answer.

79. Minerva denies all allegations in paragraph 79 of the SAC.

80. Minerva denies all allegations in paragraph 80 of the SAC.

81. Minerva denies all allegations in paragraph 81 of the SAC.

82. Minerva denies all allegations in paragraph 82 of the SAC.

83. Minerva denies all allegations in paragraph 83 of the SAC.

84. Minerva denies all allegations in paragraph 84 of the SAC.

85. Minerva denies all allegations in paragraph 85 of the SAC.

86. Minerva denies all allegations in paragraph 86 of the SAC.

87. Minerva denies all allegations in paragraph 87 of the SAC.

COUNT VII
(Alleged Tortious Interference With A Business Relationship–Delaware Common Law)

88. Minerva incorporates by reference the above paragraphs of this Answer.

89. Minerva denies all allegations in paragraph 89 of the SAC.

90. Minerva denies all allegations in paragraph 90 of the SAC.

91. Minerva denies all allegations in paragraph 91 of the SAC.

92. Minerva denies all allegations in paragraph 92 of the SAC.

93. Minerva denies all allegations in paragraph 93 of the SAC.

94. Minerva denies all allegations in paragraph 94 of the SAC.

95. Minerva denies all allegations in paragraph 95 of the SAC.

96. Minerva denies all allegations in paragraph 96 of the SAC.

97. Minerva denies all allegations in paragraph 97 of the SAC.

COUNT VIII
(Alleged Infringement of the '989 Patent)

98. Minerva incorporates by reference the above paragraphs of this Answer.

99. Minerva admits that on its face the '989 patent entitled "Moisture Transport System for Contact Electrocoagulation," was issued on February 2, 2016 to Csaba Truckai. Minerva admits that Exhibit H of the SAC purports to be a true and correct copy of the '989 patent. Minerva denies any and all remaining allegations in paragraph 99 of the SAC.

100. Minerva admits that Cytyc purports to be the assignee and lawful owner of all right, title, and interest in and to the '989 patent. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 100 of the SAC, and on that basis, denies them.

101. Minerva admits that it had knowledge of the '989 patent prior to the filing of the SAC. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 101 of the SAC.

102. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted,

Minerva denies any and all remaining allegations in paragraph 102 of the SAC.

103. Minerva denies all allegations in paragraph 103 of the SAC.

104. Minerva denies all allegations in paragraph 104 of the SAC.

105. Minerva denies all allegations in paragraph 105 of the SAC.

106. Minerva denies all allegations in paragraph 106s of the SAC.

PRAYER FOR RELIEF

1. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 1.

2. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 2.

3. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 3.

4. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 4.

5. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 5.

6. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 6.

7. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 7.

8. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 8.

9. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 9.

10. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 10.

11. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 11.

12. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 12.

13. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 13.

14. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 14.

15. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 15.

16. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 16.

17. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 17.

18. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 18.

19. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 19.

20. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 20.

21. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 21.

AFFIRMATIVE DEFENSES

In addition to the affirmative defenses described below, subject to its responses above, Minerva specifically reserves all rights to allege additional affirmative defenses that become known through the course of discovery.

FIRST AFFIRMATIVE DEFENSE
(Failure to State Claim)

107. The SAC fails to state a claim for which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Noninfringement)

108. Minerva is not infringing and has not infringed, directly, by inducement, contributorily or in any other way, any claim of the '183, '898, '348, and '989 patents.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

109. One or more asserted claims of the '183, '898, '348, and '989 patents are invalid for failing to meet the conditions for patentability in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112.

FOURTH AFFIRMATIVE DEFENSE
(Estoppel)

110. The claims of '183, '898, '348, and '989 patents are and were limited by amendment, the prior art, and/or by the statements made during their prosecution before the U.S. Patent and Trademark Office ("USPTO") such that Plaintiffs are now estopped and/or otherwise precluded from maintaining that such claims of the '183, '898, '348, and '989 patents are of sufficient scope to cover the accused products either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE
(Failure to Mark and Limitation on Damages)

111. Plaintiffs' claim for damages is barred in whole or in part by failure to provide adequate notice under

35 U.S.C. § 287. Any claim for damages for patent infringement is limited to only those damages occurring after the notice of infringement and, in any event, by 35 U.S.C. § 286.

SIXTH AFFIRMATIVE DEFENSE
(No Right to Injunctive Relief)

112. Plaintiffs are not entitled to injunctive relief because any injury to Plaintiffs is not immediate or irreparable, and Plaintiffs have an adequate money remedy for any claim that they can prove.

SEVENTH AFFIRMATIVE DEFENSE
(Safe Harbor)

113. There is no infringement—directly, by inducement, contributorily or in any other way—of any valid claim of the '183, '898, '348, and '989 patents by Minerva for any allegedly infringing activities falling within the safe harbor under 35 U.S.C. § 271(e).

EIGHTH AFFIRMATIVE DEFENSE
(Laches)

114. Plaintiffs' claims against Minerva regarding the '183, '898, '348, and '989 patents are barred, in whole or in part, by 35 U.S.C. § 286 and/or the doctrine of laches.

NINTH AFFIRMATIVE DEFENSE
(Obviousness-Type Double Patenting)

115. The asserted claims of the '348 and '989 patents are subject to the doctrine of obviousness-type double patenting. In order to issue, the asserted claims of the '348 and '989 patents should have been subject to a terminal disclaimer setting their respective expiration date as April 12, 2016.

TENTH AFFIRMATIVE DEFENSE
(Unclean Hands)

116. Plaintiffs' claims are barred by the doctrine of unclean hands, the facts and circumstances of which are generally described in Minerva's counterclaims below, including Plaintiffs filing this lawsuit in bad faith and making false and misleading statements related to Minerva and Minerva's products.

ELEVENTH AFFIRMATIVE DEFENSE
(Lack of Standing)

117. Plaintiff Hologic lacks standing to assert any claims relating to the '183, '898, '348 and '989 patents because it did not have sufficient rights in the asserted patents at the time the suit was filed.

COUNTERCLAIMS

PARTIES

118. Minerva hereby pleads the following counterclaims against Plaintiffs.

119. Minerva is a corporation organized under the laws of Delaware, having its principal place of business at 101 Saginaw Drive, Redwood City, CA, 94063.

120. On information and belief, based on Plaintiffs' allegations, Hologic is a corporation organized and existing under the laws of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752 and Cytyc is a limited liability company organized and exiting under the laws of the Commonwealth of Massachusetts with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752.

JURISDICTION AND VENUE

121. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

122. Plaintiffs are subject to personal jurisdiction in this judicial district because Plaintiffs availed themselves of the jurisdiction of this Court and engaged in acts giving rise to this controversy in this district.

123. Venue is appropriate in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

124. Since the company's formation in 2008, Minerva has been dedicated to developing and bringing to market new technology that would significantly advance the treatment of abnormal uterine bleeding ("AUB"). To date, Minerva has raised tens of millions from private investors to fund this singular purpose and, having received FDA clearance in July 27, 2015, Minerva is at a critical inflection point for its survival as it begins to commercialize the technology that has been under development for years.

125. Hologic has been well-aware of Minerva's technology and its work since 2009 and has spent years preparing for Minerva's launch. In anticipation of the entrance of new endometrial ablation technology—the first in 15 years—Hologic prepared and is now executing an anti-competitive, no-holds-barred campaign against Minerva that is designed to stamp-out any competition and to prevent Minerva from gaining any traction in the market whatsoever. In doing so, Hologic has gone too far in employing a host of unfair business practices, including the dissemination of false and misleading statements in

the marketplace to customers and prospective customers that were carefully designed to permanently and irreparably harm and malign Minerva, its technology, and its employees.

126. Hologic does so not to protect patients or the physicians that treat them, or to fairly engage on the merits competing products, but to protect its market-share at all costs—NovaSure® generates [redacted] for Hologic.

127. As Hologic is well-aware, the FDA-approved clinical studies demonstrate that Minerva is a safe, effective product. Indeed, clinical studies demonstrated the following efficacy rates in comparison to the Objective Performance Criteria ("OPC") (*i.e.*, combined rates of other endometrial ablation devices approved by FDA) of 66%, which include NovaSure®:

	"Success" (Less than normal bleeding- PBLAC < 75)	**Amenorrhea (Zero bleeding)**	**Adverse Events (>2 Weeks–1 Year)**	**Recom-mend to a Friend**	**Average Procedure Time**
Minerva	91.8%	66.4%	0%	99%	3.9 minutes
NovaSure®	77.7%	36%	12%	95%	5 minutes

128. Minerva achieved these significant results by developing new endometrial ablation technology using scientific advancement and innovation as well as by drawing on the years of experience that its founders

and executives have in this field—several of whom were the original inventors and developers of the NovaSure® technology. Knowing that Minerva's technology was a significant advancement and that its business and scientific team were well-respected innovators, Hologic took note of this rising threat more than six years before a single Minerva unit was sold in the market.

129. [redacted]

130. [redacted]

131. In addition, Hologic has employed a number of business practices designed to unfairly inhibit Minerva's ability to compete in the marketplace, including the dissemination of false and/or misleading statements to customers and prospective customers of Minerva. These unfair business practices began in anticipation of Minerva's entry to the market, and have continued since then.

132. Even before Minerva's system was launched, Hologic began disseminating false and deceptive messages about the safety and technological attributes of Minerva's system. Since then, Hologic has approached and continues to approach physicians and hospital administrators who have used, expressed interest in and/or are potential customers of Minerva's system, with a false and deceptive message that physicians should not use Minerva's system because the device is unsafe for patients.

a. [redacted]

[redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. On February 15, 2015, Minerva formally demanded that Hologic cease and desist from continuing its misleading campaign and to provide a corrective disclosure to those physicians who had exposed to Hologic's false and misleading statements about Minerva and its system. On February 25, 2016, Hologic denied knowledge of any such false or misleading conduct and did not agree to correct its prior statements.

133. On information and belief, Hologic has made and continues to make false and misleading statements about other aspects of Minerva's system, including that the system (i) is associated with a high number of adverse events (contrary to the findings in Minerva's FDA-approved clinical studies); (ii) is associated with a high number of injuries to patients "all over the country"; and (iii) cannot be used in ablation procedures where the patient must first undergo certain other treatments (*e.g.*, removal of polyps or fibroids).

134. Hologic also presents physicians with misleading information about the efficacy of Hologic's NovaSure® device, including on its product label, in articles/advertising sponsored by Hologic, and in direct communications. Since learning the results of Minerva's clinical trials, including efficacy and amenorrhea rates of 91.8% and 66.4% respectively, Hologic continues to depart from the FDA approved results of the NovaSure® clinical study utilized for FDA approval, by advertising on the NovaSure® website that, "The NovaSure® procedure is effective: For 90% of women, menstrual bleeding is dramatically reduced or stopped." The FDA-approved results state efficacy rates of 77.7% (Success rate) and 36% (Amenorrhea or zero bleeding rate). Hologic also advertises that the hysterectomy rate over the five

years following the NovaSure® treatment is less than 3%, when the FDA-approved hysterectomy rate over just three years is 6.3%. Minerva is informed and believes that Hologic has not submitted any supplemental study to the FDA for approval of the improved claims. At the same time, Hologic without basis, mischaracterizes and disparages the results of Minerva's clinical study. In doing so, Hologic is in not only in violation of FDA labeling laws, but is also engaged in deceptive advertising under state law, including the law of Delaware.

FIRST COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '183 Patent)

135. Minerva realleges and incorporates by reference the foregoing paragraphs.

136. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '183 patent.

137. Plaintiffs have charged in the SAC that one or more claims of the '183 patent have been infringed by Minerva.

138. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '183 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or indirectly, any valid or enforceable claims contained in the '183 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

139. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '183

patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

140. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '183 patent.

SECOND COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '898 Patent)

141. Minerva realleges and incorporates by reference the foregoing paragraphs.

142. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '898 patent.

143. Plaintiffs have charged in the SAC that one or more claims of the '898 patent have been infringed by Minerva.

144. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '898 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or indirectly, any valid or enforceable claims contained in the '898 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

145. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '898 patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

146. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '898 patent.

THIRD COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '348 Patent)

147. Minerva realleges and incorporates by reference the foregoing paragraphs.

148. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '348 patent.

149. Plaintiffs have charged in the SAC that one or more claims of the '348 patent have been infringed by Minerva.

150. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '348 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or indirectly, any valid or enforceable claims contained in the '348 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

151. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '348 patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

152. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '348 patent.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Noninfringement
of the '989 Patent)

153. Minerva realleges and incorporates by reference the foregoing paragraphs.

154. Plaintiffs allege in the SAC that Cytyc is the owner of all rights, title, and interest in the '989 patent.

155. Plaintiffs have charged in the SAC that one or more claims of the '989 patent have been infringed by Minerva.

156. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '989 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or indirectly, any valid or enforceable claims contained in the '989 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

157. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '989 patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

158. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '989 patent.

FIFTH COUNTERCLAIM
(Declaratory Judgment of Invalidity
of the '183 Patent)

159. Minerva realleges and incorporates by reference the foregoing paragraphs.

160. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '183 patent.

161. Each and every claim of the '183 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes, including but not limited to §§ 101, 102, 103, and/or 112.

162. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '183 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

163. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '183 patent are invalid.

SIXTH COUNTERCLAIM
(Declaratory Judgment of Invalidity
of the '898 Patent)

164. Minerva realleges and incorporates by reference the foregoing paragraphs.

165. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '898 patent.

166. Each and every claim of the '183 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes,

including but not limited to §§ 101, 102, 103, and/or 112.

167. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '898 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

168. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '898 patent are invalid.

SEVENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity
of the '348 Patent)

169. Minerva realleges and incorporates by reference the foregoing paragraphs.

170. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '348 patent.

171. Each and every claim of the '348 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes, including but not limited to §§ 101, 102, 103, and/or 112.

172. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '348 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

173. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '348 patent are invalid.

EIGHTH COUNTERCLAIM
(Declaratory Judgment of Invalidity
of the '989 Patent)

174. Minerva realleges and incorporates by reference the foregoing paragraphs.

175. Plaintiffs allege in the SAC that Cytyc is the owner of all rights, title, and interest in the '989 patent.

176. Each and every claim of the '989 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes, including but not limited to §§ 101, 102, 103, and/or 112.

177. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '989 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

178. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '989 patent are invalid.

NINTH COUNTERCLAIM
(Unfair Competition Under 15 U.S.C. § 1125(a) & (c))

179. Minerva realleges and incorporates by reference the foregoing paragraphs.

180. Hologic has used a false or misleading description of facts in connection with its marketing and sale of the NovaSure® device.

181. Hologic markets and/or sells the NovaSure® device throughout the United States and travels in interstate commerce.

182. Hologic's conduct has caused and continues to cause confusion or mistake, or has deceived and continues to deceive existing and potential Minerva customers about the relative characteristics of the NovaSure® and Minerva devices.

183. Hologic's conduct has caused further harm to Minerva in the form of tarnishment of Minerva, its device and its mark.

184. Hologic's conduct constitutes unfair competition in violation of 15 U.S.C. § 1125(a) and (c).

185. As a result of Hologic's false description of facts, Minerva has suffered and continues to suffer damages, including loss of sales.

186. Hologic's false and misleading description of facts is willful, making this an exceptional case entitling Minerva to recover Hologic's profits of sales of NovaSure®, actual and enhanced damages, and costs Minerva incurred in prosecuting its claims, pursuant to 15 U.S.C. § 1117(a) and (c).

187. Hologic's false and misleading description has caused and will continue to cause irreparable harm to Minerva for which there is no adequate remedy at law, unless the Court enjoins Hologic's false and misleading statements pursuant to 15 U.S.C. § 1116(c).

TENTH COUNTERCLAIM
(Deceptive Trade Practices Under 6 Del. C. § 2532)

188. Minerva realleges and incorporates by reference the foregoing paragraphs.

189. Hologic in the course of its business, has engaged and continues to engage in conduct that disparages the Minerva system, including without

limitation, but and through its false and misleading representation that the Minerva system is unsafe [redacted]

190. Hologic in the course of its business, has engaged and continues to engage in conduct that causes a likelihood of confusion or misunderstanding about the Minerva system, including without limitation, but and through its false and misleading representation that the Minerva system is unsafe [redacted]

191. Hologic in the course of its business, by and through its false and misleading representations of fact, has engaged and continues to engage in deceptive trade practices in violation of 6 Del. C. § 2532, including without limitation, but and through its false and misleading representation that the Minerva system is unsafe [redacted]

192. As a result of Hologic's conduct, Minerva has suffered and continues to suffer damages, including loss of sales.

193. Equity favors enjoining Hologic's conduct pursuant to 6 Del. C. § 2533(a).

194. Hologic's conduct has been and is willful such that Minerva is entitled to its attorneys' fees and costs.

195. Minerva is entitled to damages under Delaware common law thereby entitling Minerva to treble damages under 6 Del. C. § 2533(c).

ELEVENTH COUNTERCLAIM
(Unfair Competition–Delaware Common Law)

196. Minerva realleges and incorporates by reference the foregoing paragraphs.

197. Minerva had a reasonable expectancy of entering and continuing valid business relationships with existing and potential customers.

198. Hologic has wrongfully interfered with Minerva's existing and potential business relationships by approaching customers that were using, interested in and/or potential customers of Minerva's system and [redacted] (ii) making false and misleading statements of fact regarding the contraindications of Minerva's system; (iii) disparaging Minerva's system, Minerva, and its employees; (iv) making false and misleading statements about the efficacy of Hologic's NovaSure® device; and [redacted]

199. Hologic has used and continues to use false and/or misleading descriptions of facts in connection with its marketing and/or sale of the NovaSure® system.

200. Hologic's conduct has caused and continues to cause confusion or mistake, or has deceived and continues to deceive existing and potential customers of Minerva about the relative characteristics of the NovaSure® and Minerva devices.

201. Hologic's conduct has caused and continues to be undertaken with the purpose of deceiving

customers and appropriating Minerva's business relationships, goodwill, and competitive advantages.

202. Hologic's conduct constitutes unfair competition under the common law, including without limitation by its activities in Delaware.

203. As a result of Hologic's misconduct, Minerva has suffered and continues to suffer economic harm, including loss of sales. As a result of Hologic's misconduct, Hologic has caused and will continue to cause customer confusion or misunderstanding and has caused and will continue to cause damage to Minerva's goodwill with customers and potential customers.

204. Hologic's misconduct has caused and will continue to cause irreparable harm to Minerva for which there is no adequate remedy at law, unless its conduct is enjoined.

TWELFTH COUNTERCLAIM
(Interference with Contract/Business Advantage)

205. Minerva realleges and incorporates by reference the foregoing paragraphs.

206. Minerva had a reasonable expectancy of entering and continuing valid business relationships with existing and prospective customers as well as others, including clinical investigators under contract with Minerva.

207. On information and belief, Hologic had knowledge of Minerva's business relationships and prospective customers as Hologic has been tracking Minerva's activity, including the whereabouts of its sales staff, since before Minerva's system was commercially available and all times since.

208. Hologic has intentionally interfered with Minerva's existing and potential business relationships by approaching customers that were using, interested in and/or potential customers of Minerva's system and (i) making false and misleading statements of fact regarding the safety of Minerva's system, [redacted] (ii) making false and misleading statements of fact regarding the contraindications of Minerva's system; (iii) disparaging Minerva's system, Minerva, and its employees; (iv) making false and misleading statements about the efficacy of Hologic's NovaSure® device; and (v) [redacted]

209. Hologic, by and through its false and misleading statements and conduct, has engaged and in and continues to engage in wrongful conduct in violation of federal and state law, including 15 U.S.C. § 1125 and 6 Del. C. § 2532.

210. Hologic's conduct constituted tortious interference with a business relationship under the common law, including without limitation its activities in Delaware.

211. As a result of Hologic's intentional interference, Minerva has suffered and continues to suffer economic harm, including loss of sales.

212. Hologic's actions and conduct are willful and undertaken with the purpose of deceiving customers.

213. Hologic's intentional interference has caused and will cause irreparable harm to Minerva for which

there is no adequate remedy at law, unless the conduct is enjoined.

THIRTEENTH COUNTERCLAIM
(Breach of Contract)

214. Minerva realleges and incorporates by reference the foregoing paragraphs.

215. [redacted]

216. [redacted]

217. [redacted]

218. [redacted]

219. [redacted]

220. [redacted]

FOURTEENTH COUNTERCLAIM
(Trade Libel)

221. Minerva realleges and incorporates by reference the foregoing paragraphs.

222. Through systematic communications and misrepresentation made by Plaintiffs, Plaintiffs have intentionally published and perpetuated false and malicious statements about Minerva.

223. Plaintiffs' statements are false and were known by Plaintiffs to be false when made.

224. Plaintiffs have made statements about Minerva willfully, with intent to disparage Minerva, and the products offered for sale by Minerva.

225. Plaintiffs' statements were made with the intent and knowledge that individuals and entities with whom Minerva dealt would cease its business dealings with Minerva.

226. Plaintiffs' conduct has caused, and if allowed to continue will continue to cause, Minerva to suffer substantial irreparable injury, for which there is no adequate remedy at law.

227. Minerva has suffered damages as a result of Plaintiffs' actions, including but not limited to a loss of revenue, profits, goodwill, and future earnings.

JURY DEMAND

Minerva demands a trial by jury on all issues so triable.

REQUEST FOR RELIEF

WHEREFORE, Minerva respectfully requests that the Court enter judgment as follows:

A. A judgment in favor of Minerva on all of its Counterclaims;

B. Dismissal of all of Plaintiffs' claims in their entirety with prejudice;

C. A judgment that Plaintiffs take nothing by their Second Amended Complaint;

D. A declaration that Minerva does not infringe, directly or indirectly, literally or by the doctrine of equivalents, any valid enforceable claims of the '183, '898, '348, and '989 patents;

E. A declaration that each and every claim of the '183, '898, '348, and '989 patents is invalid;

F. Awarding damages to Minerva for tortuously interfering with Minerva's business relationships and for unfairly competing with Minerva under both Federal and Delaware law;

G. Awarding damages to Minerva for breach of contract;

H. An order preliminarily and permanently enjoining Plaintiffs, their affiliates and subsidiaries, and each of their officers, agents, servants and employees and those acting in privity of concert with them, from:

i. Threatening to assert or otherwise attempt to enforce the '183, '898, '348, and '989 patents against Minerva, its customers, suppliers, or anyone in privity with Minerva;

ii. Distributing or using any advertising, promotional material, sales material, solicitations, or mailing (electronic or otherwise), or making any statement to its customers, potential customers or suppliers, which contains an express or implied claim that Minerva has infringed or is infringing the '183, '898, '348, and '989 patents unless and until

there is such a judgment of infringement against Minerva;

iii. Using this action or any other lawsuit between any of the parties to this action to solicit business for Plaintiffs;

iv. Soliciting or accepting orders from a customer using the false and or misleading advertising or unfair competitive statements discussed herein, or any other advertising or statements containing similar false or misleading claims;

v. Using false and/or misleading representations or descriptions in commerce that are likely to cause confusion regarding the characteristics of Minerva's accused system;

vi. Using false and/or misleading representations or descriptions in commerce that interfere with or are likely to injure Minerva's business relations;

vii. Unfairly competing with Minerva; and

viii. Committing any acts which are likely to injure Minerva's business reputation.

I. A judgment that this is an "exceptional case" and an award of Minerva's reasonable attorneys' fees, expenses, and costs in this action under 35 U.S.C. § 285; and

J. An award of such other relief as the Court may deem appropriate and just under the circumstances.

Respectfully submitted,

ROSS ARONSTAM & MORITZ LLP

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Dated: March 4, 2016

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 15-1031-SLR

HOLOGIC, INC. and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs,
v.
MINERVA SURGICAL, INC.,
Defendant.

JURY TRIAL DEMANDED
FILED UNDER SEAL

DECLARATION OF DR. EVGUENI SKALNYI M.D. IN SUPPORT OF DEFENDANT MINERVA SURIGICAL, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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Dated: March 11, 2016

I, Evgueni Skalnyi, M.D., the undersigned, state and declare as follows:

A. Qualifications

1. I am employed by Minerva Surgical, Inc. ("Minerva"). I have worked at Minerva for over 5 years. My current title is Vice President Medical Affairs.

2. I am a trained Gynecologist. I am over twenty-one years of age, and unless otherwise stated, I have personal knowledge of the facts set out in this declaration, and if called upon to testify, I could and would testify competently regarding these facts.

3. I earned my Medical Degree from State University of Medicine and Pharmacy Nicolae Testemitanu in 1988. I worked as a practicing Obstetrician/ Gynecologist, served as an Associate Professor at Department of Obstetrics and Gynecology at State University of Medicine and Pharmacy Nicolae Testemitanu. After my immigration to the United States I worked as a Clinical Instructor at the Stanford University Endoscopy Center, followed by a number of positions in a variety of medical device companies. During all these years I became intimately familiar with endometrial ablation. I personally performed, taught and supported thousands of endometrial ablation procedures in USA, Canada, UK, Germany, The Netherlands, Norway, Hungary, Mexico, Australia, New Zealand, and many other countries. I made numerous scientific presentations on this subject at a variety of national and international specialty meetings and congresses. For over a decade I serve as an AdHoc reviewer at the Journal of Minimally Invasive Gynecology. In 2011 I became and currently serve as a Member of the Editorial Advisory Board for the same Journal. I was the architect of a

significant number of clinical research efforts, including studies performed under the FDA's Investigational Device Exemption (IDE) regulations. Outcomes of these research efforts were published in many reputable specialty peer-reviewed Journals. I have personal experience using both the NovaSure system and Minerva's Endometrial Ablation System ("EAS") on live patients, and have used earlier technology – including the roller ball, when the NovaSure and Minerva Systems were not available.

4. In 1998 I joined Novacept and was a key participant in the group that designed, developed and commercialized the NovaSure system. After acquisition of Novacept by Cytyc in 2004, I joined Cytyc and served in the capacity of Vice President of Medical Affairs at Cytyc Surgical Products until the transfer of the company to Hologic in 2007. I was never employed by Hologic in any capacity.

5. I am very familiar with the clinical testing conducted to support FDA approval of both the NovaSure and Minerva endometrial ablation devices, as well as the true clinical value of such data. I am also well aware of the differences between the clinical research needed to support FDA approval of endometrial ablation devices and other post-approval research efforts. I am generally very familiar with most of the intricacies of the NovaSure technology, steps of the procedure, etc. I have educated thousands of doctors in the NovaSure procedure, as well as prepared many to serve as educators, speakers, and trainers for NovaSure. I am also very familiar with most of the intricacies of the Minerva EAS technology, steps of the procedure, etc. I have also educated doctors in the use of the Minerva EAS.

B. The Condition

6. About 10 million American women suffer from menorrhagia (excessive and often painful menstrual bleeding) each year. Many women begin to experience heavy and/or irregular bleeding in their 30s and 40s, as they begin to get closer to menopause. Heavy periods are more than just an annoyance—they can take a physical, social, and emotional toll as well. Menorrhagia can be a debilitating condition that can negatively impact a woman's quality of life. Between 15-20% of healthy women experience debilitating menorrhagia that interferes with their normal activities. In the absence of a better and less invasive alternative, in the 1990s the most common treatment available to such women was a hysterectomy (removal of the uterus).

7. Uterine ablation, also referred to as endometrial ablation, is an in-office procedure performed by a trained physician to lighten or stop heavy periods in woman with menorrhagia. It is performed by ablating (destroying) the endometrial lining of the uterine cavity using a variety of techniques (Radio frequency, or RF, energy, thermal energy including heat or cold). Endometrial ablation techniques are divided into two broad categories: First and Second Generation. First Generation technologies, Nd:YAG laser (Goldrath 1981) and the rollerball technique (Vancaillie 1996 ablation), were developed starting in the 1980's. Although efficacious, these technologies are associated with a significant learning curve and have a higher incidence of intra-operative adverse events: uterine perforation, hemorrhage, fluid intra-vasation, hyponatremia, encephalopathy, death (Hulka 1993).

8. Due to the significant complexity of First Generation endometrial ablation systems, Second

Generation endometrial ablation technologies were developed. There are currently six endometrial ablation systems approved by the FDA (ThermaChoice UBT®, HydroThermablator® (HTA)–Her Option®, NovaSure®, MEA, and Minerva's EAS) and five are commercially available in the U.S. (ThermaChoice UBT®, HydroThermablator® (HTA)–Her Option®, NovaSure®, and Minerva's EAS). These new technologies are generally faster, less complex and, in most cases, allow for a significant reduction in the incidence of complications associated with endometrial ablation when compared to the First Generation "Gold Standard," namely, rollerball ablation. These Second Generation technologies allow the average gynecologist to offer a less invasive treatment option for his or her patients with menorrhagia. These Second Generation technologies include the use of heated liquid, either contained within a balloon inflated in the uterus (ThermaChoice) or instilled directly into the uterus (HTA). Others employ the use of super-low temperatures (Her Option). Yet others employ RF energy (NovaSure) or microwave energy (MEA) to achieve endometrial tissue destruction. There is a significant body of scientific evidence demonstrating the safety and effectiveness of all of these systems relative to the First Generation systems.

C. The NovaSure System

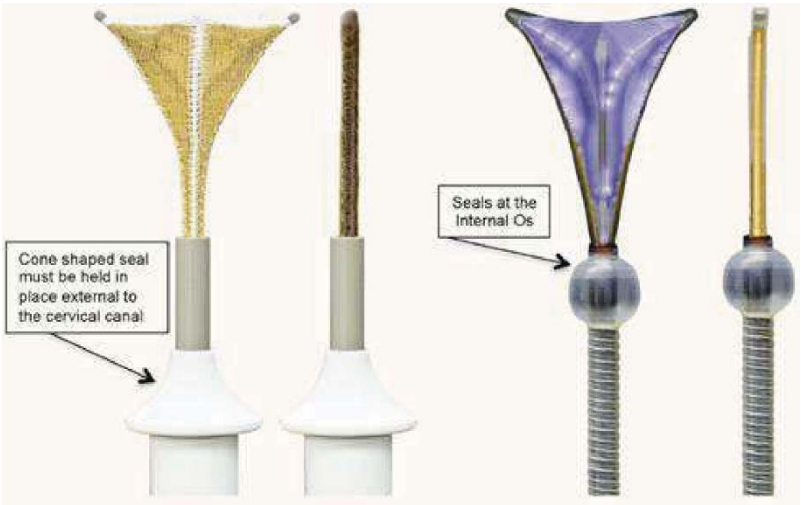
9. The founder of Minerva, Mr. Csaba Truckai, also founded Novacept Corporation in 1996. The Novacept design team, which included Mr. Truckai, and with whom I worked: (i) conceived of the original NovaSure design; (ii) filed the Pre-Market Approval ("PMA") with the FDA for the NovaSure system; (iii) performed the necessary R&D, including clinical trials; (iv) filed the first patent applications relating to

the NovaSure design; (v) obtained FDA approval for the NovaSure in 2001; (vi) established the market for NovaSure; and (vii) significantly expanded the endometrial ablation market with approximate annual revenues in 2002 of $18M, 2003 of $36M, and revenues in 2004 of $78M, the year Novacept was acquired by Cytyc Corporation. D.I. 13-1 (2004 Merger Agreement).

10. The NovaSure system's Success Rate, based on the Summary of Safety and Effectiveness Data (SSED) issued by the FDA upon approval of the device, is 77.7%. Ex. 5 at MSI00017058. Also, the NovaSure system's Amenorrhea Rate according to the same SSED is 36.0%. *Id*.

11. Although back in 2001 the NovaSure system provided benefits that practitioners favored over the existing alternatives at the time, such as the roller-ball, like any technology, the NovaSure had its drawbacks as well. Minerva's design team includes not only Mr. Truckai, but

* * *



Any visual similarity to the devices, i.e., an elongated "Y", is a consequence of the anatomical shape and position of the uterus within the human body.

19. Hologic states that I "suggested" in a podcast that Minerva's system provides the "same benefits" as the NovaSure system. Mot. 7. I did not say or suggest that Minerva's system provides the same benefits, nor does Hologic say at what point in the roughly hour-long program I said anything about the "same benefits." I strongly disagree with Hologic' statement. What I discussed is how the Minerva EAS provides superior results and advantages above and beyond other treatment alternatives. I reviewed the podcast and, if anything, in the podcast I state that the current Minerva team is and was aware of the detriments and weaknesses of the NovaSure and other systems. The discussion is about positives and negatives of all currently available endometrial ablation systems and how the Minerva EAS was designed to be better by addressing the drawbacks of existing (older) designs. D.I. 24 (podcast at approx. 23 minutes).

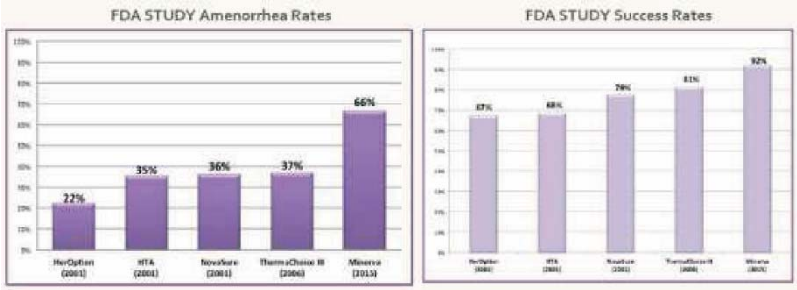
E. Clinical Studies Required For FDA Approval

20. Two measurements used by the FDA when evaluating the efficacy of endometrial ablations systems are (i) Success Rate (i.e., reducing menstrual bleeding to a level that is normal or below normal) and (ii) Amenorrhea Rate (i.e., reducing excessive menstrual bleeding to zero). Minerva conducted two separate clinical studies that were submitted to the FDA, and are the basis for FDA approval.

21. The first study begun in June 2011 was the "Minerva Single Arm Study." The Single Arm Study compared Minerva's efficacy to an Objective Performance Criteria (OPC) control group comprised of

the combined Success Rates of all previously FDA approved endometrial ablation products (ThermaChoice, Her Option, HTA, NovaSure, MEA).

E.g., Ex. 10 at MSI00004515.



Minerva's Success Rate based on its FDA issued Summary of Safety and Effectiveness Data (SSED) is 91.8%, which is statistically significantly superior to the OPC results. Ex. 6 at MSI00017115. The Minerva Single Arm Study Amenorrhea Rate (zero bleeding) according to the same SSED was 66.4%. *Id*. In the chart below, I contrast Minerva's FDA-reported Success and Amenorrhea Rates reported in the Minerva Single Arm Study with the FDA-reported Success and Amenorrhea Rates for the NovaSure system:

FDA- Reported Rates	NovaSure System[1]	Minerva EA[2]S
Success Rate	77.7%	91.8%
Amenorrhea Rate	36.0%	66.4%

22. The second study, the Minerva "Randomized Study," began in March 2012. The Randomized Study compared effectiveness results (Success Rate and

[1] Ex. 5 at MSI00017058.

[2] Ex. 6 at MSI00017115.

Amenorrhea Rate) of Minerva patients with a control group that were treated with Rollerball ablation, which was the same control group assigned by the FDA to all previous FDA clinical studies of endometrial ablation devices, including NovaSure. Minerva's Success Rate of 93.1% in this second study was statistically significantly superior to the Rollerball Success Rate of 80.4%. In addition, the Minerva Amenorrhea Rate (zero bleeding) was 71.6% when compared to the Rollerball Amenorrhea Rate of 49%. Importantly, Minerva is the first product in history to be statistically significantly superior to the "Gold Standard" Rollerball ablation in FDA approved clinical studies. In both of the above studies, Minerva's system achieved the highest efficacy rates in the endometrial ablation field in FDA clinical trial history.

F. Benefits of the Minerva EAS

23. Unlike the NovaSure handpiece, Minerva's EAS design uses a Plasma Forming Array (PFA) and fluid-tight sealed silicone membrane to accomplish the ablation, among many other distinct features. Minerva's PFA glows a bright blue during operation. Exs. 7 (PFA in operation), 19 (PFA in saline), 15 (PFA in egg white). Minerva's use of its PFA technology has numerous benefits over other existing designs, including the NovaSure System. Some of these benefits are described in Minerva documentation. E.g., Ex. 10 at MSI00004516-17.

24. For example, Minerva's PFA uses a thermally-conductive sealed silicone membrane to heat the uterine tissue more gently than older devices including the NovaSure system. The smooth silicon membrane results in easier insertion and removal. Minerva's design also results in easier deployment with a reduced requirement for perfect positioning

within the uterus; better ablation of cavities with irregularities; and the ablation is performed using a significantly lower power level (approximately a quarter of the power required to perform an ablation with the NovaSure). It is desirable to deliver less power (i.e., voltage times current) into the patient's body, rather than more power. Minerva's lower power requirement also results in a more comfortable procedure for the patient, which translates to generally less anesthesia having to be used, which in itself is a benefit to the patient. Minerva's lower power requirement also results in a (anecdotally reported) more comfortable procedure for the patient, which translates to generally less anesthesia having to be used, which in itself is a potential benefit to the patient.

G. Hologic's Awareness of Minerva

25. I am aware that on January 6, 2010, Hologic and Minerva entered into a Non-Disclosure Agreement (NDA) that reflected Minerva's interest at the time of "evaluating a potential business collaboration." Ex. 3. The NDA was signed by Mr. Rohan Hastie, Hologic's Senior Director of Business Development. As a start-up, Minerva was naturally interested in a meaningful investment or acquisition.

26. On April 15, 2011, Mr. Russell Layton, Hologic's Senior Director of Strategy & Emerging Technologies – GYN Surgical, reached out to our CEO, Dave Clapper, introduced himself and asked to meet at "the upcoming ACOG meeting." Ex. 17.

27. On or about May 13, 2011, Mr. Layton paid a visit to Minerva. Ex. 20 (redacted Minerva visitors register showing R. Layton entry).

* * *

35. Minerva's EAS (originally code named Aurora) operates in a completely different way than the NovaSure. *Id*. at MSI00001661. It uses a fluid-tight sealed silicone membrane and a patented Plasma Formation Array technology to thermally heat the tissue gently and effectively. *Id*. at MSI00001662, MSI0001669-1672. During our presentation to Ms. Petrovic we showed her a video of our Minerva PFA operating to heat egg white. Ex. 15 (PFA in eggwhite) at MSI00001673. Different from the NovaSure, the Minerva EAS relies on, and benefits from, the accumulation of a moisture layer during ablation at the tissue/membrane interface. Minerva's external sealed silicone membrane heats this liquid layer, which effectively gets into the nooks and crannies of the uterine tissue, and so facilitates a more complete and gentle ablation.

36. Here I refer to recent side-by-side video of the Minerva device (left) and NovaSure (right) operating in a beaker of egg white for demonstration purposes. The video shows how because the NovaSure delivers significantly more RF power to the applicator head, it consequently also generates significantly more steam (see significantly more bubbling for the NovaSure) than Minerva's lower power device. Ex. 25.

37. As an added benefit, Minerva's external sealed silicone membrane is smooth. This smooth surface, in conjunction with the moisture layer, make it much easier to pull the Minerva's PFA away from the tissue (*i.e*., retract it) following the procedure, since the smooth membrane generally does not stick to the tissue. In contrast, the NovaSure uses RF energy to electrically heat the external metallic mesh. The NovaSure transports moisture away from the tissue as I described, and so during the ablation, the hot metal-

lic mesh is drawn into direct contact with the tissue. As a consequence, when the ablation is done, tissue will often stick to the surface of the mesh, complicating its retraction and withdrawal of the device from the patient. Ex. 16; Ex. 10 at MSI00004480 ("Device Removal is Difficult").

* * *

I declare under penalty of perjury of the laws of the State of California and the United States that each of the above statements is true and correct. Executed on March 7, 2016, in Redwood City, California.

/s/ Evgueni Skalnyi
Evgueni Skalnyi, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civ. No. 15-1031-SLR

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

v.

MINERVA SURGICAL, INC.,
Defendant.

MEMORANDUM ORDER

At Wilmington this 2nd day of June, 2016, having reviewed the papers filed in connection with plaintiffs' motion for preliminary injunction, and having heard oral argument on same;

IT IS ORDERED that plaintiffs' motion (D.I. 9) is denied, for the reasons that follow:

1. **Procedural background.** On November 6, 2015, plaintiffs Hologic, Inc. and Cytyc Surgical Products, LLC ("Cytyc") (collectively plaintiffs or "Hologic") filed a complaint alleging infringement of U.S. Patent Nos. 6,872, 183 ("the '183 patent"),[1] 8,998,898 ("the '898 patent"),[2] and 9,095,348 ("the

[1] Titled "System and Method for Detecting Perforations in a Body Cavity," filed May 24, 2004 and issued March 29, 2005.

[2] Titled "Moisture Transport System for Contact Electrocoagulation," filed May 15, 2014 and issued April 7, 2015.

'348 patent"),[3] against defendant Minerva Surgical Inc. ("Minerva").[4] (D.I. 1) On February 5, 2016, Hologic filed a second amended complaint pursuant to a stipulation, adding allegations relating to U.S. Patent No. 9,247,989 ("the '989 patent").[5], [6] (D.I. 69, 70) On February 29, 2016, the court denied Minerva's motion to transfer and strike Hologic's preliminary injunction motion.[7] (D.I. 82) On March 4, 2016, Minerva answered the complaint and counterclaimed. (D.I. 83) On March 28, 2016, Hologic answered the counterclaims. (D.I. 106)

2. Hologic, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business in Marlborough, Massachusetts. It provides women's health care services including diagnostics, screening, and imaging, as well as medical intervention and treatment. Cytyc is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business in Marlborough, Massachusetts.

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[3] Titled "Moisture Transport System for Contact Electrocoagulation," filed August 8, 2013 and issued August 4, 2015.

[4] On January 6, 2016, Minerva filed a motion to dismiss, which was subsequently withdrawn. (D.I. 43, 62) On January 25, 2016, Hologic filed an amended complaint. (D.I. 59)

[5] Titled "Moisture Transport System for Contact Electrocoagulation," filed March 2, 2015 and issued February 2, 2016.

[6] For purposes of the preliminary injunction motion practice, the parties agreed not to rely on the '898 patent. (D.I. 42 at 2) Neither party refers to the '989 patent. (D.I. 11, 86)

[7] The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

Cytyc is engaged in designing, developing, and selling medical devices for the treatment of excessive or abnormal endometrial bleeding. Cytyc is a wholly-owned subsidiary of Hologic, Inc. (D.I. 70 at ¶¶ 2-4) Minerva is a corporation formed in 2008. It is organized and existing under the laws of the State of Delaware with a principal place of business in Redwood City, California. Minerva has developed and brought to market a new technology for the treatment of abnormal uterine bleeding. (D.I. 83 at ¶¶ 119, 124)

3. **Factual background.** "Menorrhagia" is abnormally heavy menstrual bleeding in amount or duration. One treatment for this condition is an "endometrial ablation," wherein lining of the uterus is destroyed. In the early 1990s, physicians had to visually inspect the uterus for perforations using a hysteroscope, as such perforations can allow steam or hot fluids generated during ablation to escape the uterus and cause serious injury to nearby organs. Furthermore, small perforations were hard to detect. To perform the ablation, physicians used instruments such as an electrified metal ball or wire loop to burn tissue away inside the uterus. The procedures were lengthy and carried serious risks. (D.I. 11 at 2-3)

4. NovaCept Corporation ("NovaCept") under the direction of Csaba Truckai ("Truckai") and his design team developed the NovaSure system ("NovaSure") in the late-1990s. The U.S. Food and Drug Administration ("FDA") approved NovaSure in 2001. (D.I. 70 at ¶ 10; D.I. 86 at 2) In May 2004, Cytyc Corporation, a leading provider of diagnostic and therapeutic treatments for women, acquired NovaCept for $325 million. In 2007, Hologic, Inc. acquired Cytyc Corporation. (D.I. 11 at 5; D.I. 86 at 2)

5. Prior to an ablation procedure, NovaSure uses computerized monitoring to detect perforations in the uterus, by applying CO_2 gas to the uterus and measuring whether there is any flow of gas out of the uterus. NovaSure employs an application head with a triangular shape designed to conform to the shape of the uterus, which ablates the endometrial lining throughout the cavity in two minutes or less. The procedure is considerably shorter, less expensive, and more convenient for the patient. NovaSure also provides a "moisture transport" function with a vacuum used to remove steam and moisture from the cavity during energy delivery. (D.I. 11 at 3-5)

6. In July 2015, Minerva obtained FDA approval for a new device for the treatment of menorrhagia ("Minerva EAS"), developed by Truckai and his design team. Minerva has hired and trained a sales force to begin selling Minerva EAS to physicians. (D.I. 86 at 4)

7. **Standard.** "The decision to grant or deny . . . injunctive relief is an act of equitable discretion by the district court." *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006); *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1334 (Fed. Cir. 2006). The grant of such relief is considered an "extraordinary remedy" that should be granted only in "limited circumstances." *See Kos Pharma., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004) (citation omitted). A party seeking preliminary injunction relief must demonstrate: (1) a reasonable likelihood of success on the merits; (2) the prospect of irreparable harm in the absence of an injunction; (3) that this harm would exceed harm to the opposing party; and (4) the public interest favors such relief. *See, e.g.*, *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d

1253, 1259 (Fed. Cir. 2012); *Abbott Labs v. Sandoz, Inc.*, 544 F.3d 1341, 1344 (Fed. Cir. 2008). "If either or both of the fundamental requirements—likelihood of success on the merits and probability of irreparable harm if relief is not granted—are absent, an injunction cannot issue." *Antares Pharma., Inc. v. Medac Pharma., Inc.*, 55 F. Supp. 3d 526, 529 (D. Del. 2014) (citing *McKeesport Hosp. v. Accreditation Council for Graduate Med. Educ.*, 24 F.3d 519, 523 (3d Cir. 1994)).

8. At the preliminary injunction stage of a case, the movant "'must demonstrate that . . . at least one of [the] allegedly infringed claims will . . . likely withstand the validity challenges presented by the accused infringer.'" *Abbott Labs.*, 452 F.3d at 1335 (citation omitted).

> As to the burden regarding invalidity allegations, "[v]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial." . . . In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity at trial.

Id. (citation omitted).

9. Even if a movant demonstrates a likelihood of success on the merits, there is no presumption of irreparable harm. *See, e.g.*, *eBay*, 547 U.S. at 393. To

establish irreparable harm, the movant must "clearly establish[ ] that monetary damages could not suffice." *Id.* at 1348. Moreover, Federal Circuit precedent requires a showing of some causal nexus between the alleged infringement and the alleged harm. *See Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012) ("Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature.").

10. **The '348 patent.** The '348 patent is directed to "an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ." It uses "an electrode array," which "includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon." To use the apparatus, "the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue." ('348 patent, 2:34-45) The specification describes two exemplary embodiments. The first embodiment describes an ablation device comprised generally of three major components – RF applicator head, main body, and handle. (*Id.* at 4:55-58) The applicator head includes an array of electrodes formed on the surface of an electrode carrying means. (*Id.* at 4:58-61) "The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array." Aspects of the two "exemplary embodiments and their methods of operation may be

combined without departing from the scope of the present invention." (*Id.* at 11:50-58) Claim 1 recites:

> 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) (emphasis added)

11. **Likelihood of success on the merits – infringement.** As to claim 1, Minerva argues that Minerva EAS lacks the claimed "deflecting mechanism," "applicator head," and "indicator mechanism." (D.I. 86 at 14, 16, 18) For each of these limitations, Hologic asserts that the claim language is clear and readily understood, therefore, expert testimony or extrinsic evidence is unnecessary for claim construction. (D.I. 11 at 9) Minerva offers specific constructions for the disputed limitations, which the court discusses below.

12. **"Deflecting mechanism."** In the description of the second embodiment, the '348 specification explains that the "[a]pplicator head 102 includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue." ('348 patent, 12:5-8) The "[d]eflecting mechanism 102b and its deployment structure is enclosed within electrode array 102a." (*Id.* at 13:8-9) The deflecting mechanism is preferably configured such that the distal tips of the flexures 124 are sufficiently flexible to prevent tissue puncture during deployment and/or use." (*Id.* at 14:1-3) "The deflecting mechanism formed by the flexures 124, 136, and [transverse] ribbon 138 forms the array into

the substantially triangular shape shown in [figure] 23, which is particularly adaptable to most uterine shapes." (*Id.* at 14:21-24) The specification further explains that "[e]ach internal flexure 136 is connected at its distal end to one of the flexures 124 and a transverse ribbon 138 extends between the distal portions of the internal flexures 136." The transverse ribbon "is preferably pre-shaped such that when in the relaxed condition the ribbon assumes the corrugated configuration shown in [figure] 23 and such that when in a compressed condition it is folded along the plurality of creases 140 that extend along its length." (*Id.* at 13:60-54) Dependent claim 2 recites "[t]he device of claim 1 further comprising a transverse ribbon coupled to a distal end of the first and second external flexures, wherein the transverse ribbon is in a relaxed condition when the applicator head is in the expanded state." (*Id.* at 19:43-46)

13. Hologic identifies the flexures in the applicator head of Minerva EAS as satisfying the "deflecting mechanism" limitation. (D.I. 11 at 11) Minerva's proposed construction[8] is repetitive in the context of the actual claim language, which recites and describes "flexures." Minerva's non-infringement argument relies on this construction, i.e., that Minerva EAS does not use or need a transverse ribbon to conform to the shape of the uterus. (D.I. 86 at 16) Neither claim 1 nor the specification requires that the transverse ribbon be part of the "deflecting mechanism." Given the language of the specification

[8] "A deployment structure enclosed within the electrode array of the applicator head that consists of outer flexures, inner flexures and a transverse ribbon that extends between the flexures." (D.I. 86 at 14)

and claims, Hologic has made a prima facia showing that Minerva EAS satisfies this limitation.

14. **"Applicator head."** The summary of the invention explains that the "electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon . . . and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue." ('348 patent, 2:37-45) In the first embodiment, the applicator head "includes an electrode carrying means 12 mounted to the distal end of the shaft 10 and an array of electrodes 14 formed on the surface of the electrode carrying means 12." (*Id.* at 4:58-61) The electrode carrying means is "preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture . . . . Alternatively, the electrode carrying means may be formed of a metallized fabric." (*Id.* at 5:52-61) The main body of the ablation device includes a shaft with a "suction/insufflation tube" extending through it. (*Id.* at 4:57, 5:3-4) The suction/insufflation tube is "coupled to the flow pathway so that gas fluid may be introduced into, or withdrawn from the suction/insufflation tube 17 via the suction/insufflation port 38. For example, suction may be applied to the fluid port 38 using a suction/insufflation unit 40." (*Id.* at 8:20-25) The water vapor from the uterine cavity passes "thorough the permeable electrode carrying means 12, into the suction/insufflation tube 17 via holes 17a, through the tube 17, and through the suction/insufflation unit 40 via the port 38." (*Id.* at 8:27-29) The specification also describes the operation of the ablation device, including that "[m]oisture removal from the ablation site may be further facilitated by the application of

suction to the shaft 10 using the suction/insufflation unit 40." (*Id.* at 10:65-67) The specification explains that "liquid build-up at the ablation site is detrimental" and that moisture is shunted away from the ablation site, which prevents liquid build-up. (*Id.* at 11:1-13) Suction may also be used to help draw the organ tissue towards the electrode carrying means and into better contact with the electrodes. (*Id.* at 9:1-6) The specification provides that "additional components inside" the electrode carrying means may "add structural integrity to [it] when it is deployed within the body." For example, "a pair of inflatable balloons may be arranged inside the electrode carrying means," which balloons can then be inflated after insertion of the apparatus into the organ. (*Id.* at 8:47-67)

15. In the second embodiment, the applicator head "includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue." (*Id.* at 12:5-8) The array "is formed of a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material."(*Id.* at 12:10-12) The embodiment describes using a vacuum source, which causes "application of suction" to help "draw uterine tissue into contact with the array." (*Id.* at 18:40-43) The embodiment describes a "plurality of longitudinally spaced apertures" formed in each flexure that allow moisture to pass through the flexures and be drawn into a hypotube 120 using a vacuum source. (*Id.* at 13:13-18) In describing the operation of the second embodiment, the specification explains that as moisture is released from the tissue, the vacuum source helps to draw moisture from the uterine cavity into the hypotube. (*Id.* at 18:44-52)

16. Hologic identifies Minerva EAS' applicator head as meeting this limitation. Minerva argues that Minerva EAS "uses a fluid-tight, sealed silicone outer membrane, which is not permeable to moisture;" instead, the formation of a moisture layer is beneficial to the operation of Minerva EAS. (D.I. 86 at 17) Minerva's proposed construction[9] seeks to narrow the claim language to the second embodiment and adds limitations which are not required by the specification or claim language. Specifically, the use of suction to draw in moisture is not required. As to permeability, the specification contemplates that the electrode array be made of a material that is permeable to moisture. Hologic's reference to the balloon example in the first embodiment is not helpful, as the context of that example is to provide stability to the electrode carrying means.[10] Minerva

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[9] "A working end having a permeable external electrode array into which moisture is drawn using suction." (D.I. 86 at 16)

[10] The specification describes the shortcomings of the prior art methods including that "water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow" and "the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths." ('348 patent, 2:9-19) The specification also states that "liquid build-up at the ablation site is detrimental." (*Id.* at 11:1-13) The court concludes that such disclosures do not rise to the level of disclaimer, sufficient to narrow the disputed claim limitation as desired by Minerva. *Cf. Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1025 (Fed. Cir. 2015) (citing *Inpro II Licensing, S.A.R.L. v. T-Mobile USA Inc.*, 450 F.3d 1350, 1354-55 (Fed. Cir. 2006)) ("Likewise, we have used disclaimer to limit a claim element to a feature of the preferred embodiment when the specification described that feature as a 'very important feature . . . in an aspect of the present invention,' and disparaged alternatives to that feature.").

has raised a substantial question regarding whether Minerva EAS satisfies this limitation.

17. **"Indicator mechanism."** In the second exemplary embodiment, the specification describes a "measurement device," "for easily measuring the uterine width and for displaying the measured width on a gauge." A dial face "includes calibration markings corresponding to an appropriate range of uterine widths." The uterine width is

> preferably input into an RF generator system and used by the system to calculate an appropriate ablation power . . . . Alternately, the width as measured by the apparatus of the invention . . . may be used by the user to calculate the power to be supplied to the array to achieve the desired ablation depth.

('348 patent, 14:32-67)

18. Hologic identifies Minerva EAS' red and green areas and the lines of 3, 4, and 5 dots as meeting the "indicator mechanism" limitation. (D.I. 11 at 11) Minerva EAS' manufacturing specification refers to the indicator on the handpiece as a "width indicator." (D.I. 115, ex. 10 at 6.2.12, 6.3.13) The dot scale on the width indicator shows widths of about 3, 4, and 5 cm, respectively, via the rows of 3, 4, and 5 dots. (D.I. 115, ex. 8 at 42412; ex.10 at 6.3.13) Minerva's medical director testified that Minerva's clinical data excludes women with uteri that are smaller than 2.5 cm and the width indicator on Minerva EAS' handpiece indicates when a patient's uterus is smaller than 2.5 cm. (D.I. 115, ex. 7 at 164:22-165:5) Minerva's proposed construction limiting "indicator mechanism" to "a mechanism configured to indicate a measurement of width in units" is incorrect. (D.I. 86

at 18-19) Hologic has made a prima facia showing that Minerva EAS satisfies this limitation.

19. **Likelihood of success on the merits – invalidity.** Minerva argues that there is no enabling disclosure for a plasma formation array with a non-permeable and fluid-tight silicone membrane. Minerva's expert opines that it would require undue experimentation for a person of ordinary skill in the art to arrive at Minerva EAS' design, particularly as the specification teaches away from the thermal techniques used by Minerva EAS. (D.I. 88 at ¶¶ 175-76) Hologic argues that Minerva's claim construction is incorrect and that the specification describes non-permeable arrays in figure 20. (D.I. 114 at 8-9) As discussed above regarding the construction of "applicator head," the specification contemplates membrane permeability. Minerva has raised a substantial question of invalidity.[11]

20. **The '183 patent.** The '183 patent is directed to "a system and method for detecting perforations in a body cavity." The system delivers a fluid (either liquid or gas) "into a body cavity to slightly pressurize the cavity. A pressure sensing system monitors the pressure within the cavity for a predetermined test period. If cavity pressure is not substantially sustained during the test period, the physician is alerted." In the preferred form of the system, the perforation detection functionality is provided with

[11] Minerva points out that it has filed an IPR petition challenging the validity of the '348 patent and asserted a defense based on obviousness-type double-patenting to establish that the correct expiration date for the '348 patent is April 12, 2016. (D.I. 86 at 20) Such assertions carry little weight in the present analysis.

an RF ablation system. ('183 patent, 1:49-62) Claim 9 recites:

> A method of detecting a perforation in a uterus, comprising the steps of:
>
> passing an inflation medium into the uterus;
>
> monitoring for the presence of a perforation in the uterus using a **pressure sensor**;
>
> if no perforation is detected during the monitoring step, permitting ablation of the uterus using an ablation device; and
>
> if a perforation is detected during the monitoring step, preventing ablation of the uterus.

(*Id.* at 8:39-48) (emphasis added) Dependent claim 13 limits claim 9 reciting, "wherein the inflation medium is introduced using the ablation device." (*Id.* at 60-61)

21. **"Pressure sensor."** The specification explains that "a pressure sensing system" is "fluidly coupled to the medical device via [a] pressure detection/signal line" and used to monitor the pressure within the body cavity. Fluid or gas is delivered to the body cavity and the pressure sensing system detects "whether elevated pressure can be maintained above a predetermined threshold level over a predetermined period of time. If it cannot, the user is alerted that there may be a perforation in the organ." ('183 patent, 2:36-44) The pressure sensor "monitors pressure in the pressure signal line . . . and delivers the signal to the microprocessor." (*Id.* at 5:23-25) The specification explains that during testing "[w]hen the pressure at gauge 84 rises and remains above 50 mmHg for 4 seconds, the test has passed." (*Id.* at 6:44-46)

22. Hologic has identified Minerva EAS' flow meter as meeting the "pressure sensor" limitation. Minerva argues that the flow meter does not measure pressure (differential or otherwise) to operate and its output is not a pressure measurement.[12] (D.I. 86 at 8-11) Minerva EAS' operator manual describes a "uterine integrity test" aimed at detecting perforations. (D.I. 12, ex. 11 at 9, 33) Minerva's expert, Dr. Tucker, testified, "[a]s the pressure goes down, the flow rate goes up. As the pressure goes up, the flow rate goes down." (D.I. 115, ex. 2 at 64:17-20) The design documents for Minerva EAS state that "if the uterine cavity and the system is perforation free, gas used to insufflate the uterine cavity will stop flowing once the gas pressure in the uterine cavity matches the supply pressure." (D.I. 87, ex. 82 at 2337) The court concludes that the evidence supports a prima facia showing of infringement.[13, 14]

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[12] Minerva criticizes William Churchill's ("Churchill") analysis under the doctrine of equivalents, arguing that Churchill's chart is conclusory and only analyzes a hypothetical "standard flow meter." Minerva's expert, Dr. Tucker, testified that Minerva EAS uses a "standard flow meter." (D.I. 115, ex. 2 at 33:20-25)

[13] Minerva's argument that Minerva EAS embodies Minerva's patent (U.S. Patent No. 8,343,078) and uses a flow meter is relevant but not dispositive of the issue at bar. *National Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1192 (Fed. Cir. 1996) ("The fact of separate patentability is relevant and entitled to due weight.").

[14] The court declines to analyze Minerva's prosecution history estoppel argument at length. (D.I. 86 at 12-13) During the prosecution history of a related application, the PTO rejected a claim with the limitation "monitoring a pressure within the body cavity for a predetermined amount of time," because the prior art disclosed "a system and method for . . . monitoring pressure within the body cavity for a predetermined amount of

23. **Likelihood of success on the merits – invalidity.** Dr. Tucker opines that a person of ordinary skill would need to engage in undue experimentation to use a flow meter to perform the claimed "monitoring" function. Therefore, Minerva argues that the disclosure lacks enablement. (D.I. 88 at ¶¶ 116-19) Hologic disputes this conclusion, arguing that Dr. Tucker agreed that a person of ordinary skill could measure flow rate and pressure. (D.I. 115, ex. 2 at 64:24-66:2; ex. 6) According to Hologic, known methods may be used to quantify the relationship between flow and pressure in the uterus. (D.I. 114 at 5) Based on the evidence presented by the parties, the court concludes that Minerva has not raised a substantial question of invalidity in this regard.

24. **Likelihood – conclusion.** As to the '348 patent, Minerva has advanced plausible non-infringement and invalidity arguments with respect to the "applicator head" limitation. As to the '183 patent, Hologic has put forth a prima facia showing of infringement and Minerva has not raised a substantial question of invalidity with its lack of

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time." The claim was ultimately allowed after amending other elements of the claim to overcome the rejection. In the application which issued as the '183 patent, the patentee included a claim with the same limitation. Such claim was then cancelled and a new claim was added reciting "monitoring for the presence of a perforation in the uterus using a pressure sensor." Contrary to Minerva's argument, the court discerns no clear and unmistakable surrender of all equivalents to a "pressure sensor." Cf. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003) (A presumption of prosecution history estoppel is established by showing that the patentee made a narrowing amendment and that "the reason for that amendment was a substantial one relating to patentability.").

enablement argument. For these reasons, Hologic has met its burden of showing likelihood of success on the merits with respect to the '183 patent only.

25. **Irreparable harm.** Minerva's correspondence introducing Minerva EAS to physicians states that it was designed to address "difficulties with 'seating' the array, obtaining accurate width measurement, obtaining a secure cervical seal, and most importantly disappointing clinical outcomes." (D.I. 12, ex. 13) Minerva argues that "physicians are trying [Minerva EAS] because it is new technology and [has] new features." In support, Minerva offers a physician's declaration stating that he tried Minerva EAS because "it might offer . . . patients significant benefits over and above the NovaSure System." (D.I. 86 at 24; D.I. 90 at ¶ 12) Despite this argument, the description of Minerva EAS in Minerva's correspondence suffices to show "some causal nexus" between the infringing product (and certain patented features) and the alleged harm. *See Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 642 (Fed. Cir. 2015) ("[T]he district court should have considered whether there is "some connection" between the patented features and the demand for Samsung's products. That is, the district court should have required Apple to show that the patented features impact consumers' decisions to purchase the accused devices.) (citations omitted); *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012) ("If the patented feature does not drive the demand for the product, sales would be lost even if the offending feature were absent from the accused product. Thus, a likelihood of irreparable harm cannot be shown if sales would be lost regardless of the infringing conduct.").

26. **Reputation and goodwill.** Hologic offers the declarations of its sales territory manager (D.I. 14), chief operating officer (D.I. 16), and vice president of surgical sales (D.I. 19), to argue that Minerva is representing that it "invented the NovaSure system and now developed [Minerva EAS] as a 'new NovaSure' that addresses the 'weaknesses' of the existing NovaSure." Hologic alleges that these representations are confusing customers. (D.I. 11 at 16) The evidence presented in support includes an email from a Minerva sales representative that reads "the group who developed [Minerva EAS] is the same exact group who created and developed the NovaSure procedure 14 years ago." (D.I. 12, ex. 13) A template letter from a sales representative sent to potential customers reads "Minerva was developed by the same person that invented NovaSure over 15 years ago. It is an evolutionary product that addresses many unmet needs . . . ." (D.I. 116, ex. 37 at 4746; ex. 38 at 34963; ex. 39 at 34896) The same representative tells customers that Minerva EAS was developed by the same person who invented NovaSure, as it establishes credibility and is true. (D.I. 115, ex. 27 at 106:17-107:5) Minerva responds that such correspondence is not misleading as it "displays Minerva's logos, "Minerva Surgical, Inc." signature blocks, @minervasurgical.com email addresses, and other distinctive features." (D.I. 15, exs. 13-14) Minerva offers the declaration of its vice president for sales and marketing, stating that Minerva's sales staff is instructed to compare Minerva EAS to all endometrial ablation products, not just to NovaSure. (D.I. 91 at ¶¶ 8-12) According to the record at bar, the specific representations in the evidence are true, that is, Truckai and his research group were the original inventors of NovaSure at NovaCept and have now

invented Minerva EAS at Minerva. Hologic has not offered specific evidence that Minerva is representing itself as currently affiliated with Hologic or NovaSure.[15] Therefore, this fact weighs in favor of Minerva.

27. **Lost sales and price erosion.** Hologic's declarant states that several of Hologic's large customers have requested price discounts on future long-term agreements as a result of Minerva's entry into the market. (D.I. 11 at 17; D.I. 19 at ¶¶ 11-13) Minerva's sales correspondence to physicians acknowledges such discounts,[16] while encouraging physicians to try Minerva EAS. (D.I. 116, ex. 31 at 19844, ex. 32 at 2669, ex. 33 at 19444, ex. 34 at 5386) According to Hologic, it will be nearly impossible to calculate the lost downstream sales to the customers that Minerva lures away. This is due to the differing types of sales and contracts that are possible, i.e., purchasing the controller and then purchasing the disposables or receiving the controller for free and purchasing the disposables at a higher price. Hologic also asserts that price erosion will be difficult to calculate as prices are negotiated on a per customer basis. Hologic concludes that money damages will not compensate for the damage to its brand and reputation as the pioneer in endometrial ablation.[17] (D.I. 11 at 17-18) Minerva counters that Hologic has

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[15] Hologic's declarant agreed at deposition that if Minerva sales staff "followed their script," such communications would not be misleading. (D.I. 87, ex. 35 at 139-40)

[16] For example, stating that Hologic is providing free NovaSure controllers and offering discounts in an effort to retain its customers and compete with Minerva EAS.

[17] Hologic has not offered to license the patents-in-suit to a third party.

discounted NovaSure in recent years to compete with other treatments and enter into multi-product agreements, which offer discounts across product lines, but result in higher volume and increased revenue. (D.I. 86 at 22-23)

28. Sales of NovaSure were flat in the fiscal year ending in September 2012 and declined in the fiscal years ending in September 2013-2015. In its SEC filings, Hologic attributed the sales decline to lower cost alternatives and market forces.[18] (D.I. 87, exs. 30-33) There was an increase in NovaSure sales in fiscal year 2016, with Hologic reporting a $3.2 million revenue increase in NovaSure sales for the first quarter of fiscal year 2016 (October to December 2015) and NovaSure sales of $55.2 million (an increase of 8.1%) for the second quarter (January to March 2016).[19] (D.I. 87, ex. 34; D.I. 124, ex. 1) In sum, Hologic carefully tracks the average price and sales volume of NovaSure for each of its accounts, weakening Hologic's argument that money damages would not suffice. (D.I. 87, ex. 35 at 13, 164-65) The court concludes that this factor is neutral.

29. **Other factors.** Hologic points out that it is in direct competition with Minerva and Minerva is focusing its efforts on Hologic's existing high volume customers. The record demonstrates that the parties compete with each other as well as with other

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[18] Minerva also points to Hologic's unsuccessful launch of NovaSure 4.0, which failed in early 2015, as a factor in the fluctuating price for NovaSure. (D.I. 86 at 22)

[19] According to Hologic, the most recent increase was the result of the unexpected recall and exit from the market of Johnson & Johnson's competing "ThermaChoice" product, which left a sudden, large demand that both Hologic and Minerva have sought to satisfy. (D.I. 125)

endometrial ablation products (e.g., Johnson & Johnson's ThermaChoice and Boston Scientific's HTA), lower cost treatments and procedures (e.g., over-the-counter hormone pills and intrauterine devices ("IUDs")), and traditional surgical procedures (e.g., hysterectomies and dilation/curettage). (D.I. 86 at 21-22; D.I. 87, exs. 30-33) This factor is neutral.

30. Hologic asserts that Minerva's willful copying shows irreparable harm. Hologic bases its copying allegations on the similarity in key product features of NovaSure and Minerva EAS (D.I. 11 at 9),[20] as well as the allegations of misrepresentation by Minerva discussed above in relation to reputation and goodwill. Minerva denies the copying allegations, representing that it uses a different technology,[21] a single return electrode on the exterior of a plasma forming array to ablate tissue. The plasma forming array has a thin silicone membrane allowing thermal ablation. Minerva's technology is the result of seven years of research, with FDA trials and patent applications. Moreover, visual dissimilarity and branding dispel confusion. (D.I. 86 at 5-7) This factor is neutral.

31. Minerva argues that Hologic unreasonably delayed bringing the lawsuit and present motion, which should weigh against a finding of irreparable harm. Hologic had some notice and knowledge of Minerva EAS as it investigated acquiring Minerva in 2011-12 with information provided pursuant to a

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[20] At least two physicians noted the similarities in the technology. (D.I. 115, ex. 8; D.I. 116, ex. 66 at 32624)

[21] Minerva represented to the FDA that Minerva EAS was "almost dead identical to NovaSure except [that it uses] plasma energy (RF)." (D.I. 116, ex. 67)

non-disclosure agreement. Hologic avers that the FDA approved Minerva EAS in August 2015, Hologic obtained a device in September 2015 to analyze whether there was a good faith basis for infringement, filed the present lawsuit in November 2015, and moved for the present injunction in December 2015. While Hologic's initial investigation may not have been focused on infringement, it does appear that the timing of its lawsuit and motion strategically coincides with the launch and starting sales of Minerva EAS. *Hybridtech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988) ("A period of delay is but one circumstance that the district court must consider in the context of the totality of the circumstances."). This factor is neutral.

32. **Irreparable harm – conclusion.** Based on the arguments presented above, most of the factors presented to the court are neutral. Therefore, Hologic has not demonstrated irreparable harm due to competition from Minerva.

33. **Balance of harms.** This factor is largely neutral. Hologic alleges that it has invested heavily in making NovaSure the leading treatment in endometrial ablation through additional clinical work and research, training and education for physicians, and training a salesforce. The court has determined that Hologic may be adequately compensated by money damages. Although Minerva took a calculated risk launching its product, an injunction precluding Minerva from selling its only product would cause it great harm.

34. **Public interest.** This factor is largely neutral. Although the public has an interest in protecting valid patents, patients have an interest in new developments in medical technologies. Each party

holds up data and argument regarding "safety and efficacy" for the court to consider in the present analysis. The FDA has approved Minerva EAS and any analysis of the safety and efficacy thereof is outside the purview of the court in the present context.

35. **Conclusion.** For the foregoing reasons, Hologic's motion for preliminary injunction (D.I. 9) is denied.

/s/ Sue L. Robinson
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civ. No. 15-1031-SLR

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

v.

MINERVA SURGICAL, INC.,
Defendant.

MEMORANDUM ORDER

At Wilmington this 24th day of April, 2017, having heard argument on, and having reviewed the papers submitted in connection with, the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language of U.S. Patent Nos. 6,872, 183 ("the '183 patent"), 9,095,348 ("the '348 patent"), 8,998,898 ("the '898 patent"), and 9,247,989 ("the '989 patent") shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. **"Pressure sensor:"**[1] "A device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal." Plaintiffs had proposed "a device that senses pressure," and defendant had proposed "a device whose input detects a force per unit area and that outputs a corresponding electrical signal." (D.I. 155 at

[1] Found in '183 patent, claims 1 and 9.

1) At oral argument, the court articulated the above construction, and the parties agreed with the exception of the "or indirectly" component. (D.I. 225 at 37:25-38:27) Defendant argued that the pressure sensor must measure the force per unit area "directly." (D.I. 199 at 3) Plaintiffs contended that indirect forms of measuring pressure are equally valid. (D.I. 201 at 7; D.I. 202 at ¶ 19) The specification describes a "pressure sensing system" that monitors the presence of a perforation in the uterus:

> Pressure sensing system 24 monitors the pressure within the body cavity BC while fluid/gas is being (or after it has been) delivered to the body cavity, and detects whether elevated pressure can be maintained above a predetermined threshold level over a predetermined period of time. If it cannot, the user is alerted that there may be a perforation in the organ.

('183 patent, 2:37-43; *see also id.*, abstract; 1:53-57; 5:18-37) Nothing in the specification requires the pressure sensor to measure pressure "directly" so long as the pressure sensor can "detect whether elevated pressure can be maintained [in the uterus] . . . over a predetermined period of time."[2]

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[2] Defendant presented extensive extrinsic evidence to support its argument that a pressure sensor must measure pressure directly and cannot measure pressure indirectly. Dr. Robert Tucker ("Dr. Tucker") opined that a person having ordinary skill in the art "would know that pressure can be measured in millimeters of mercury ('mmHg') . . . that refers to a size of a column of elemental mercury that can be supported by the force exerted by a given amount of pressure." (D.I. 200 at ¶ 23) The data sheet for the SenSym amplified SCX series sensor (identified as an example embodiment in the '183 patent)

2. **"Monitoring:"**[3] "Monitoring."[4]

3. **"Applicator head:"**[5] "A distal end portion of an ablation device that applies energy to the uterine tissue."[6] Claim 1 of the '348 patent recites:

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measures pressure by its effect on "an integrated circuit sensor element." (D.I. 172, ex. P at A-3) In these examples, the measurement is based upon the effect of pressure on a physical component (e.g., a column of mercury or a semiconductor) and known physical relationships (gravity, temperature, atmospheric pressure, and so forth). Dr. Gregory T. Martin ("Dr. Martin") explained that "[i]n fact, commercially available pressure sensors almost always measure pressure by some indirect means." (D.I. 202 at ¶ 19) Based upon this record, defendant's proposed construction (limiting the term to "direct" measurement) would exclude commercially-available pressure sensors from the scope of the term "pressure sensor."

[3] Found in '183 patent, claims 1, 5-7, 9, and 11.

[4] The court adopts plaintiffs' proposal. Defendant proposed "measuring a condition in a system" but did not identify any support in the specification for such a construction. (D.I. 199 at 13-14)

[5] Found in '348 patent, claims 1, 5, 8, and 12.

[6] The court adopts plaintiffs' proposal. Defendant proposed "an applicator having a permeable or absorbent tissue contacting surface into which moisture is drawn." (D.I. 155 at 2) The specification describes the shortcomings of the prior art methods including that "water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow" and "the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths." ('348 patent, 2:9-19) The specification also states that "liquid build-up at the ablation site is detrimental." (*Id.* at 11:1-13) Defendant presented extensive argument for reading these limitations from the specification into the claims. (D.I. 199 at 15-24) However, "[t]he court concludes that such disclosures do not rise to the level of disclaimer, sufficient to narrow the disputed claim limitation as desired by [defendant]." (D.I. 127 at 11, n.10)

> A device for treating a uterus comprising:
>
> . . . .
>
> 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; . . .

('348 patent, 19:9-21) The '348 patent describes an embodiment with reference to figures 1 and 2 in which

> an ablation device . . . is comprised generally of three major components: RF applicator head 2, main body 4, and handle 6. . . . The RF applicator head 2 includes an electrode carrying means 12 mounted to the distal end of the shaft 10 and an array of electrodes 14 formed on the surface of the electrode carrying means 12.

('348 patent, 4:55-61; figures 1 & 2, item 2) In another embodiment,

> applicator head 102 extends from the distal end of a length of tubing 108 which is slidably disposed within the sheath 104. Applicator head 102 includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue.

('348 patent, 12:3-8; figure 23, item 102)

4. **"An energy applicator:"**[7] "An applicator of an ablation device that delivers energy to the uterine tissue." The court adopts plaintiffs' construction for the same reasons as "an applicator head," above.

5. **"A working end:"**[8] "A distal end portion of an ablation device that applies energy to the uterine tissue." Claim 1 of the '898 patent recites an "ablation device comprising a tubular member coupled to a working end, the working end comprising a first electrode and a second electrode" ('898 patent, 19:31-33) The specification describes that "[a]n ablation device is provided which has an electrode array carried by an elongate tubular member" and "[d]uring use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue." ('898 patent, 2:38-44)

6. **"An indicator mechanism:"**[9] "A mechanism configured to indicate a dimension."[10] Claim 1 of the '348 patent recites "an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus." ('348 patent, 19:40-42) With reference to the second embodiment of the '348 patent, the "ablation device . . . includes a measurement device for easily measuring the uterine width and for displaying the measured width on a gauge 146." ('348 patent, 14:33-

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[7] Found in '989 patent, claims 1, 11, 13-15.

[8] Found in '898 patent, claims 1-5, 14, and 22.

[9] Found in '348 patent, claim 1.

[10] The court adopts plaintiffs' proposal. Defendant proposed "a measuring device used to display a value in units of measure." (D.I. 155 at 2) Nothing in the specification suggests that applicant intended to limit "an indicator mechanism" to devices that solely display uterine widths in "units of measure."

36; *see also id.*, 15:55-56) Figure 32b shows that "dial face 158 includes calibration markings corresponding to an appropriate range of uterine widths." (*Id.*, 14:47-49; figure 32b, item 158)

7. **"One or more electrodes:"**[11] "One or more electrical conductors." The "applicator head" in claim 1 of the '348 patent "includ[es] one or more electrodes for ablating endometrial lining tissue of the uterus."[12, 13] ('348 patent, 19:19-21) **Extrinsic evidence:** a technical dictionary definition of "electrode" is "[a]n electrical conductor through which an electric current enters or leaves a medium." (D.I. 161, ex. 21 at 3)

8. **"At least one electrode:"**[14] "One or more electrical conductors."[15]

9. **"First and second electrodes:"**[16] "First and second electrical conductors."[17]

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[11] Found in '348 patent, claim 1.

[12] The court adopts plaintiffs' proposal. Defendant proposed that "each electrode has a polarity and contacts the tissue surface during ablation." (D.I. 155 at 2-3) Nothing in the specification suggests applicant intended to limit the claim term to having a polarity or to contacting the tissue surface during ablation.

[13] Claim 1 of the '348 patent is a system claim. The construction proposed by defendant constrains the manner in which the claim limitation ("at least one electrode") is used (in contact with the tissue surface). Such a construction would make the claim indefinite. *See IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005) (holding a claim invalid for claiming a system and a method for using that system).

[14] Found in '989 patent, claim 2.

[15] *See supra* note 12.

[16] Found in '898 patent, claims 1, 8, 14, and 22

10. **"Sack:"**[18] "An electrode-carrying member having a bag-like shape." Claim 3 recites "[t]he method of claim 2 wherein the working end includes a sack comprised of a non-conductive material." ('898 patent, 19:47-48) With respect to the first embodiment, the specification states that "[e]lectrode carrying means 12 is preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture, and which may be compressed to a smaller volume and subsequently released to its natural size upon elimination of compression." ('898 patent, 5:58-63) Defendant argued that the additional limitations (i.e., permeability, moisture absorption, and compression) from this embodiment should be included in the construction. (D.I. 199 at 21-22; D.I. 155 at 2) Applicant chose to explicitly limit the "sack" in claim 2 to "non-conductive material," but nothing in the intrinsic record suggests that applicant intended the term to implicitly include the limitations proposed by defendant.

11. **"Balloon:"**[19] "An inflatable member." The specification discloses an embodiment in which "a pair of inflatable balloons 52 may be arranged inside the electrode carrying means 12 as shown in figure 20." ('898 patent, 9:3-5) Defendant proposed "an inflatable member inside the energy

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[17] The court adopts plaintiffs' proposal. Defendant proposed that "the first and second electrodes are of opposite polarity and each contacts the tissue surface during ablation." (D.I. 155 at 2-3) Nothing in the specification suggests applicant intended to limit the claim term to having opposite polarities or to contacting the tissue surface during ablation.

[18] Found in '898 patent, claim 3.

[19] Found in '898 patent, claims 4, 5; '989 patent, claims 5, 6, 17, 18.

applicator/working end and not in contact with the tissue." (D.I. 155 at 2-3) Defendant presented attorney argument that "[t]he 'balloon' itself does not contact the tissue. Rather, a purpose of balloon 52 is to be inflated and thereby hold the external electrodes 'in contact with the interior surface of the organ to be ablated.'" (D.I. 199 at 31 (citing '898 patent, 8:59-60)) While the disclosed embodiment includes the balloon inside the "electrode carrying means 12," which is the "energy applicator" or "working end" in the relevant patents, nothing in the specification suggests this is the only possible embodiment. Moreover, a balloon located inside the "stretchable metallized fabric mesh" of the "RF Applicator Head" of the second embodiment may contact uterine tissue. Therefore, the court adopts plaintiffs' proposal.

12. The court has provided a construction in quotes for the claim limitations at issue. The parties are expected to present the claim construction consistently with any explanation or clarification herein provided by the court, even if such language is not included within the quotes.

/s/ Sue L. Robinson
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 15-1031-SLR-SRF

HOLOGIC, INC. and CYTYC SURGICAL PRODUCTS, LLC,

Plaintiffs and Counterdefendants,

v.

MINERVA SURGICAL, INC.,

Defendant and Counterclaimant.

JURY TRIAL DEMANDED

DECLARATION OF CSABA TRUCKAI

TABLE OF CONTENTS

I, Csaba Truckai, declare as follows:

1. I am the current President and Chief Executive Officer of Corinth MedTech, Inc., in Cupertino, California. I am also a current Director of Minerva Surgical, Inc. in Redwood City, California – a company I founded in 2008. I am also a named inventor on over 140 U.S. patents and approximately the same number of pending patent applications.

2. I have founded and served as an executive in a number of medical device companies over the past 20 years. One such company was Novacept, Inc., which I co-founded in 1993 and which was located in Palo Alto, California, at the time. A copy of my Curriculum Vitae is at MSI00299668-669 (Ref. 1).[1]

3. I served as President of Novacept until March 2000. Novacept marketed a product called the NovaSure endometrial ablation system, which my team and I designed and developed. The NovaSure system consists of two primary components: a non-disposable Radio Frequency ("RF") Controller and a disposable handpiece. By the late 1990's, our development efforts led to the final design of our NovaSure endometrial ablation system that received FDA approval in 2001, and which Novacept then began to sell commercially.

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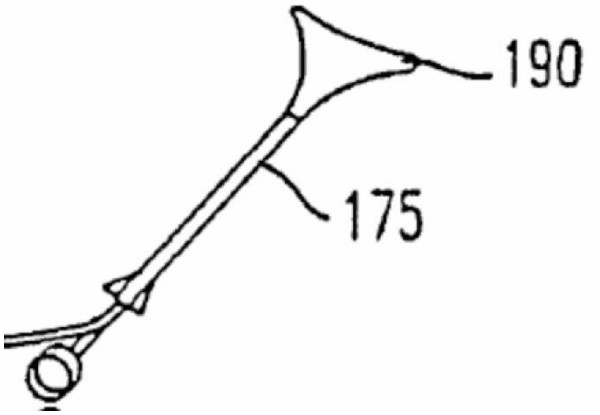
[1] Throughout my report I refer to certain references. I have not attached these references directly to this declaration, although I do expressly incorporate them by reference. Each reference I cite in this document has been produced in this litigation, and I include a chart at the end of my declaration identifying the Bates number for each.

I. THE '348 AND '989 ("MOISTURE TRANSPORT") PATENTS

A. The Moisture Transport Prototypes and Patents

4. In the mid-to-late 1990s, my co-inventors and I designed various prototypes for use in the ablation of human tissue, including prototypes for an endometrial ablation device. In that same timeframe we filed a number of applications with the U.S. Patent & Trademark Office (Patent Office) based on these prototypes. Our initial prototype for use in the uterus consisted of three basic components, as was common at the time for such surgical devices, including: (i) a handle; (ii) a slender tube used for inserting the device into the uterus via the cervical canal; and (iii) an applicator head (i.e., the distal end of the device) designed to be inserted in a compressed state, and then expanded into an uncompressed state that approximates the roughly triangular shape of the uterus. See e.g., U.S. Patent No. 5,443,470, (Ref. 2), Figs. 1 and 12, disclosed in the "Background" section of the '348 and '989 patents (i.e., the "Asserted Moisture Transport patents"):



5. Our initial prototype for what evolved into the NovaSure handpiece included the following features:

- The exterior, tissue-contacting portion (which I will refer to as the "external electrode array") of the applicator head was composed of a liquid-permeable mesh designed to draw the tissue in close contact with the bipolar electrodes to deliver RF energy to the targeted tissue, and to permit moisture and steam generated as a result of the RF tissue heating process to be drawn into the interior of the applicator head for subsequent evacuation through a central tube;
- Our prototype was Radio Frequency-only (i.e., an RF-only) ablation device with the electrodes (both positive and negative) located on the exterior surface of the external electrode array because they had to contact the uterine tissue in order to deliver energy and ablate the tissue;
- We experimented with various patterns of positive and negative electrodes on the surface of the array, but in all cases the electrodes were placed on the exterior surface of the array so that they could contact the tissue;
- By the mid-1990s, we understood that it was detrimental to the operation of our prototype device to allow a layer of moisture to build up between the electrodes and the uterine tissue for all the reasons we described and disclosed in our patents and provisional identified below; and
- We also tried prototypes where the distal end was made of an absorbent material (e.g., open celled sponge) in order to draw moisture into

the distal end and away from the electrode/ tissue interface.

6. On April 12, 1996, based on our initial prototyping efforts, my co-inventor, Dr. David Auth, and I filed U.S. Patent Application No. 08/632,516. The '516 Application later issued as U.S. Patent No. 5,769,880 (the '880 patent). Ref. 3. The '880 patent generally describes an endometrial ablation device with a tissue-contacting surface composed of either a permeable mesh or an absorbent material (e.g., open cell sponge). By April 12, 1996, Dr. Auth and I had realized that it was very important to the effective operation of our device to actively or passively draw the moisture into the external electrode array and away from the uterine tissue during ablation. This initial prototype, on which the disclosures in the '880 patent were based, had a syringe-like handle with finger grips.

7. Over approximately the next two years, we continued to refine our initial prototype. In that timeframe we came to realize that it was not just important, but critical, to the effective operation of our device to use suction to actively draw the moisture into the applicator head using a permeable mesh array and away from the uterine tissue during ablation. Basically, our experiments showed that the failure to prevent the formation of a moisture layer between our surface electrodes and the tissue would result in an uncontrolled and uneven depth of ablation. We concluded that the failure to draw the moisture away from the tissue and into the array during the ablation was highly detrimental to the operation of our prototype of the NovaSure for at least several reasons, the details of which we disclosed to the Patent Office in the

specification of our patents as well as our May 8, 1998 provisional application.

8. To summarize, the presence of a moisture layer would: (i) divert the current from flowing through the target tissue; (ii) cause undesirable thermal ablation by heating the moisture layer in an uncontrolled way; (iii) interfere with how the system controlled the depth of ablation; and (iv) draw more current than necessary to perform the ablation. I believed at the time (as I still do today) that it is highly undesirable to use more electric current than necessary inside the human body.

9. In the late 1990's, I considered the mechanism I describe above and used in our prototype for drawing moisture into the applicator head and away from the tissue to be the "moisture transport" system central to the proper operation of all of our endometrial ablation prototypes, as reflected by the title and content of our various filed applications including the May 8, 1998 provisional I describe below.

10. Due to the importance of our moisture transport system, our refined prototype used only a permeable metallic mesh external electrode array (we no longer considered a merely absorbent external electrode array to be an option). Our refined design also included the addition of holes along the outer flexures (to better draw moisture across and into the mesh array), as well as the non-optional use of suction to actively draw moisture away from the tissue so that it could be evacuated through a tube inside the array (illustrated as item 122 of Fig. 23 below). We illustrated and described our moisture transport system—including the permeable mesh and its advantages over prior art non-permeable RF balloons and other

thermal techniques—in our various applications; see e.g., Ref. 4, Figs. 23, 26A showing the mesh, and Fig. 28 showing the moisture being drawn into the array:

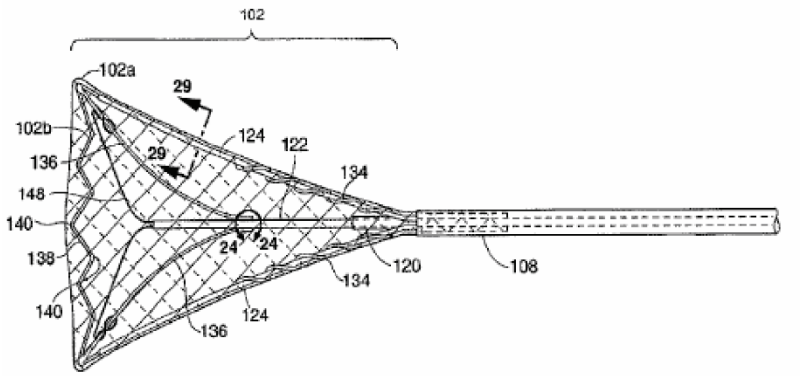


FIG. 23

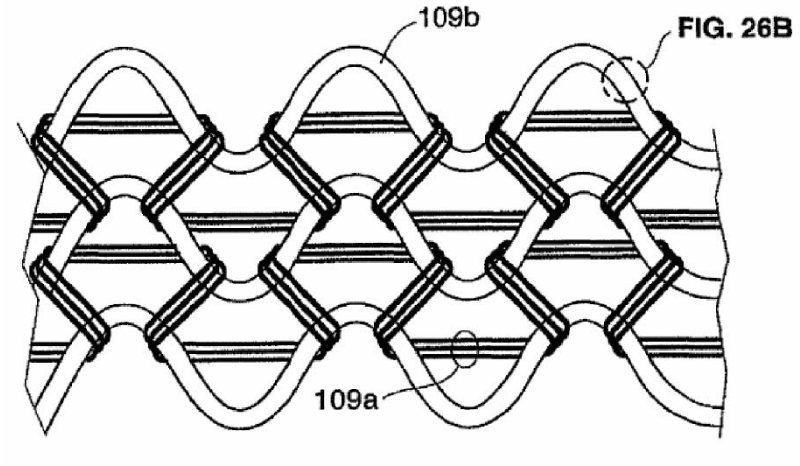


FIG. 26A

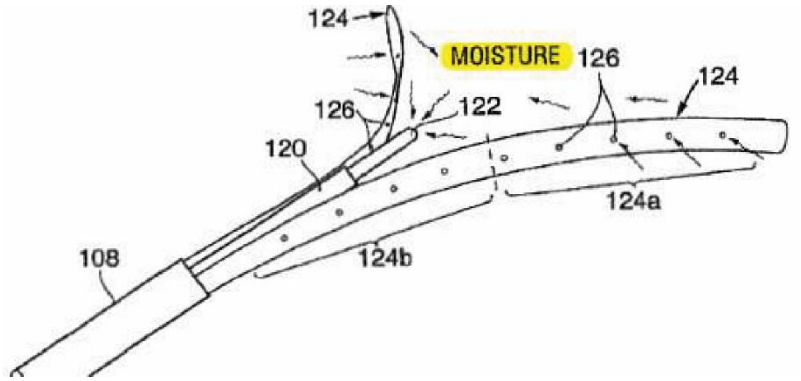
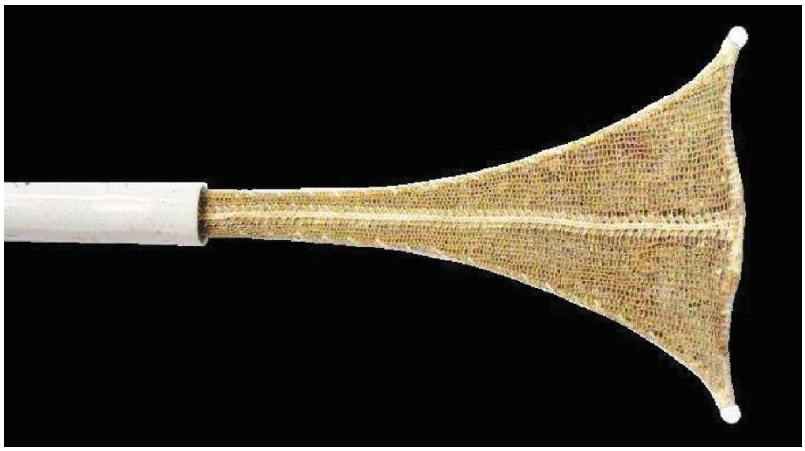


FIG. 28

11. On May 8, 1998, based on our refined prototype, Novacept filed U.S. Provisional Application No. 60/084,791 (the "Moisture Transport" or "MT" Provisional), titled, "Moisture Transport System for Contact Electrocoagulation." Ref. 5. The MT Provisional lists me and four other individuals (Russel Sampson, Stephanie Squarcia, Alfonzo Ramirez, and Estela Hilario) as inventors/applicants.

12. On June 23, 1998, shortly after filing the MT Provisional, Novacept filed U.S. Application No. 09/103,072. The '072 application issued as U.S. Patent No. 6,813,520 (the '520 patent). The '520 patent is titled, "Method For Ablating And/Or Coagulating Tissue Using Moisture Transport," and lists me and four other individuals (Russel Sampson, Stephanie Squarcia, Alfonzo Ramirez, and Estela Hilario) as inventors. Ref. 4. The '520 patent is a continuation-in-part of the '880 and claims the benefit of U.S. Provisional Application No. 60/084,791. Our refined prototype, on which the disclosures in the MT Provisional and '072 application were based, used a handle with distal and proximal grips pivotally attached at a pivot point, rather than the earlier syringe-like handle.

13. The above filings with the Patent Office basically reflect the evolution of our endometrial ablation prototypes during the mid-to-late 1990s. The final design of the distal end of our NovaSure endometrial ablation system, which received FDA approval in 2001, included a permeable metallic mesh external electrode array as I show below:



14. Prior to May 8, 1998 (or even June 23, 1998), the exterior, tissue-contacting surface of the applicator head of our endometrial ablation system prototypes (on which we based our patent applications) were made of a fluid-permeable mesh or an absorbent material (I recall trying gray open cell urethane packaging foam). At no time prior to May 8, 1998 (or even June 23, 1998) did our endometrial ablation system prototypes use a non-permeable external membrane (e.g., a balloon), as that would have frustrated the entire purpose of our moisture transport system.

15. At no time prior to May 8, 1998 (or even June 23, 1998) do I recall any of our prototypes for an endometrial ablation device including an internal electrode designed and/or intended to remain out of contact with the tissue.

16. At no time prior to May 8, 1998 (or even June 23, 1998) do I recall any of our prototypes for an endometrial ablation device including any sort of plasma formation capability; nor do I recall my co-inventors and I even discussing how to use plasma to ablate uterine tissue, much less how to use an internal electrode to ignite an inert noble gas to create an ionized plasma for ablating uterine tissue through a non-permeable, thin-walled, sealed silicone membrane.

17. Novacept was sold to Cytyc Corporation in 2004. In 2007, Cytyc Corp. was in turn acquired by Hologic, Inc. Over time, the various owners filed a series of applications all stemming directly from the '520 patent, all listing me as a named inventor. I show the sequence over time of filings that led to the Asserted Moisture Transport patents (highlighted in yellow) in the chart below. See also Ref. 37 (MT Family Genealogy):

FILING DATE	APPLICATION	ISSUED AS
May 8, 1998	MT Provisional Application No. 60/084,791	N/A
June 23, 1998	U.S. Application No. 09/103,072	U.S. Patent No. 6,813,520
October 6, 2004	U.S. Application No. 10/959,771	U.S. Patent No. 7,604,633
October 19, 2009	U.S. Application No. 12/581,506	U.S. Patent No. 8,506,563
August 8, 2013	U.S. Application No. 13/962,178	U.S. Patent No. 9,095,348

May 15, 2014	U.S. Application No. 14/278,741	U.S. Patent No. 8,998,898
March 2, 2015	U.S. Application No. 14/635,957	U.S. Patent No. 9,247,989

18. On August 8, 2013—five years after Minerva was formed—Hologic filed the first of two applications describing the moisture transport system now being asserted against Minerva in this lawsuit. Specifically, Hologic filed U.S. Patent Application No. 13/962,178, which issued as U.S. Patent No. 9,095,348. Ref. 6.

19. On March 2, 2015—seven years after Minerva was formed—Hologic filed U.S. Patent Application No. 14/635,957. In November 2015, Hologic sued Minerva in this case. About three months later, the '957 Application issued on February 2, 2016, as U.S. Patent No. 9,247,989 (the '989 patent). Ref. 7 (highlighted in yellow in chart above). The '989 patent is the second of the two moisture transport system patents now being asserted against Minerva in this lawsuit.

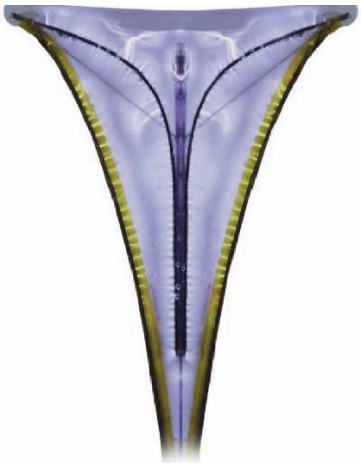
20. Collectively, I will refer to the '348 and '989 patents as the "Asserted Moisture Transport" or "Asserted MT" patents. I am aware from my experience with patents that because the Asserted MT patents are direct descendants of the '520 patent, they share a common specification with the '520 patent (i.e., basically only the claims of each patent starting with the '520 are different). See Ref. 37.

B. Minerva's Accused Plasma Formation Array (PFA) Technology

21. Minerva began the development of a plasma-formation array in 2008—ten years after we filed our May 8, 1998 Moisture Transport Provisional.

22. Minerva refers to the distal end (i.e., the portion that a surgeon deploys inside the uterus to ablate the tissue) of its disposable handpiece as a Plasma Formation Array ("PFA"). Unlike the NovaSure, the exterior of Minerva's PFA consists of a smooth, non-permeable (i.e., fluid tight) sealed silicone membrane carefully selected for its conductive properties. The non-permeable sealed silicone membrane is designed to enclose an inert Argon gas that circulates within the membrane. Both prior to and during an ablation procedure, the Argon flows into, circulates, and flows out of the membrane via a lumen in the center of the Minerva device.

23. In the center of the PFA is, among other things, an electrode of one polarity. That inner electrode is enclosed within the non-permeable, sealed silicone membrane, and thus does not contact the uterine tissue. The inner electrode is used to ignite the Argon gas and thereby create a plasma, which in turn, creates filaments that strike the inner surface of the membrane. See e.g., Ref. 33 (Video of PFA in action; filaments appear as blue microbolts); see illustration below:



24. As may be obvious, Minerva's PFA simply would not work if the external membrane was permeable for a number of reasons, including that the Argon gas would escape into the uterine cavity, would not circulate properly within the membrane, and would be contaminated by moisture and thus could not be ignited. Basically, if perforated, our PFA would not function as intended. In fact, as I discuss below with respect to our UIT, our Minerva system would alert the physician if a perforation in the PFA were detected.

25. The second "return" electrode of the opposite polarity consists of two conductive strips located on the exterior narrower sides of the PFA.

26. The Minerva PFA relies on three mechanisms to ablate the uterine tissue: two thermal and one RF. The primary mechanism used by Minerva's PFA is thermal. During the ablation procedure, plasma filaments strike the interior surface of the silicone membrane (i.e., not the tissue). This action creates heat along the interior surface of the membrane. That heat is conducted through the membrane to its exterior surface, where the heated exterior surface of the PFA starts ablating the adjacent uterine tissue.

27. The second mechanism used by Minerva's PFA is also thermal. The uterine cavity is naturally moist to some extent. However, as uterine tissue begins to ablate, the cells of the endometrium begin to desiccate and exude moisture (essentially saline). By design, because Minerva's PFA has a sealed, non-permeable outer membrane, it purposely retains the moisture in the uterine cavity as that moisture builds up during the ablation. Because the exterior surface of the PFA heats up, it also heats the retained moisture.

28. Importantly, uterine tissue is not flat. It is composed of millions of tiny folds of tissue. The moisture heated by Minerva's PFA flows into those folds during the ablation, resulting in a more gentle and even ablation of the uterine tissue than we were able to achieve with the NovaSure design. Minerva's PFA thus relies on the presence of the heated moisture within the cavity as a second thermal mechanism to ablate the tissue. Minerva's handpiece purposefully does not use the older moisture transport mechanism to draw fluid/steam away from the uterine tissue and into the interior of the PFA.

29. The third mechanism used by Minerva's PFA is a radio frequency (RF) mechanism. A relatively small amount of RF current (as compared to the NovaSure) flows between the single internal electrode and the second external "return" electrode on the exterior of the PFA. During the ablation, a small amount of RF current travels through the plasma, the non-permeable silicone membrane and the uterine tissue.

30. Also, as I describe further below, the results of our electro-chemical testing during the R&D phase of our PFA design revealed a surprising and non-predictable benefit due to the physics of how the plasma energy and RF current would very rapidly seek out the low-impedance paths through the target tissue (the "scanning" mechanism I describe in more detail below). Due to the unique and novel physics of Minerva's design, the plasma energy and small amount of RF current effectively seeks out the less ablated tissue, thereby facilitating a more gentle and even ablation while using roughly a quarter of the power used by the NovaSure endometrial ablation system.

C. The Development of Minerva's Accused Device

31. Starting in approximately March/April 2008, my team and I began exploring an initial concept as a first step in a multi-year process that eventually culminated in the current Minerva PFA design, which the FDA approved for use in July 2015. This initial concept was to make a lab bench prototype that would ablate tissue with ionized gas in fulguration mode using a prototype bi-polar Argon gas coagulator with a porous ceramic membrane, as well as an isolation/insulating gas (other than Argon) to control the plasma distribution contacting the tissue. Due to the thickness and variable pore size of the ceramic membrane, the results of this initial electro-chemical testing were not predictable.

32. This initial non-routine development and testing extended through approximately August 2008. In approximately August 2008, my team and I also conducted an important experiment. This experiment took place when, using a sheet of silicone (a "dielectric") instead of the ceramic membrane as part of a fulguration chamber, we accidentally discovered during a fulguration experiment that the sheet of silicone had created a barrier discharge plasma-forming prototype that could ablate/coagulate tissue.

33. In approximately August 2008 (shortly before Minerva was formed) and based on the accidental discovery noted above, my team and I redirected our efforts and modified our initial concept into an alternative design. This alternative design became a lab bench prototype that would ablate tissue through heating of an impermeable dielectric layer (the silicone sheet). The distal end of the prototype had to create one or more a fluid-tight interior chambers to

hold the gas, which allowed formation of a barrier discharge plasma. The use of this dielectric layer allowed for a complete physical separation between the tissue and the plasma. Moreover, we learned that the use of a smooth silicone membrane had another advantage in comparison to older technologies such as the NovaSure disposable handpiece; namely, our smooth silicone membrane prevented tissue charring and/or sticking following the ablation (e.g., Ref. 8 at p.3).

34. Our modified design used two impermeable members that formed the two poles of the bipolar system. The two impermeable members were separated by a third chamber that contained isolation/insulating gas (other than Argon) to prevent arcing. We faced numerous choices, setbacks and challenges in coming up with a final distal configuration for our PFA. For example, we experimented with different thicknesses of the membrane, including having a membrane with regions of different thicknesses in order to alter the applied energy and depth of ablation in each region (e.g., Ref. 8 at p.3). We experimented with membranes having different dielectric constants to affect the depth of ablation; as well as a membrane with a gradient in dielectric constant to thereby provide a gradient in depth of energy delivered to the tissue (e.g., Ref. 8 at p.4). We experimented with having multiple interior chambers for the gas, each with its own interior electrode (e.g., Ref. 8, Fig. 5). We also experimented with different shapes and configurations of the membrane (e.g., Ref. 8, Figures). At the time, for a particular configuration, for example, we thought that it was preferable to use a dielectric constant of at least 5 (e.g., Ref. 8 at p.4).

35. Our experimentation continued through approximately February 2009. The progression of our prototyping efforts from roughly late summer 2008 through early 2009 is reflected in the following sequence of videos and photos taken on or about this time period by our team. See Exs. 17 to 22.

36. Starting in approximately March 2009, Minerva conducted further experiments demonstrated on the bench that showed that the design concept for the PFA could be further reduced to a single impermeable (dielectric) membrane with a small non-heating electrode because of the unique electrical characteristics of the ionized Argon gas. An important breakthrough is that we came to understand what we called the "scanning" mechanism we had developed and how it led to a more controlled, rapid and even ablation. Simply put, the high intensity electric field that we were able to successfully generate inside the membrane would convert the gas into a plasma. In turn, this allowed plasma filaments (seen as tiny blue-glowing filaments in our videos) to form within the membrane. Those filaments appear to "jump" or "scan" around the interior surface of the membrane in a random fashion.

37. As I previously noted, as uterine tissue begins to ablate, the cells of the endometrium begin to desiccate. As they desiccate, they also become more resistive to current flow (i.e., the impedance through that tissue increases). Due to the novel physics of our PFA technology, the filaments are, in effect, drawn to the path of least resistance though the tissue—which happens to be the tissue that requires further ablation. As the target tissue becomes ablated, its impedance increases and eventually reaches a threshold where the amount of power being delivered is then

reduced resulting in the desired depth of ablation. E.g., Ref. 9 at 10:63 – 12:59 and Figs. 9A to 10.

38. In the course of our experimentation, we also discovered that the external "return" electrode can have a relatively small surface area and yet not be subject to significant heating. Ref. 9 at 12:47-50. We also continued to experiment with different shapes including variants with sharp tips for ablation of a tumor, electrosurgical jaw structures, as well as more balloon-like membranes for cardiac and other uses. One prototype had more of a cylindrical shape, while another had several needle-like ablation elements (e.g., Ref. 9 (Figures)). We also continued to experiment with different thicknesses of dielectric. Toward the end of our experimentation with this revised design, the tissue-contacting electrode of a single polarity was moved to the exterior surface of the impermeable membrane (e.g., Ref. 9 at 10:34-37).

39. The progression of our prototyping efforts from roughly March 2009 through summer 2009 is reflected in the following sequence of videos and photos taken by our team during roughly this time period. See Exs. 23 to 32.

40. With this work completed, the next phase of the project was to evolve the same concept into a design that was incorporated into an actual medical device circa June 2009. The design of our disposable handpiece continued to evolve until Q1 2011, in advance of Minerva's clinical trials. We continued to make a few modifications to the overall system culminating in our final Generation 2 design, which is FDA approved.

41. To summarize, my team and I had to perform numerous experiments during the development

phases described above to eventually arrive at the final, working design of Minerva's PFA. As my filings with the Patent Office show, our experiments during these phases helped us determine, for example:

- The novel use of plasma to ablate tissue (e.g., Ref. 9 at 7:51-67; Ref. 11 at 5:10-49);
- How my novel "scanning" mechanism worked (e.g., Ref. 9 at 10:63 – 12:59 and Figs. 9A to 10);
- The right degree of plasma ionization needed to create a "cold" plasma and how that degree of ionization is related to temperature (e.g., Ref. 9 at 8:36-9:3);
- The need to create a sealed, fluid-tight interior chamber to hold the gas (e.g., Ref. 11 at 7:59-63);
- What type of gas to use within the fluid-tight interior chambers of our various prototype configurations (e.g., Ref. 9 at 3:41-43 ("Argon or another noble gas)) and later in our PFA (e.g., Ref. 11 at 2:54-59 ("Argon"));
- The preference for the inert gas to have a gas inflow channel and gas outflow channel so that the gas can circulate and continuously flow within the interior chamber to maintain plasma quality (e.g., Ref. 9 at 13:51-54; Ref. 11 at 2:8-12, 2:43-46, 3:25-28 and 6:10-11);
- The appropriate shape, composition and thickness of the sealed thin-walled membrane (e.g., Ref. 11 at 2:28-31, 3:5-11, 4:12-13, 6:21-28 and 11:17-19);
- How to ignite and control the gas within the fluid-tight interior chamber (e.g., Ref. 9 at 7:25-39);

- How to capacitively couple the ionized plasma to the tissue via a thin-walled dielectric membrane to deliver RF current to ablate the target tissue (e.g., Ref. 9 at 10:63-11:8);
- How the use of a smooth silicone membrane had the advantage that it prevented tissue charring and/or sticking to the device following the ablation (e.g., Ref. 8 at p.3);
- The design of the internal electrode (e.g., Ref. 9 at 3:10-14);
- The importance of the first polarity internal electrode having exposure to all regions of the neutral gas and plasma within the interior chamber (e.g., Ref. 11 at 6:42-47);
- The interaction and relative placement of the internal electrode versus the external electrode (e.g., Ref. 11 at 3:56-60, 8:35-39 and 8:48-51);
- A preferred volume for the interior chamber (e.g., Ref. 11 at 3:38-39);
- The need for a low pressure in the interior chamber (e.g., Ref. 11 at 6:36-42 and 11:21-25);
- A practical degree of ionization for the membrane to provide feedback control of applied power (e.g., Ref. 9 at 8:36-47);
- A workable flow rate of the non-conductive gas (e.g., Ref. 11 at 3:64-65 and 11:15 16);
- The proper level of RF power and frequency needed to be delivered to the PFA over the duration of the procedure (e.g., Ref. 11 at 11:27-31);

- The ranges of voltage, current and frequency delivered by the RF power source to the PFA (e.g., Ref. 11 at 2:47-53);
- The dependence of the threshold voltage at which the neutral gas becomes conductive on various factors (e.g., Ref. 9 at 7:15-22 and 13:13-21);
- An appropriate delay between the initial flow of Argon gas and when the controller begins delivery of RF power to allow circulatory gas flow (e.g., Ref. 9 at 13:21-24);
- Achievable ablation depths (e.g., Ref. 9 at 6:57-62 and Ref. 11 at 11:2-5);
- How to control the depth of the ablation (e.g., Ref. 9 at 16:44-48);
- An appropriate time interval for the ablation (e.g., Ref. 11 at 11:31-34);
- The method (i.e., steps) of operation (e.g., Ref. 11 at 4:56-64, 9:50-57 and Fig. 8C); and
- The design of the subsystem and its feedback control systems for controlling operating parameters of the plasma (e.g., Ref. 11 at 9:14-48).

D. Minerva's PFA Patents

42. On October 21, 2008, I filed U.S. Provisional Application No. 61/196,870 (the "PFA Provisional"), titled, "System for Tissue Ablation." Ref. 8. I am the named inventor on the PFA Provisional. The PFA Provisional teaches the outcome and conclusions from some of my early experimentation on the use of plasma formation technology to ablate tissue.

43. U.S. Patent Application Nos. 12/541,043 and 12/541,050 were filed on August 13, 2009. These two

patent applications later issued as U.S. Patent Nos. 8,372,068 (the "PFA I" patent) and 8,382,753 (the "PFA II" patent), respectively. Exs. 9 and 10. I am the named inventor on these two Minerva patents.

44. My PFA I and PFA II patents reflect my progress and illustrate some of my various prototypical configurations for electrosurgical devices and methods for rapid, controlled ablation of tissue using a current to ignite a plasma contained within a thin dielectric layer. As the figures of the PFA I and II patents show, at the time I was contemplating a variety of different medical applications for the plasma-based ablation technology, including a device configured for ablation of various structures within the human body, such as a tumor, pulmonary veins, and cardiac applications, and of course endometrial ablation, among others.

45. U.S. Patent Application No. 12/605,546 was filed on October 26, 2009. This application later issued as U.S. Patent No. 8,500,732 (the "PFA III" patent). Ref. 11. Mr. Akos Toth and I are the named inventors on this patent. I will refer to the PFA I, II and III patents collectively as the "PFA Patents." The specifications of Minerva's PFA patents (which also incorporate the PFA Provisional by reference) collectively disclose a significant amount of detail about the findings my team and I made during our extensive experiments with materials, configurations, and other design elements in the time spent developing what is now Minerva's PFA.

46. I disclosed information about what we learned from our many experiments to the U.S Patent & Trademark Office in my PFA Provisional and PFA patents since it has been my understanding that an inventor should disclose sufficient information and

detail regarding his or her research, design and experimentation to allow others in the field to make and use the invention without having to "reinvent the wheel," so to speak.

47. As can be seen in the "References Cited" sections of each of the three PFA Patents, during prosecution Minerva (or Hermes) routinely disclosed to the Examiner numerous patents including at least several direct ancestors to the Asserted MT patents (e.g., the 5,769,880 and 6,813,520 Truckai patents, Exs. 3 and 4). See Ref. 9 at MSI00014351; Ref. 10 at MSI00013677 and Ref. 11 at MSI00013186. For example, Minerva disclosed these older '880 and '520 Moisture Transport System patents to the Examiner as prior art from the mid-to-late 1990s so that the Patent Office would be fully aware of the nature of these older prior art technologies, of which I was also an inventor, in deciding whether to grant Minerva its own patents covering its new plasma formation array technology.

48. After these prior art disclosures, the Patent Office granted all three of Minerva's PFA Patents. Therefore, since at least February 2013 when the Patent Office granted Minerva's PFA I and PFA II patents, it continues to be my belief that the U.S. Patent Office considered Minerva's PFA Patents to cover inventions that were not previously patented; in other words, that described and claimed new and useful inventions that were patentably distinct from the invention of the older Moisture Transport System patents.

II. THE '183 PATENT VERSUS MINERVA'S UTERINE INTEGRITY TEST (UIT)

A. The Pressure Sensor Family and Prototypes

49. On November 10, 1999, my co-inventors and I filed U.S. Provisional Application No. 60/164,482. Ref. 12. One year later, on November 10, 2000, my co-inventors and I filed U.S. Application No. 09/710,102, which later issued as U.S. Patent No. 6,554,780 (the '780 patent). Ref. 13. The '780 patent and its direct descendants—all continuations—are shown in the chart of Ref. 38 (Pressure Sensor Family Genealogy).

50. On May 24, 2004, my co-inventors and I filed U.S. Application No. 10/852,648, which issued on March 29, 2005, as U.S. Patent No. 6,872,183 (the '183 patent). Ref. 14. The '183 patent lists me and three other individuals (Russel Sampson, Mike O'Hara and Dean Miller) as inventors. Hologic has asserted the '183 patent against Minerva in this lawsuit. The '183

* * *

diagram of Fig. 14 shows the step "CO2 Flow Check," representing the step of using our flow meter to check the flow rate of CO2 gas to check for perforations in the uterus.

76. Our UIT patents disclose information we learned from our many experiments. I believe the information we disclose in our UIT patents includes information others in the field would need to make and use our flow meter-based solution for determining if there is a perforation in the uterus without having to go through the same experimental process.

77. During prosecution of Minerva's UIT patents, Minerva disclosed to the Examiner both the'183 patent currently being asserted against Minerva, as

well as its parent, the '780 patent. Ref. 15 at MSI00003817 and Ref. 16 at MSI00003843.

78. Although fully aware of the asserted '183 patent, the Examiner issued both Minerva's UIT I and UIT II patents and allowed Minerva to claim how to determine the presence of a perforation in the uterus using only a flow sensor. See e.g., Ref. 15 at MSI00003841 ("a flow sensor for measuring a flow rate") and Ref. 16 at MSI00003867 ("measuring a flow rate"). Minerva's UIT flow sensor only detects a flow rate (and not a pressure, whether directly or indirectly) and sends a signal that corresponds to a value of flow rate in units of ccm—and not a pressure (i.e., force per unit area)—to the microprocessor.

III. SUPPORTING REFERENCES

REF	DESCRIPTION/NOTES	PROD.#
1	Csaba's CV	MSI00299668 - MSI00299669
2	U.S. Patent No. 5,443,470	MSI00171139 – MSI00171159
3	U.S. Patent No. 5,769,880	MSI00013616 – MSI00013639
4	U.S. Patent No. 8,813,520	MSI00013582 – MSI00013615
5	U.S. Provisional Application No. 60/084,791 (the "Moisture Transport" or "MT" Provisional)	MSI00014937 – MSI00015029
6	U.S. Patent No. 9,095,348	MSI00013489 – MSI00013520

7	U.S. Patent No. 9,247,989	MSI00144513 – MSI00144544
8	U.S. Provisional Application No. 61/196,870 (the "PFA Provisional")	MSI00012999 – MSI00013019
9	U.S. Patent No. 8,372,068 (the "PFA I" patent)	MSI00014350 – MSI00014407
10	U.S. Patent No. 8,382,753 (the "PFA II" patent)	MSI00013676 – MSI00013733
11	U.S. Patent No. 8,500,732 (the "PFA III" patent)	MSI00013185 – MSI00013207
12	U.S. Provisional Application No. 60/164,482	MSI00013850 – MSI00013855
13	U.S. Patent No. 6,554,780	MSI00013084 – MSI00013096
14	U.S. Patent No. 6,872,183	MSI00012930 – MSI00012940
15	U.S. Patent No. 8,394,037 (UIT I)	MSI00003816 – MSI00003841
16	U.S. Patent No. 8,343,078 (UIT II)	MSI00003842 – MSI00003867
17	.wmv video file	MSI00148499
18	.wmv video file	MSI00148495
19	Picture	MSI00148494
20	.mov video file	MSI00148498
21	.mpg video file	MSI00148485
22	Picture	MSI00148493

23	.mov video file	MSI00148496
24	Picture	MSI00148487
25	.wmv video file	MSI00148492
26	Picture	MSI00148491
27	.mov video file	MSI00148484
28	Picture	MSI00148486
29	.wmv video file	MSI00148488
30	Picture	MSI00148489
31	.mov video file	MSI00148497
32	.wmv video file	MSI00148490
33	Minerva's video of its PFA (filaments appear as blue micro-bolts)	MSI00002327
34	May 7, 2009 Draft Function Requirements Specification Minerva Controller	MSI00297528-MSI00297535
35	June 8, 2009 Draft Product Specifications – Minerva Controller	MSI00297538-MSI00297551
36	MNmain.c	MSI_SC_0056 - MSI_SC_0074
37	Moisture Transport Family Genealogy	MSI00299670
38	Pressure Sensor Family Genealogy	MSI00299671

IV. CONCLUDING STATEMENTS

79. I declare under penalty of perjury of the laws of the State of California and the United States that each of the above statements is true and correct. Executed on June 29, 2017, in Redwood City, California.

/s/ Csaba Truckai
Csaba Truckai

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 15-1031-SLR-SRF

HOLOGIC, INC. and CYTYC SURGICAL PRODUCTS, LLC,

Plaintiffs and Counterdefendants,

v.

MINERVA SURGICAL, INC.,

Defendant and Counterclaimant.

JURY TRIAL DEMANDED

EXPERT REPORT OF DR. ROBERT TUCKER, M.D., Ph.D. REGARDING INVALIDITY OF U.S. PATENT NOS. 6,872,183, 9,095,348 AND 9,247,989

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* * *

32. As a separate basis for invalidity, in my opinion each asserted claim of each of the patents-in-suit is invalid in that each fails to meet the enablement requirement, as I explain in detail below.

VII. CLAIM CONSTRUCTION

33. I understand the Court has issued a Claim Construction Order in this case, dated April 24, 2017, which sets forth the construction of certain disputed claim terms, as well as claim terms that have been agreed to by the parties. I attach a chart of these

constructions as Exhibit C. I have assumed and applied these claim constructions for purposes of my report. I reserve the right to supplement this report if necessary or appropriate, including but not limited to, in the event that any of the claim constructions change.

VIII. GENERAL BACKGROUND

34. Millions of women suffer from a condition known as menorrhagia, which is excessive and/or prolonged bleeding of the endometrium (i.e., the interior lining of the uterus). This condition is often accompanied by debilitating cramping and other discomfort, and in extreme cases can lead to fatalities due to anemia/blood loss. Over the decades, there have been numerous medical instruments designed to alleviate this condition by "ablating" the tissue cells of the endometrium.

35. Ablation of tissue is basically the process of destroying the tissue cells. Ablation can be accomplished using various techniques and forms of energy, including radio frequency ("RF") energy that basically runs an electric current through the tissue, and thermal ablation that employs heated liquid to destroy the cells. Ablation of tissue is not unique to the uterus, but has long been used to treat tissue in many parts, organs and body cavities of the human body. Some examples include the gallbladder, heart (e.g., to treat atrial fibrillation) and tumors. The ablation devices at issue are used for endometrial ablation.

IX. THE MOISTURE TRANSPORT SYSTEM PATENTS[3]

A. The "Applicator Head" and "Energy Applicator" Terms of the Asserted Moisture Transport Claims

36. Claim 1 of the '348 patent is the sole asserted independent claim. The remaining asserted claims all depend directly or indirectly on Claim 1, and thus incorporate all of the elements of Claim 1 and any intervening claim. One term at issue for purposes of my invalidity analysis is the "applicator head" term that first appears in Claim 1 below:

> [A]n *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;

37. The Court has construed the term "applicator head" in the asserted claims of the '348 patent as: "a distal end portion of an ablation device that applies

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[3] The "Asserted Moisture Transport Claims" include all the remaining asserted claims of the '348 and '989 patents. For the sake of simplicity, throughout my report I will refer to the "Moisture Transport Patents" or the "Moisture Transport Family." This refers to the '348 and '989 Patents and, where applicable, to the other patents in this family. For the sake of simplicity, in my report I cite to the '348 patent with the understanding that the '348, '989, and the other patents of the Moisture Transport family all share one common specification.

energy to the uterine tissue."[4] Plaintiffs have asserted that the "applicator head" term reads on Minerva's Plasma Formation Array, or PFA.[5]

* * *

description support for a Plasma Formation Array (PFA) such as Minerva's since Plaintiffs assert that the full scope of the asserted claims encompasses Minerva's PFA. To look for this written description support, I reviewed at least the following documents: (i) the four corners of the Moisture Transport Patents' common specification; (ii) the May 8, 1998, MT Provisional to which every Moisture Transport Patent claims priority; (iii) the originally-filed claims of each application in the chain of priority for the Asserted Moisture Transport Patents; and (iv) for completeness, the other limitations of the Asserted Moisture Transport Patents.

C. State of the Art / Background Knowledge of a POSITA

44. By 1998, a POSITA would have known and understood that there were prior art surgical devices with a distal end designed to be inserted into a woman's cervical canal in a compressed state, and then subsequently expanded into an un-compressed state within the uterus, in order to perform some surgical procedure. These prior art devices generally had three major components: (i) a distal end designed to flare into a roughly triangular shape when in an uncompressed state in order to perform the procedure; (ii) a tubular main body designed to be inserted into

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[4] *See* Exhibit C to my report and D.I. 227.

[5] *See* Plaintiffs' April 12, 2017, Supplemental Claim Charts at 4-9.

the cervical canal; and (iii) a handle designed to hold and manipulate the device. Because the cervical canal is relatively narrow, the device is inserted into the uterus with the distal end in a compressed state. Once the device is fully inserted, the distal end is flared open into an uncompressed state in order to perform the surgical procedure. Unsurprisingly, the distal ends of these prior art devices were designed to conform to the substantially triangular shape of the uterus when in the uncompressed state.

45. Ortiz '496. For example, U.S. Pat. No. 5,358,496 to Ortiz et al. ("Ortiz '496") (MSI00043294) filed on September 30, 1993, shows such an electrosurgical device with a main body and distal end that deploys into a roughly triangular shape as shown in several of the figures:[9]

[9] *See also* Figures 1-4, 6-7, and 11-12; 3:3-24 ("The frame includes a pair of expandable fingers each comprising a flexible outer strip secured to the distal end of the actuator tube and a flexible inner strip secured to the distal end of the support shaft. The inner and outer strips are joined together at a distal finger tip. The fingers are flexed laterally outward in opposite directions by axial movement of the actuator tube relative to the shaft to provide a spatula-like platform for engaging the tissue. The fingers are selectively expandable into a tulip-shaped configuration with the finger tips spread apart and into a bulb-shaped configuration with the finger tips together. The fingers are expanded into the tulip-shaped configuration by movement of the actuator tube proximally relative to the support shaft and into the bulb-shaped configuration by movement of the actuator tube distally relative to the support shaft.") (emphasis added).

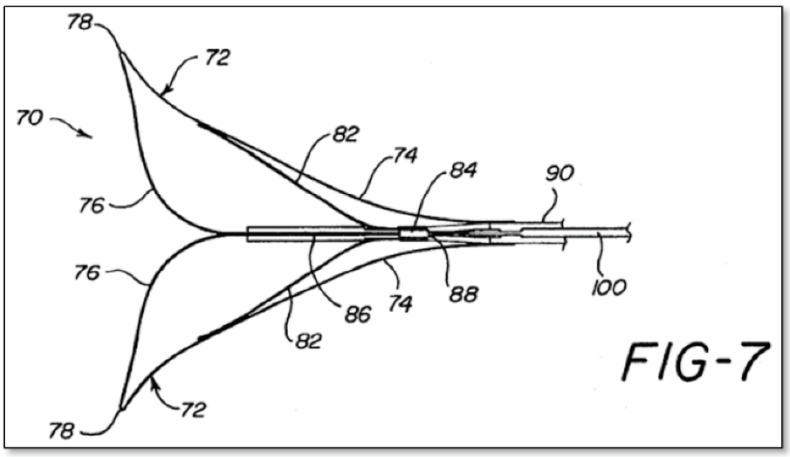

FIG-7

46. Yoon '091. Several other such devices are shown in U.S. Pat. No. 5,514,091 to Yoon ("Yoon '091") (MSI00043480) filed on May 25, 1994. This patent disclosed several expandable multifunctional manipulating instruments intended for various medical

procedures including the uterus.[10] *See* Yoon '091 at Figures 13[11] and 28A[12]:

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[10] *See* Yoon '091 at 22:14-17 ("In the expanded position, expandable portion 534a has a size and shape corresponding substantially to the size and shape of the uterus U . . .").

[11] *See also* 19: 52-67 ("A further modification of a multifunctional instrument according to the present invention is illustrated in FIG. 13 at 410, only the body assembly 412 for the instrument 410 being shown. Multifunctional instrument 410 is similar to multifunctional instrument 10 except that middle member 418 of instrument 410 is made of a non-elastic, non-stretchable, rigid material defining expandable portions 434 having a preformed predetermined shape. Multifunctional instrument 410 includes expandable portions 434a and 434b separated by a collar 420a with a collar 420b disposed proximally of expandable portion 434b, the collars 420a and 420b being similar to collars 20. Middle member 418 along expandable portion 434a has a preformed triangular or conical configuration particularly useful for uterine use and along expandable portion 434b has a preformed pear-shaped configuration. The middle member 418 is made as a collapsible bag, balloon or membrane of elastic or plastic material shaped to have the desired performed configurations along expandable portions 434a and 434b, and has connecting portions 419, which can be tubular, connecting expandable portions 434 and disposed within collars 420. The middle member 418 can be folded, rolled, crumpled or collapsed in the non-expanded position to facilitate introduction through a relatively small size anatomical opening.") (emphasis added).

[12] *See also* 9:18-24 ("As illustrated in FIG. 28A, expandable portion 1234 in the expanded position has a predetermined triangular or fan-shaped configuration in side view adjacent collar 1220. The triangular configuration of expandable portion 1234 is advantageous for universal use and, in particular, for use in uterine and kidney procedures and in the retroperitoneal space."); 9:53-61 ("FIGS. 29A-29E illustrate predetermined end view configurations for any of the expandable portions of FIGS. 28A-28D in the expanded position. FIG. 29A illustrates expandable portion 1234 of FIG. 28A in end view wherein the expandable portion 1234 has a relatively narrow oval predetermined

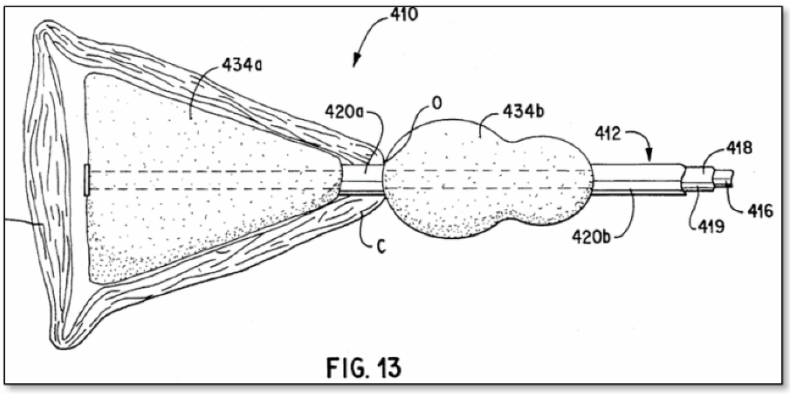

FIG. 13

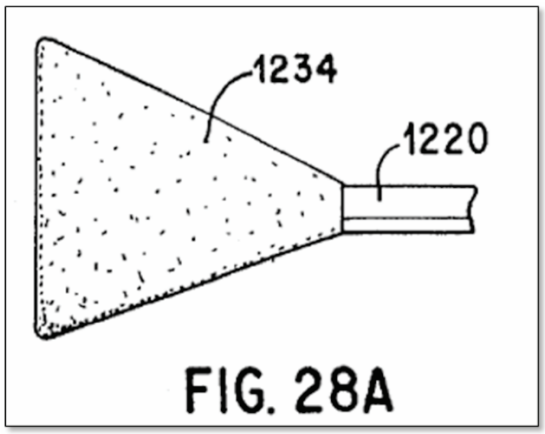

FIG. 28A

47. Nady-Mohamed '784. Yet another such device that deployed into a roughly triangular shape is shown in U.S. Pat. No. 5,353,784 to Nady-Mohamed ("Nady-Mohamed '784") (MSI00043265) filed on April 2, 1993:[13]

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configuration such that the overall configuration of the expandable portion is that of a flattened cone advantageous for universal use, in uterine and kidney procedures and in the retroperitoneal space.")

[13] *See* Claim 1 of Nady-Mohamed '784 ("a tube, having a single longitudinal bore, for insertion through a patient's cervix into the uterus; arm means for engaging the uterus, said arm means

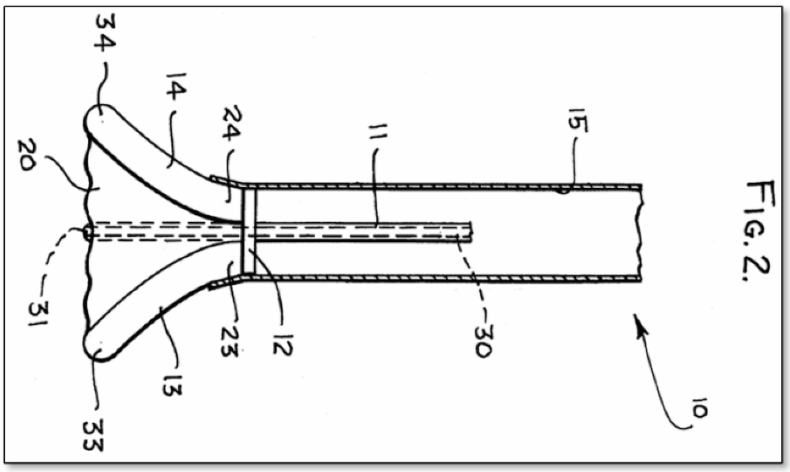

Figure 5 of Nady-Mohamed '784 discloses a hand grip.

48. Quint '044. Another such device that deployed into a roughly triangular shape is shown in U.S. Pat. No. 5,084,044 to Quint ("Quint '044") (MSI00165917) filed July 14, 1989. Quint '044 is identified in the "Background" section of the common specification of the Moisture Transport Patents. The prior art device taught by Quint '044 is an "[a]pparatus for performing thermal ablation of the endometrium of a uterus[.]"[14]The Abstract describes how the balloon on the distal end (i.e., the "inflatable member") is expanded from its collapsed position (for insertion into the uterus) into "an expanded position which approximates the shape and volume of a uterus." The "Description of the Preferred Embodiment" describes the tubular main body as, "formed by a thin walled, elongated

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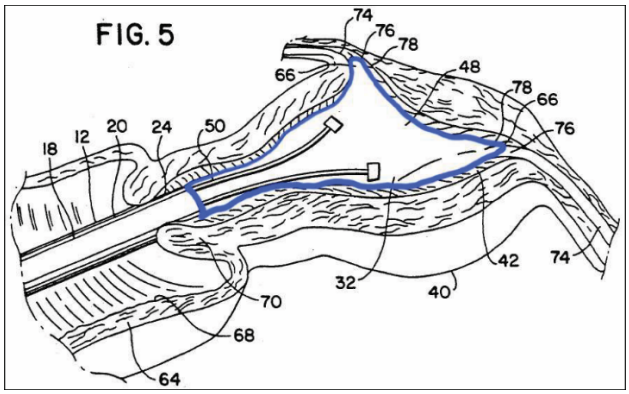
including two opposing, flexible arms slidably disposed within the distal end of said tube, said arms being curved such that they diverge to attain a shape which generally conforms to the contours of the lumen of the uterus upon extension of said arms from within said tube . . .) (emphasis added).

[14] Abstract.

cylindrical shaped member 18[.]" A POSITA would have understood that the device must also have had a handle or holding means for the surgeon to using when inserting or removing the device.[15]

49. In describing Figure 5 (shown below), the specification describes the shape of the distal end, and how it is designed to conform to the shape of the uterus when in expanded:

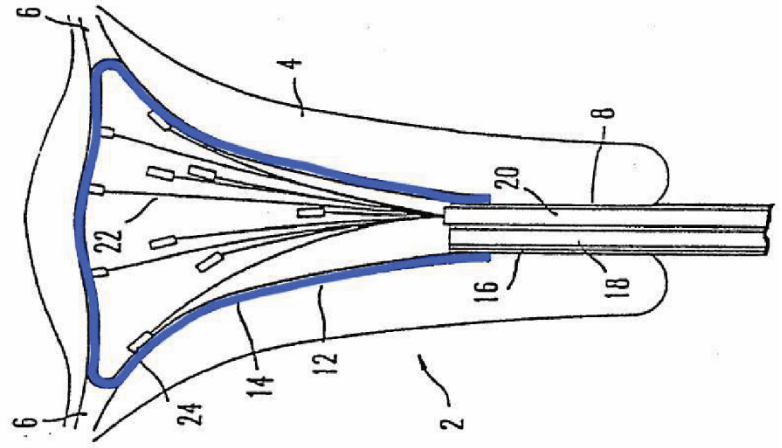
> The *inflatable member 32* is selected to be formed of an elastomeric material and *conform to the shape of the organ* under pressure derived from the fluid passed into the inflatable means. The extended arms 66 may become long and thin as shown in FIG. 5 in order to *conform to the shape of the uterus*.[16]



[15] This is true for all the devices I discuss in this section. A POSITA would know that the state of the art before the May 1998 priority date of the Moisture Transport Patents included endoscopic devices used in the uterus with a handle and a distal end that generally conformed to the shape of the uterus.

[16] 6:1-7; *see also* 6:39-41 ("wherein the inflatable means 32 is capable of expanding when filled with a fluid 26 from a collapsed position into an expanded position *which approximates the shape and volume of a uterus* 40").

50. Stern '470. Yet another such prior art electrosurgical device that was designed to be inserted into the cervical canal in a compressed state,[17] and then expanded into a substantially triangular shape in order to conform to the shape of the uterus,[18] is shown in U.S. Pat. No. 5,443,470 to Stern et al. ("Stern '470") (MSI00171139) filed April 14, 1993:



51. Figure 12 of Stern '470 (below) shows all three main components of the device, including the triangular distal end 190, which Stern '470 describes as "conforming to the inner surface of the endometrium [*i.e.*, the uterus]."[19] Stern '470 is identified in the "Background" section of the common specification of the Moisture Transport Patents.

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[17] *E.g.*, Fig. 2 (the distal end is item 14).

[18] *E.g.*, Fig. 1 (the distal end, item 14, is shown as conforming to the shape of uterus in its expanded state).

[19] *See also* 4:3-5 (The device of "FIG. 1 expands to conform to the endometrial surface to be treated").

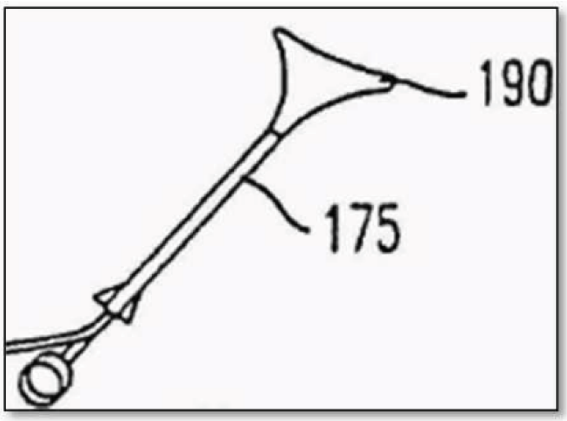

FIG. 12

52. In my opinion, a POSITA aware of even just this prior art—so before even reading the common specification of the Moisture Transport Patents—would already have understood that a well-known, basic and logical shape for an surgical instrument intended to be inserted and deployed inside a body cavity, such as a uterus, had three major components; namely: (i) a triangular or tulip-shaped distal end for applying energy to the uterine tissue; (ii) a tubular main body; and (iii) a handle.

53. As a named inventor on several patents, it is my understanding that a basic principle of patent law is that you cannot patent something that was already in the prior art. Therefore, a POSITA would have understood that, certainly by May 1998, a surgical device shaped to have (i) a roughly triangular distal end designed to conform to the shape of the uterus when in an uncompressed state; (ii) a tubular main body; and (iii) a handle—in and of itself—was not something that could be claimed as a new or patentable invention. Rather, the overall shape of a triangular distal end intended to conform to the shape of the

uterus, along with a tubular main body and a handle—*i.e.*, this "basic shape"—was a well-known and logical construct. Since the shape of the uterus is roughly triangular, it would dictate the shape of the expanded distal end, which necessarily had to collapse to a smaller diameter for insertion/removal. The surgeon also typically had to have a means of holding and manipulating the device, ergo some sort of handle.

54. The state of the art by May 1998 reinforces my opinion below that what the inventors were describing as *the invention* in the common specification of the Moisture Transport Patents was something more than this basic shape; namely, a novel moisture transport system where the RF applicator head had to draw moisture away from the tissue and into a permeable (or absorbent) array for subsequent evacuation.

55. In addition, a POSITA before May 1998 would have understood that an RF ablation device worked by applying radio frequency ("RF") energy (essentially an electrical current) to the target tissue by putting both positive and negative electrodes in contact with the tissue to be ablated. For example, the disclosures of the Stern '470 patent I discuss above specifically disclosed an RF endometrial ablation device with various patterns of electrodes all on the surface of the distal end.[20] Such a POSITA would have understood that applying a current in this manner was a form of "resistive" heating, as opposed to "thermal" heating that involves heating a liquid.[21]

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[20] *E.g.,* Stern '470 2:43-48.

[21] *See* 1:54-2:19 of the common specification.

D. The Teachings and Disclosures of the Moisture Transport Patents

1. The Common Specification

56. As I previously noted, every utility application in the Moisture Transport Family chain for the '348 and '989 patents (shown in the genealogy in Paragraph 116 below)—beginning in time with U.S. Patent Application No. 09/103,072, which was filed on June 23, 1998, and continuing through to the application that ultimately issued as the '989 patent (the last in the chain)—shares a common specification. Likewise the patents that issued from each of these applications in the chain also share the same common specification. To remain consistent with my earlier declarations, I will use the specification of the '348 patent as the representative and common specification for purposes of my validity analysis of the Asserted Moisture Transport Claims.

57. As a threshold matter, I note that in describing both the "First" and "Second" Exemplary Embodiments (so all embodiments), the common specification consistently refers to the working end of the ablation device (*i.e.*, the distal end that is inserted into the uterus by a surgeon and that actually ablates the uterine tissue) as the "RF applicator head."[22] Thus, my discussion of what the common specification discloses and teaches regarding the claim terms "applicator head" and "energy applicator" will be in terms of the "RF applicator head" of the common specification.

[22] *See* 2:51; 2:55; 3:4-25; 4:57-58; 8:8-9; 8:58; 10:15-17; 11:41-46; 11:60; and 12:1.

a. Overview of What a POSITA Would Have Understood From the Common Specification

58. In my opinion, a POSITA reading the common specification would have understood that what the inventors had possession of was a moisture transport system for an endometrial ablation device that requires the external electrode array of the RF applicator head (basically the outer cover) to be formed of a permeable or absorbent material in order to draw the moisture that builds up during the ablation away from the uterine tissue and into the array for evacuation. As the specification states: "It is therefore desirable to provide an ablation device which eliminates the above-described problem of steam and liquid buildup at the ablation site."

59. To start with, the common specification describes a device with three basic components: (i) an RF applicator head; (ii) a tubular main body; and (iii) a handle.[23]

60. A POSITA would have understood that it is the RF applicator head component that is the most technologically significant in that it is the component that actually performs the ablation. I note that the RF applicator head of the common specification itself has two main components: (i) an external tissue-contacting array that carries the electrodes on its surface (i.e., the "array"); and (ii) an expansion means for deploying the array into its uncompressed state.[24]

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[23] *See, e.g.*, Figs. 1 and 2; 4:55-63.

[24] *See, e.g.*, 12:5-8 (Referring to Figure 23 and stating, "Applicator head 102 includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue.").

It is the external array that the common specification describes as either permeable or absorptive.

61. There are two embodiments described in the common specification. The "First Exemplary Embodiment" ("1st Embodiment") is described at 4:54-11:49 and by Figs. 1-20. The "Second Exemplary Embodiment" ("2nd Embodiment") is described at 11:50 to 18:67 and by Figs. 21-37B. Both embodiments refer to the distal end of the device as the "RF applicator head."[25] However, I note that the two embodiments use slightly different terminology when referring to the RF applicator head's external array (i.e., the tissue-contacting surface of the RF applicator head). The 1st Embodiment refers to the outer array as the "electrode carrying means 12," while the 2nd Embodiment—added roughly two years later in 1998[26]—refers to the tissue contacting surface of the RF applicator head as the "external electrode array 102a."[27] A POSITA reading the common specification would understand the inventors to be referring in each case to the outer array that contacts the tissue surface and on the surface of which the electrodes are formed. For simplicity, I will refer to the tissue-contacting surface of the RF applicator head in this report as the "external electrode array" or "array."

62. The common specification overall describes a particular solution to a particular problem that existed in the prior art. As a matter of biology, when uterine tissue is ablated, the tissue dehydrates and exudes moisture (essentially saline). The greater the amount of energy transferred to the tissue, the greater

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[25] 4:57 and 11:60.

[26] Truckai Decl., ¶ 12.

[27] *See, e.g.*, 4:59 and 12:5-6.

the extent of this dehydration and exuding of moisture. The resulting dehydration and exuding of moisture during the ablation procedure would thus cause a layer of moisture to build up between the uterine tissue and the exterior of prior art non-permeable applicator heads. The common specification teaches that the formation of this moisture layer is highly detrimental to the operation of the RF applicator head for several reasons.

63. First, the common specification teaches that the moisture layer is electrically conductive. Therefore, the RF energy (which manifests as electric current) that is intended to flow into the target tissue is instead diverted away from the tissue into the moisture layer:

> Moreover, in prior art RF devices the water drawn from the tissue creates a *path of conductivity* through which current traveling through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated.[28]

64. Second, the common specification teaches that another detrimental effect of the presence of a moisture layer is that the diversion of current into the moisture layer caused prior art devices to use more current than necessary to ablate the tissue. As the common specification teaches, "[m]oreover, the presence of this current path around the electrodes causes current to be continuously drawn from the electrodes."[29] A POSITA would have known that it was undesirable to use more current than necessary inside the human body.[30]

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[28] 2:9-12.

[29] 2:12-14.

[30] *See also* Truckai Decl., ¶ 8.

65. The common specification describes how yet another detrimental effect of the moisture layer is that heating the moisture layer turns the intended RF ablation into an unintended thermal ablation. Thermal ablation relies on the presence of moisture (*i.e.*, heated liquid) to ablate the tissue, which the common specification describes in multiple places as undesirable and less subject to control:

> The current heats the liquid drawn from the tissue and thus turns the ablation process into a passive heating method in which the heated liquid around the electrodes causes *thermal* ablation to continue well beyond the desired ablation depths.[31]

66. A POSITA would understand the common specification to be teaching away from the use of thermal ablation techniques as less subject to control. For example, the common specification describes how the undesirable "passive heating" of the liquid can result in either "too much or too little tissue" being ablated.[32] Thus, the inventors framed the problem addressed by their invention as a need to "eliminate" the formation of a moisture layer at the tissue/device interface during the ablation procedure. As the common specification states:

> It is therefore desirable to provide an ablation device which *eliminates* the above-described problem of steam and liquid buildup at the ablation site.[33]

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[31] 2:15-19; *see also* Exhibit F, (Websters Ninth, 1990) at 1224 ("thermal . . . of, relating to, or marked by the presence of hot springs <~waters>").

[32] 2:20-24.

[33] 2:25-27.

67. The common specification describes in detail and in several places how to solve this problem of steam and liquid buildup between the tissue and the electrodes on the exterior of the device. Specifically, the invention solves the problem by requiring the exterior of the RF applicator head to be made of a *permeable* fabric (a "mesh") or absorbent material (e.g., a "open cell sponge") in order to draw the moisture away from the surface electrodes and into the RF applicator head for subsequent evacuation (i.e., a moisture transport system).[34]

68. Moisture Transport. Thus, a POSITA reading the common specification would understand this moisture transport system using a permeable (or absorbent) array to be a fundamental characteristic of every embodiment. A POSITA would understand that for an RF ablation device, contact between the electrodes and the tissue is necessary for the claimed invention to operate. The removal of the moisture layer permits the electrodes on the surface of the applicator head to remain in contact with the tissue during the ablation cycle. I discuss more detailed support for my opinions below. In my opinion, some portion of both positive and negative active electrodes would have to contact the tissue in order for current to flow and ablate the tissue.[35]

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[34] *See, e.g.*, 5:52-61 and 12:1-64; Fig. 26A.

[35] *See* my declarations at D.I. 205 ¶¶ 50-55 and D.I. 196 ¶¶ 36-45.

b. The Titles Support My Opinions Regarding What a POSITA Would Have Understood From the Common Specification

69. I observe that it is the May 8, 1998 MT Provisional that the Plaintiffs—and both Asserted Moisture Transport Patents—identify as the earliest filed application on which they rely for priority.[36] That May 8, 1998 MT Provisional is titled: "A *Moisture Transport* System For *Contact* Electrocoagulation."[37] This is consistent with my opinion that a POSITA would have understood that an RF endometrial ablation device relied on contact between external, surface electrodes of the array and the uterine tissue (i.e., the tissue/electrode interface). The title would have reinforced for a POSITA that a fundamental characteristic of the invention is to transport the moisture away from the tissue so that the external electrodes can better *contact* the tissue during the ablation. The solution required a permeable (or absorbent) array.

70. It further supports my opinion that every application in the MT family chain was titled "*Moisture Transport System* for *Contact* Electrocoagulation," with the exception of the '520 application, which was titled, "Method for Ablating and/or Coagulating Tissue Using Moisture Transport"—so even that one emphasized moisture transport.

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[36] Plaintiffs' Supplemental Responses and Objections to Minerva's Interrogatory No. 6; MSI00013511 ('348 patent, "Related Applications") and MSI00144535 (same).

[37] MSI00014943.

c. The Abstract Supports My Opinion Regarding What a POSITA Would Have Understood From the Disclosures of the Common Specification

71. A POSITA would have understood the importance and emphasis placed on the need for a permeable or absorbent external electrode array, and the need to prevent a moisture layer from forming, from the "Abstract" of the common specification, which states:

> An apparatus . . . includes a metallized fabric electrode array which is substantially *absorbent and/or permeable to moisture* and gases such as steam . . . As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The *moisture permeability and/or absorbency* of the electrode carrying member allows the moisture to leave the ablation site so as to *prevent* the moisture from providing a path of conductivity for the current.

d. The Figures Support My Opinion Regarding What a POSITA Would Have Understood From the Disclosures of the Common Specification

72. Next, a POSITA would have understood the Figures of the common specification to show the permeable nature of the external array, based both on

the drawing as well as the textual description of the drawing.[38] For example, see Figs. 23 and 26A below:

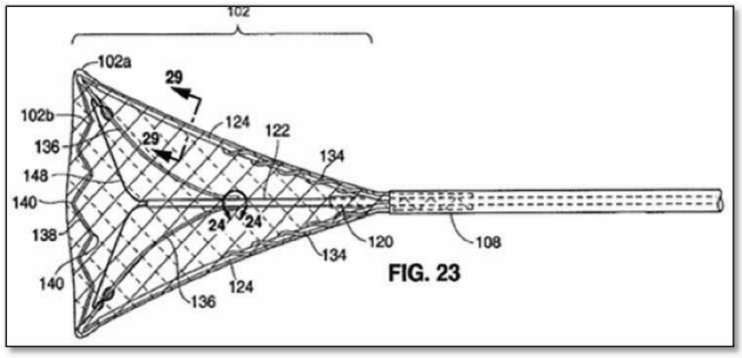


FIG. 23

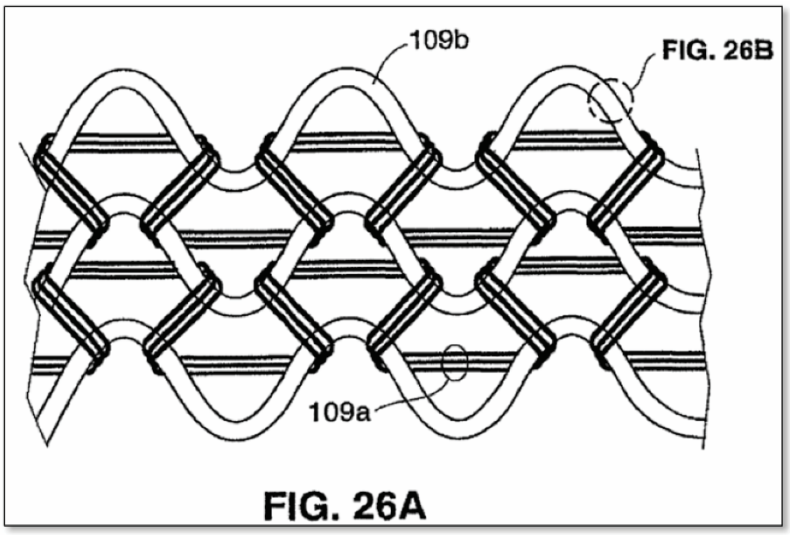


FIG. 26A

Figure 26A above shows an example of the permeable mesh that forms the external electrode array.

73. Also, a POSITA would have understood that Fig. 28 shows how the undesirable moisture is drawn

[38] *See, e.g.*, Figs. 23 (item 102a, the external electrode array), 26A-B, 27A-C, and 3:60-67 (describing the permeable "mesh" or "knit" of the external array).

into the RF applicator head, and how the removal of moisture is facilitated by means of holes in the outer flexures 124, and evacuated via central hypotube 122:

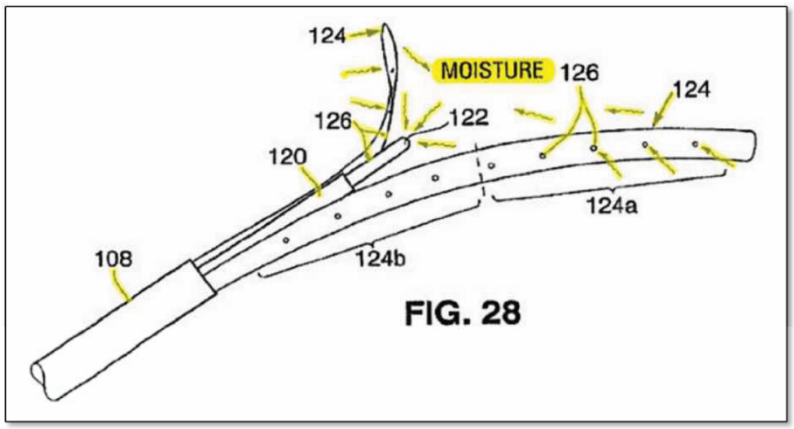


FIG. 28

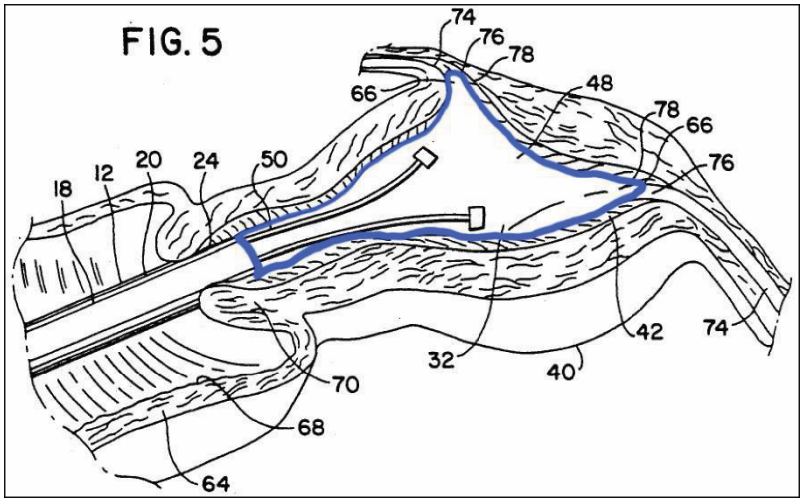
e. The "Background of the Invention" Supports My Opinions Regarding What a POSITA Would Have Understood From the Disclosures of the Common Specification

74. A POSITA reading the "Background" section of the common specification would have understood that the inventors were describing the problems and drawbacks of prior art endometrial ablation devices in order to better explain, later in specification, how their invention overcomes those drawbacks. In other words, the inventors were distinguishing their invention from the prior art and thereby conveying to a POSITA what *not* to do—what I understand in patent law is sometimes referred to as "teaching away from" or "disparaging" the prior art.

75. In general, the "Background of the Invention" section disparages *thermal* ablation techniques that relied on heated fluid to thermally ablate the uterine

tissue, describing thermal techniques as "very passive and ineffective."[39]

76. The "Background" provides an example of a prior art endometrial ablation device (Quint '044) where the exterior of the applicator head is composed of a thermal balloon (item 32). The "Background" section of the Moisture Transport Patents' common specification describes how Quint '044's balloon 32 is expanded into contact with the endometrium and how it then "thermally" ablates the endometrium, as can be seen from Figure 5 from Quint '044:[40]



A POSITA in May 1998 reading the common specification of the Moisture Transport Patents and Quint '044's disclosure would understand that Quint '044's exterior balloon 32 is, by its nature, *non-permeable*. Consequently, such a POSITA would understand that

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[39] *See, e.g.*, 1:54-64 ("For example, the heated fluid method is a very passive and ineffective heating process which relies on the heat conductivity of the tissue."); also 1:31-33 and 1:65-67.

[40] *See* 1:33-38 of the Moisture Transport Patents' common specification.

Quint's balloon would retain the moisture in the uterine cavity—not remove it. As described in the common specification, such a result was undesirable. As previously noted, the primary motivation behind the invention of the Moisture Transport Patents was to "eliminate" that moisture layer.

77. The Moisture Transport Patents' "Background" section also discusses Stern '470, which is a prior art radio frequency (RF) apparatus for endometrial ablation. According to the Moisture Transport Patents' specification, Stern '470 teaches an RF applicator head whose exterior is composed of an expandable balloon (i.e., non-permeable) with electrodes on the surface of the balloon:

> U.S. Pat. No. 5,443,470 [Stern '470] describes an apparatus for endometrial ablation in which an expandable bladder is provided with electrodes on its outer surface. After the apparatus is positioned inside the uterus, a non-conductive gas or liquid is used to fill the balloon, causing the balloon to push the electrodes into contact with the endometrial surface. RF energy is supplied to the electrodes to ablate the endometrial tissue using resistive heating.[41]

Indeed, this can be seen from Figures 4a,b and 6 of Stern '470, which shows electrodes on the exterior of Stern '470's expandable balloon:[42]

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[41] Moisture Transport Patents' common specification at 1:37-45.

[42] *See also* Stern '470 at 3:13-16 ("FIGS. 4a-b is a representation of an embodiment of an expandable member which uses a plurality of surface segments with each surface segment having a separate conductive surface and a temperature sensor"); and Stern '470 at 3:20-23 ("FIG. 6 illustrates an embodiment of the

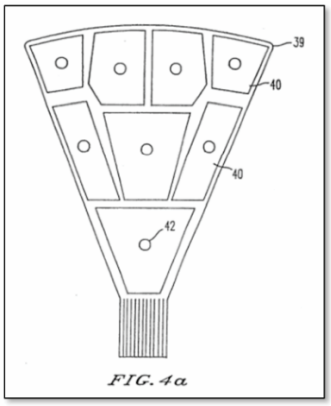

FIG. 4a

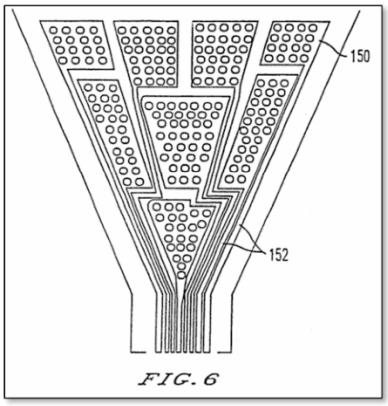

FIG. 6

78. After discussing these prior art devices, the Moisture Transport Patents' "Background" Section then discusses the various shortcomings of these prior art applicator heads—both of which were *non-permeable balloons*—by relating:[43]

- How they had trouble "controlling the ablation depth, which could only be done by "assumption";
- How "the heated fluid method [i.e., thermal ablation] is a very passive and ineffective heating process";
- How "[b]oth the heated fluid techniques and the latest RF techniques must be performed using great care to prevent over ablation"; and
- How a disadvantage of the prior art balloon is that "steam cannot escape" which could result in unintended burning.

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multi-segment element having perforated electrodes with illustrated power traces on the outside surface of the expandable member").

[43] 1:47-2:7.

79. The inventors go on to describe the fundamental problem with these prior art endometrial ablation devices, which was their inability to draw moisture away from the surface of the applicator head. This is because the exterior of the applicator heads of those prior art devices (both thermal and RF) were *non-permeable* balloons with no moisture transport mechanism (i.e., no mechanism for drawing moisture away from the tissue/electrode interface through a permeable array and into the applicator head).

80. As I have noted earlier in my report, a POSITA would have understood that when tissue begins to ablate, it exudes moisture (essentially saline).[44] That moisture creates a low-impedance path for electrical current (i.e., the current will tend to seek out a low-impedance path over a high-impedance path). The problem the inventors describe with prior art non-permeable RF applicator heads is that, once that moisture layer forms, the RF current that is supposed to travel through the uterine tissue to ablate it instead gets diverted into that undesirable low-impedance moisture layer (*i.e.*, the "path of conductivity"):

> Moreover, in prior art RF devices the water drawn from the tissue creates *a path of conductivity* through which current traveling through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated.[45]

81. A POSITA would understand the inventors to then elaborate on how that undesirable moisture layer, in turn, creates other problems. For example, the presence of the moisture layer causes more current

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[44] 10:59 ("As the endometrial tissue heats, moisture begins to be released from the tissue.").

[45] 2:9-13.

to be drawn from the electrodes than is necessary to perform the ablation, resulting in excess current (and therefore excess power) being used within the human body:

> Moreover, the presence of this current path around the electrodes *causes current to be continuously drawn* from the electrodes.[46]

As I already noted, a POSITA would understand that it is undesirable to use more current/power than necessary inside a patient's body.[47]

82. A POSITA would understand how the inventors next describe yet another drawback of non-permeable, prior art RF applicator heads; namely, how the current that is diverted into the undesirable moisture layer heats that liquid. Consequently, what was intended to be a "resistive" RF ablation turns into an unintended "thermal" ablation wherein again the depth of the ablation cannot be controlled, thereby causing "thermal ablation to continue well beyond the desired ablation depths":

> The current heats the liquid drawn from the tissue and thus turns the ablation process into a passive heating method in which the heated liquid around the electrodes *causes thermal ablation to continue well beyond the desired ablation depths*.[48]

83. As the next paragraph in the "Background" section describes, again with the prior art non-permeable applicator heads, the liquid retained in the cavity would heat up and there was no mechanism to

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[46] 2:10-14.

[47] *See also* Truckai Decl., ¶ 8.

[48] 2:15-19.

control the extent to which that heated liquid would ablate the tissue (i.e., lack of control over the depth of ablation). As a result, often either too much or too little tissue would be ablated:

> Another problem with prior art ablation devices is that it is difficult for a physician to find out when ablation has been carried out to a desired depth within the tissue. *Thus, it is often the case that too much or too little tissue may be ablated* during an ablation procedure.[49]

84. A POSITA would understand that the inventors concluded the "Background" section by summarizing the goal and import of their invention, which was to make the external electrode array of their RF applicator head either permeable or absorbent in order to draw moisture into the array (i.e., the "moisture transport system"). In this manner, they eliminated the core problem of a moisture layer building up between the tissue and the electrodes on the surface of the array during the ablation, and thereby preventing current from being diverted from the tissue into that undesirable moisture layer:

> It is therefore desirable to provide an ablation device which *eliminates* the above-described problem of steam and liquid buildup at the ablation site.[50]

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[49] 2:20-24.

[50] 2:25-27.

f. The "Summary of the Invention" Supports My Opinions Regarding What a POSITA Would Have Understood From the Disclosures of the Common Specification

85. A POSITA reading the "Summary of the Invention" section of the common specification would have understood that the inventors described their invention as an ablation device where moisture is drawn into a permeable (or absorbent) array and away from the tissue (i.e., the moisture transport system). In part, this is because the Summary literally starts this one-paragraph description by saying "[t]he present invention is . . . ." In addition, the Summary emphasizes how the array "*includes*" a fluid permeable elastic member, and how moisture "*is*" drawn into the array and away from the tissue. I note that this language does not say that the array "could be" or "may be" permeable, or that moisture "could be" or "may be" drawn into the array. In my opinion, this phrasing would inform a POSITA that drawing moisture into a permeable (or absorbent) array and away from the tissue was not optional:

> *The present invention is* an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ. An ablation device is provided which has an electrode array carried by an elongate tubular member. The electrode array includes a *fluid permeable* elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon. During use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and *moisture*

generated during dehydration is actively or passively drawn into the array and away from the tissue.[51]

g. The "Detailed Description" Supports My Opinions Regarding What a POSITA Would Have Understood From the Disclosures of the Common Specification

86. A POSITA reading the Detailed Description section would first see that it starts by describing the invention in terms of two exemplary embodiments: "The ablation apparatus according to *the present invention* will be described with respect to two exemplary embodiments."[52]

87. The description of the 1st Embodiment teaches how the external electrode array is "permeable to moisture and/or which has a tendency to absorb moisture" and can be made of an absorptive "open cell sponge," or alternatively "a metallized fabric."[53] The specification also describes the "flow pathway" where moisture passes through the "permeable" array and is evacuated by means of a central hypotube 17 from within the array.[54]

88. The description of the 1st Embodiment also teaches the importance of contact between the tissue and the external electrodes of the array (i.e., with no

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[51] 2:32-45.

[52] 4:59-61.

[53] 5:52-65.

[54] 8:19-35.

intervening moisture layer).[55] As I noted above, a POSITA would have understood that the RF ablation apparatus being described worked by putting both positive and negative surface electrodes in contact with the target tissue.

89. A POSITA would also have understood other passages in the specification to again reinforce how the moisture transport system disclosed by the inventors was designed to draw moisture "away from the electrodes" through a permeable external electrode array:

> As the endometrial tissue heats, moisture begins to be released from the tissue. *The moisture permeates the electrode carrying member 12 and is thereby drawn away from the electrodes.* The moisture may pass through the holes 17a in the suction/installation tube 17 and leave the suction/insufflation tube 17 at its proximal end via port 38 as shown in FIG. 7. Moisture removal from the ablation site may be further facilitated b_5 the application of suction to the shaft 10 using the suction/insufflation unit 40.[56]

90. At column 11, a POSITA would have understood the inventors to again be reinforcing why it was important to use a permeable array to draw the moisture away from the tissue/electrode interface. Specifically, a POSITA would have understood that the formation of the moisture layer would be detrimental to the operation of the described ablation device because it would interfere with the device's ability to control the depth of ablation. As discussed earlier

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[55] 9:3-6 ("better contact"), 10:5-9 ("good electrode contact") and 10:15-19.

[56] 10:59-67.

when describing the problems with the prior art endometrial ablation devices in the "Background" section, the inventors here add more detail about how excess current diverted into that moisture layer would heat the moisture, thereby transforming what was intended to be an RF-only "resistive" heating of the tissue into an undesirable and less predictable "thermal" ablation:

> Removal of the moisture from the ablation site prevents formation of a liquid layer around the electrodes. As described above, *liquid build-up at the ablation site is detrimental* in that [it] provides a conductive layer that carries current from the electrodes even when ablation has reached the desired depth. *This continued current flow heats the liquid* and surrounding tissue, *and thus causes ablation to continue by unpredictable thermal conduction means*.[57]

91. Next, a POSITA would understand the inventors to go on to describe how, by using a permeable array to draw moisture away from the ablation site, a physician could determine when the proper depth of ablation has been reached by monitoring the flow of current through the tissue (or put another way, by monitoring the impedance through the tissue):

> Tissue which has been ablated becomes dehydrated and thus decreases in *conductivity*. By shunting moisture away from the ablation site and thus preventing liquid build-up, there is no liquid conductor at the ablation area during use of the ablation device of the present invention. Thus, when ablation has reached the desired depth, the *impedance* at the tissue surface

[57] 11:1-8.

> becomes sufficiently high to stop or nearly stop the flow of current into the tissue. RF ablation thereby stops and thermal ablation does not occur in significant amounts. If the RF generator is equipped with an impedance monitor, a physician utilizing the ablation device can monitor the impedance at the electrodes and will know that ablation has self-terminated once the impedance rises to a certain level and then remains fairly constant.[58]

92. Stepping through some concepts in this passage at column 11, a POSITA would have understood the inventors to be explaining that, as tissue becomes dehydrated (i.e., as the ablation progresses), it becomes less "conductive." Less conductive tissue means that it becomes harder for the current to flow through the tissue. Thus, as tissue ablates, the "conductivity" *decreases*. The specification also describes this effect in terms of "impedance," which is another way to think of this effect. In particular, as tissue dehydrates it becomes denser and starts to "impede" the flow of current. So a POSITA would have understood the inventors to be teaching that, as the tissue ablates, its "impedance" *increases*. Thus, in the parlance of the common specification, if the tissue conductivity decreases, then the impedance increases, and vice versa.

93. The rest of the passage above informs a POSITA that by "preventing liquid build-up" between the tissue and the surface electrodes, the current will flow through the tissue (instead of being diverted into a moisture layer). In the absence of a moisture layer, the physician can obtain an accurate reading of the

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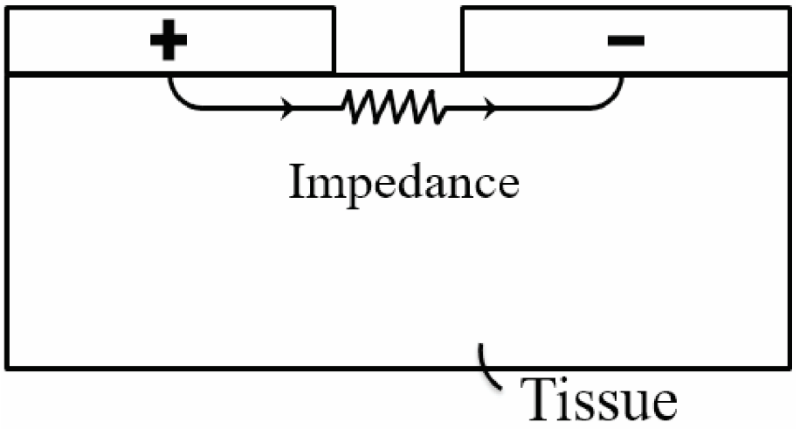
[58] 11:9-22.

impedance through the tissue. The impedance of the tissue is related to the degree to which it has been ablated. Thus, the *absence* of the moisture layer is a prerequisite for the invention to be able to accurately monitor and control the depth of ablation.

94. The drawing below graphically illustrates this concept. In the absence of a moisture layer, the current will flow as it should through the tissue, and therefore the actual impedance of the tissue (represented by the —ww— symbol) can be more accurately monitored.



95. A POSITA would understand that in the disclosures of column 11, the inventors were providing more detail regarding an advantage of their moisture transport invention mentioned earlier in the "Background" section of the common specification, where they stated:

> It is further desirable to provide an ablation method and device which allows the depth of ablation to be controlled and which automatically

> discontinues ablation once the desired ablation depth has been reached.[59]

96. Further down in column 11, a POSITA would understand that the inventors were again contrasting the advantages of their moisture transport invention with the *drawbacks* of prior art RF ablation devices that failed to prevent the formation of a liquid layer at the tissue/electrode interface:

> By contrast, if a prior art bipolar RF ablation device was used together with an impedance monitor, *the presence of liquid around the electrodes would cause the impedance monitor to give a low impedance* reading regardless of the depth of ablation which had already been carried out, since current would continue to travel through the low-impedance liquid layer.[60]

A POSITA would understand the inventors to be explaining how the presence of the liquid layer around the surface electrodes would distort any impedance reading, since the current would be diverted to that low-impedance liquid layer instead of through the tissue. Because the liquid layer is a low impedance layer, the physician would get a false reading indicating that the tissue is not yet sufficiently ablated, when in fact the correct depth of ablation may have been reached. The drawing below graphically illustrates this problem where the current flowing between positive and negative electrodes is diverted through the low-impedance liquid layer instead of through the tissue:

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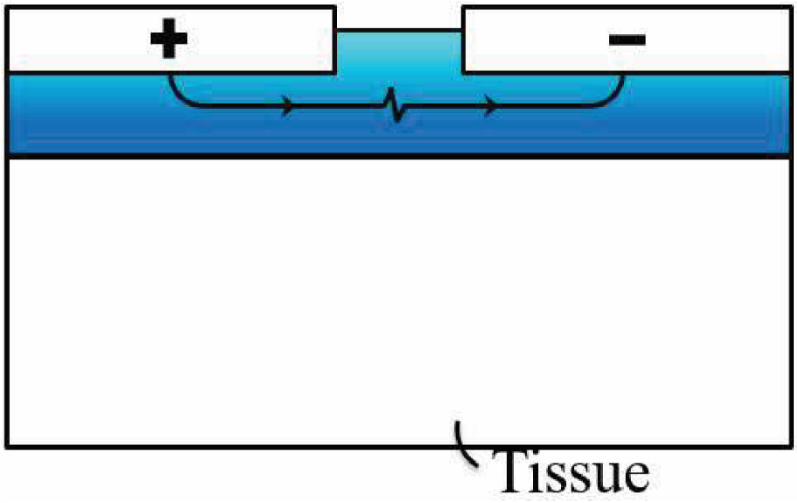
[59] 2:25-31.

[60] 11:22-28.



97. Also, as the inventors describe in the "Background" section, the diversion of the current through the liquid layer heats the liquid and turns what was intended to be an RF ablation into an undesirable and uncontrolled thermal ablation.

98. I understand that the inventors added the subject matter of the 2nd Embodiment two years after they disclosed the 1st Embodiment and after they had continued to refine their prototype.[61] In contrast to the 1st Embodiment, the 2nd Embodiment does not describe the use of an "open cell sponge" or other absorbent material as an option.[62] Rather, the 2nd Embodiment teaches that the external electrode array "is formed" of a permeable "mesh" without the use of optional language, such as "may be."[63] In addition, the

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[61] Truckai Decl., ¶ 12.

[62] Compare 5:52-60.

[63] *See* 12:9-11 ("the array 102a of applicator head 102 *is formed* of a stretchable metallized fabric *mesh*"); 12:49-50 ("The *mesh* may be configured in a variety of shapes, including . . ."); 12:9-64 (repeatedly describing the external electrode array as a

2nd Embodiment drops any mention of "passive" moisture removal and instead describes the use of suction (i.e., *active* moisture removal) to draw the moisture into the array. The 2nd Embodiment also adds additional holes along the outer flexures, as illustrated in Figure 28 below:[64]

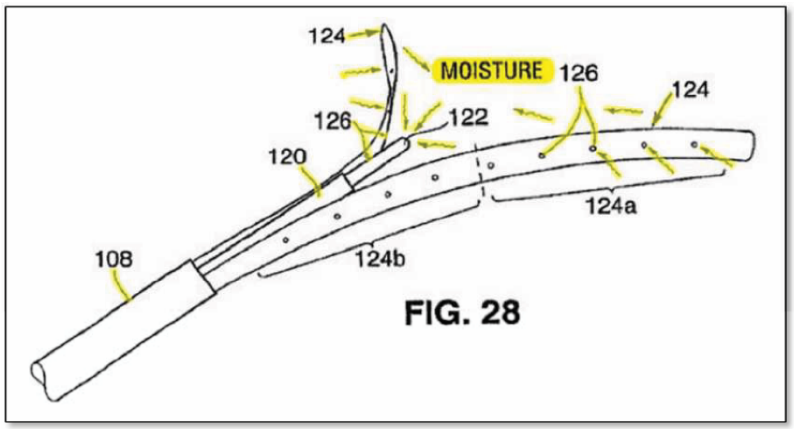

FIG. 28

A POSITA would understand that these changes allowed the device to even more efficiently draw moisture into the permeable external array and away from the tissue.

99. The common specification also informs a POSITA that the array must be permeable in other ways. For example, it describes suction/insufflation tube 17 as a dual-use tube. The common specification teaches and illustrates that, at one point during the operation of the device, the central tube 17 is used to flow CO2 into the uterine cavity (see the arrow just

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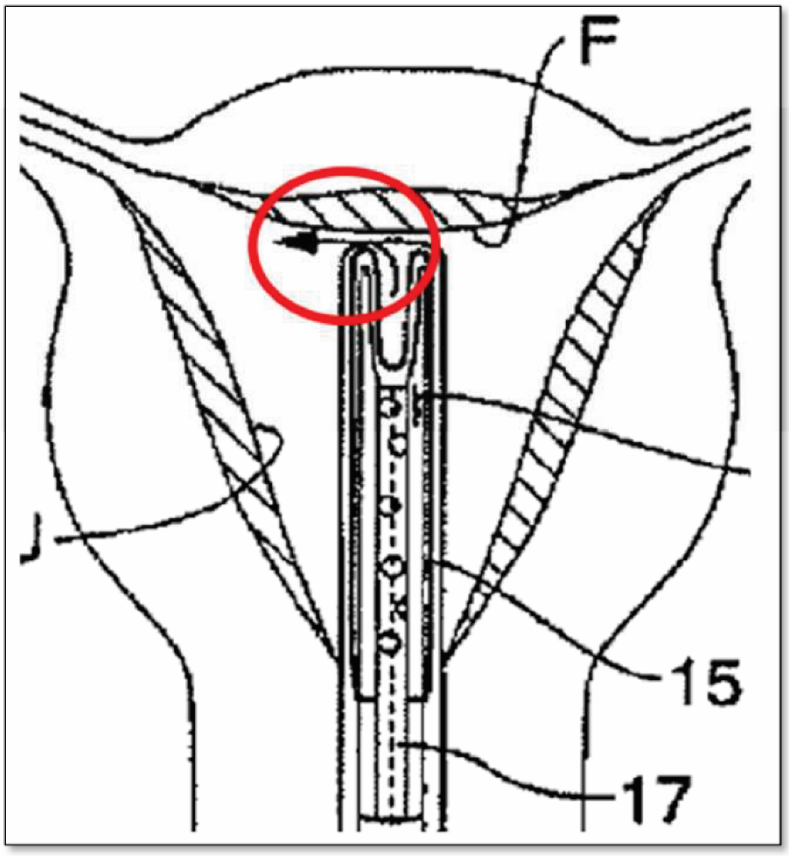
permeable "mesh" and preferably as a "knit"); 15:22-23 (describing "the *porosity* of the array fabric"); also for example Fig. 26A.

[64] *See also, e.g.,* 13:15-18, 18:40-52; Figs. 23 (item 102a), 26A-B, 27A-C, and 28.

below the fundus "F" in Fig. 6).[65] Importantly, the common specification teaches how suction/insufflation tube 17 is located *inside* the RF applicator head:



A POSITA would understand that in order to flow CO2 in through tube 17 (which sits *inside* the array) and have that gas flow out and into the uterine cavity, by necessity the array must be permeable—and the specification so states:

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[65] *See also* 9:29-39 ("carbon dioxide gas is introduced into the tube 17 via the port 38, and it enters the uterine cavity, thereby expanding the uterine cavity").

> If insufflation of the uterine cavity is desired, insufflation gas, such as carbon dioxide, may be introduced into the suction/ insufflation tube 17 via the port 38. The insufflation gas travels through the tube 17, through the holes 17a, and into the uterine cavity through the *permeable* electrode carrying member 12.[66]

100. The common specification also teaches a POSITA that the other use of suction/insufflation tube 17 is to apply suction during the ablation itself to improve the contact between the electrodes and the uterine tissue:

> As described above, the application of suction to the RF applicator head 2 via the *suction/insufflation tube 17* collapses the uterine cavity onto the RF applicator head 2 and thus assures better contact between the electrodes and the endometrial tissue.[67]

A POSITA would again have understood that the use of suction through tube 17 to collapse the uterine tissue onto the surface of the RF applicator head (and thereby assure better contact between the tissue and the electrodes on the surface of the array) only works because the array is permeable. If the array were non-permeable, it would not have the described effect of collapsing the tissue into better contact with the electrodes.

101. Turning to the "electrode"-related terms such as "one or more electrodes," a POSITA reading the common specification would understand that what-

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[66] 8:19-35.

[67] 10:14-19 and 18:40-43 (describing how vacuum/suction is used to, "draw uterine tissue into contact with the array 102").

ever the number or pattern of electrodes, in every embodiment, all of the electrodes reside on the surface of the external electrode array. All of the electrodes are placed on the surface of the array in order to make contact with the uterine tissue. Put another way, the common specification does not disclose or describe any embodiment where one or more electrodes reside completely inside the array such that it (or they) do *not* contact the tissue during the ablation.

102. My opinion is consistent with what I described earlier; namely, that by the 1990s a POSITA would have understood that RF ablation devices designed for use in human body cavities were generally designed to have the electrodes contact the tissue in order to ablate it. These RF devices used "resistive" heating, as opposed to "thermal" heating of the tissue. As I discuss above, a POSITA would have understood that the focus of the invention described is to eliminate the intervening moisture layer by drawing the liquid into a permeable or absorbent external electrode array. This "moisture transport" system allows better contact between the electrodes on the surface of the external electrode array and the uterine tissue. It is the elimination of this undesirable moisture layer that allows the unimpeded contact between the surface electrodes and the tissue, thereby allowing a physician to better monitor and control the depth of ablation.

103. Working again through the common specification, a POSITA would note that the title of the common specification refers to the need for the electrodes to contact the tissue, (i.e., ". . . *Contact* Electrocoagulation").

104. The Abstract states, "[f]ollowing placement of the ablation device into *contact* with the tissue to be ablated[.]"

105. A POSITA would note that every Figure in the common specification relating to the electrodes shows the electrodes on the exterior surface of the RF applicator head such that they can contact the tissue. E.g., Figs. 2, 5A, 23 and 25A-B.

106. Although the common specification describes different shapes and patterns of electrodes, Figures 18 and 19A-C illustrate how nevertheless all of the electrodes are shown in direct contact with the uterine tissue.[68] See e.g., Fig. 19C (the electrodes are labeled "+" and "-", while the Tissue is labeled "T" below):

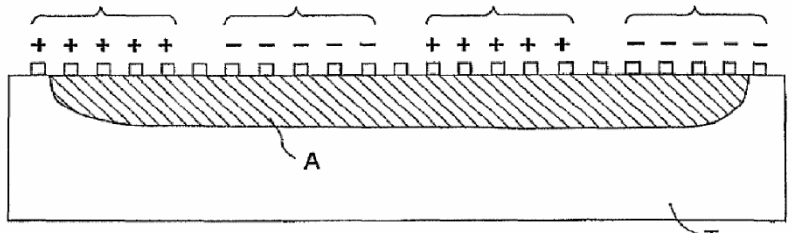

FIG. 19C

107. Next, a POSITA would understand that the "Background" section of the common specification describes the problems caused when the moisture layer creates an undesirable current path "around *the electrodes*." There is no language of exclusion or mention that this problem only relates to some subset of the electrodes. Thus, a POSITA would understand that not just one, but all of the electrodes are designed to contact the tissue. The common specification reinforces the importance of drawing moisture away from

[68] 3:34-41 (Description of figures, "showing electrode***s*** in contact with the tissue surface").

the electrodes, since otherwise the liquid build-up around them would obstruct contact with the tissue.[69]

108. Again, the "Summary of the Invention," which is describing "[t]he present invention," describes how the "electrode array" has "conductive regions thereon," and unambiguously states that, "[d]uring use, the electrode array is positioned *in contact* with tissue to be ablated."

109. A POSITA would take account of how the "Detailed Description" of the common specification teaches how "according to the present invention" the RF applicator head includes an array of electrodes "formed on the surface" of the array:

> Referring to FIGS. 1 and 2, an ablation device *according to the present invention* is comprised generally of three major components: RF applicator head 2, main body 4, and handle 6. Main body 4 includes a shaft 10. *The RF applicator head 2 includes* an electrode carrying means 12 mounted to the distal end of the shaft 10 and *an array of electrodes 14 formed on the surface of the electrode carrying means 12*.[70]

110. There is no statement to the contrary. There is no description in the common specification of one or more electrodes designed to reside only *inside* the applicator head, or designed *not* to contact the tissue. The clear statement put in terms of "the present invention" about the electrodes being "formed on the

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[69] 2:9-19 ("liquid *around the electrodes*"), 10:59-62, 11:1-8 ("Removal of the moisture from the ablation site prevents formation of a liquid layer *around the electrodes*.") and 11:22-28 (disparaging prior art RF devices that allow for "the presence of liquid *around the electrodes*").

[70] 4:54-61.

surface" would inform the POSITA that indeed, all electrodes relevant to the claimed invention are formed on the surface (and not the interior) of the array.[71]

111. The common specification goes on to describe how the electrodes: (i) may have a variety of patterns, (ii) can be made from a variety of materials, and (iii) can be formed on the exterior surface of the RF applicator head in a variety of ways. However, in every embodiment without exception the electrodes are formed on the tissue-contacting surface of the RF applicator head.[72] The common specification describes in detail how the electrodes can be formed on the surface of the array by plating the outer surface with gold or some other conductive material.[73]

112. The common specification goes on to reinforce the importance of how, "during use it is most desirable for the electrode*s* 14 on the surface of the electrode carrying means 12 to be held *in contact* with the interior surface of the organ to be ablated[.]"[74]It also describes various alternative ways to improve contact between the electrodes and the tissue by means of: (i) "spring members"; (ii) "a pair of inflatable balloons . . .

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[71] *See also* Fig. 5A and 5:40-41.

[72] 5:52-6:11 and 12:53-13:7 (describing a four-electrode surface pattern of the 2nd Embodiment).

[73] 12:9-48

[74] 2:40-41 ("During use, the electrode array is positioned in *contact* with tissue to be ablated,"), 3:35 ("ablation electrodes in *contact* with the tissue surface"), 3:39, 6:21, 8:47-49 ("Because during use it is most desirable for the electrodes 14 on the surface of the electrode carrying means 12 to be held in *contact* with the interior surface of the organ to be ablated"), 11:61-67, 12:5-8 and 18:33-34 ("deflecting mechanism 102b has deployed the array 102a into *contact* with the uterine walls.").

arranged inside the electrode carrying means 12;" or (iii) "the application of suction" to "draw the organ tissue towards the electrode carrying means 12 and thus into *better contact* with the electrodes 14."[75]

113. The common specification describes in detail the operation of the ablation device "according to the present invention." For example, it describes in detail the use of sensors to establish contact between the electrodes and the endometrium.[76] A POSITA would also understand that "[t]he second embodiment differs from the first embodiment primarily in its electrode *pattern*"—but not in the fundamental need to make contact with the tissue.[77] As with the 1st Embodiment, the RF applicator head is designed to "expand into contact with body tissue."[78] A POSITA would also understand that in describing the "Operation" of the endometrial ablation device, the need for "contact" between the electrodes and the tissue is never described as optional. Rather, the specification repeatedly discusses alternate and/or more effective ways to insure contact with the tissue.[79] Ergo, it follows that the electrodes are only being described as on the surface or exterior of the RF applicator head. I see no written description support for one or more electrodes

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[75] 8:47-9:6.

[76] 9:18-21 and 9:59-10:25 (refers in various places to "sufficient contact," "good contact," and "better contact").

[77] 11:50-58 and 12:1-8.

[78] 11:59-67; 15:16-45 (describing the "adjacent electrodes" at 15:21); Figs. 25A, 25B and 33.

[79] *E.g.*, 18:33-34 ("deployed the array 102a into *contact* with the uterine walls.") and 18:41-43 ("Suction helps to draw uterine tissue into *contact* with the array 102.").

designed to reside on the interior of the RF applicator head, or otherwise out of reach of the tissue.

E. Prosecution History of the Asserted Moisture Transport Claims

114. For purposes of my analysis, I was asked to assume that the Asserted Moisture Transport Patents have a May 8, 1998, date of invention, which corresponds to the earliest application filed with the Patent Office to which both asserted patents claim the benefit (i.e., priority):

Asserted Patent	Asserted Date of Invention
'348 Patent	May 8, 1998[80]
'989 Patent	

115. I am informed that Plaintiffs have asserted even earlier dates of conception, but that those dates do not apply to this analysis regarding validity based on the written description and enablement requirements, which focus on the applications actually filed with the Patent Office and their respective actual filing dates.

F. The Moisture Transport Family: Dates of Applications and Patents

116. I understand that the Asserted Moisture Transport Patents are related to U.S. Application No. 09/103,072 ("the '072 Application") through a string of related patent filings. The '072 Application was filed on June 23, 1998, and issued as U.S. Patent No. 6,813,520. The '072 Application, in turn, claims the benefit of U.S. Provisional Application No.

[80] '348 patent, 1:12-13; '989 patent, 1:14-16.

60/084,791.[81] The following diagram depicts the Moisture Transport Family:

Every utility application in the Moisture Transport Family shares a common specification, as I have previously indicated.

117. I note that all of the issued claims in the moisture transport family chain, starting with the issued claims of the '072 Application through the '506 Application included limitations regarding the permeable nature of the external array of the applicator head, or the need for suction through the applicator head (which necessarily requires the applicator head to be permeable).

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[81] '348 patent, 1:1-13; '989 patent, 1:1-16.

118. On August 8, 2013—15 years after the May 8, 1998 priority date—Plaintiffs filed the application that issued as the '348 Patent. The '348 patent was the first patent in the family chain to issue with claims that no longer included any permeability-related limitations, and thus were broader and more generic with respect to the nature of the "applicator head" element. Likewise, the later '989 patent also included broader and more generic claims with respect to the nature of the "energy applicator" element.

G. The NovaSure Product

119. Plaintiffs' endometrial ablation system has two basic components: a disposable handpiece and an RF Controller. It is the handpiece—and in particular the distal end—that is at issue for purposes of my analysis, as it is the distal end that corresponds to the "applicator head" and "electrode" elements of the Asserted Moisture Transport Patents. The NovaSure uses only RF energy to ablate tissue.

120. The NovaSure device includes an external electrode array that is formed from a metalized, porous fabric. All electrodes (both positive and negative) are formed on the exterior, tissue-contacting surface of the array. Steam and moisture are continuously from the tissue as it dessicates by the use of suction. This moisture is drawn into the applicator head, and is then sucked out through a central hypotube.[82] This use of a fluid-permeable fabric on the exterior of the applicator head to draw moisture from the interface between the fabric and the uterine tissue

[82] *See* D.I. 87, Exhibit 11 (NovaSure Operator Manual) at MSI00017165

during the ablation is fundamental to the NovaSure design.[83] [84]

121. During a procedure, the NovaSure device delivers up to 180 watts of ablation energy to the patient during a procedure.[85] Consequently, ablated tissue tends to stick to the NovaSure's RF Applicator head during a procedure.[86]

122. Also, I am aware that some physicians have found the Minerva device to be easier to insert into a uterus than the NovaSure device. On at least one occasion, a physician made "many attempts" to insert a NovaSure device but was "unable to gain access to the cavity with the NovaSure device." This physician was able to complete the procedure with the Minerva device.[87]

123. The following is an image of the RF applicator head from a NovaSure device (see positive and negative electrodes in gold on one face of the RF applicator head):

[83] *Id.*; *see also* D.I. 29 (Redacted Evantash Decl.) at ¶ 11.

[84] *See also* my previous descriptions of the NovaSure product from my prior declarations in this case.

[85] *See* D.I. 87, Exhibit 11 (NovaSure Operator Manual) at MSI00017165

[86] *See* the video at MSI00002329.

[87] *See* HOL-MIN_005788

H. Minerva's Plasma Formation Array (PFA)

124. Minerva's Endometrial Ablation System ("EAS") has two basic components: a disposable handpiece and a Controller. It is the handpiece—and in particular the distal end—that is at issue for purposes of my analysis, since it is the distal end that Plaintiffs assert falls within the scope of the "applicator head"- and "electrode"-related elements of the Asserted Moisture Transport Patents.

125. Minerva's handpiece employs what is in my experience a very unique Plasma Formation Array ("PFA") to ablate uterine tissue. Initially, I note that Minerva's Pre-Training Study Manual includes a relatively layman-friendly tutorial of the scientific and technical concepts underlying Minerva's technology (such as a discussion of plasma, argon, ionization and RF energy).[88] I also note here the description in Mr. Truckai's declaration regarding the design, development, and technology built into Minerva's PFA.[89]

126. The distal end of Minerva's handpiece (a.k.a. the PFA) deploys an external sealed silicone membrane into the uterine cavity—not a permeable fabric, mesh, or other porous material as is used for the exterior of the NovaSure's applicator head.[90] Minerva's sealed silicone membrane is fluid-tight and non-

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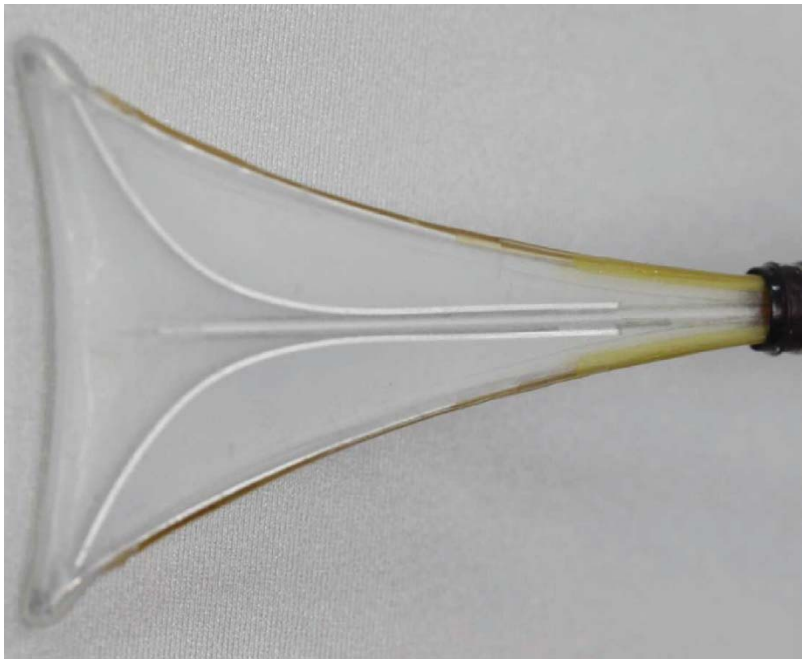
[88] D.I. 87, Ex. 10 at pages MSI00004508-13

[89] Truckai Decl., ¶¶ 31-41.

[90] D.I. 87, Ex. 10 at MSI00004500 ("The Minerva Endometrial Ablation System uses bipolar RF electrical current . . . to ionize argon (AR) gas, which is fully contained and circulating within a *sealed* silicone membrane covering the plasma formation array ("PFA").").)

permeable.[91] Below is an image of Minerva's working end complete with the external sealed silicone membrane:



Unlike the NovaSure's/'348 patent's moisture transport system, Minerva's EAS does not draw moisture through an external permeable cover and away from the uterine tissue. This is because Minerva's external membrane is sealed and fluid tight, as described in at least in the following documents:

- Pre-Training Study Manual at MSI00004500: "During the ablation cycle, the Minerva system does not proactively evacuate the liquid

[91] D.I. 87, Ex. 12 (Minerva Operator Manual) at MSI00001987 ("Argon gas is fully contained within the Minerva Disposable Handpiece silicone membrane and is not released into the uterine cavity during the ablation procedure.")

contents from the uterine cavity. These liquids remain in the uterine cavity, are heated by the membrane, and used to ablate the endometrial tissue that is not in direct contact with the membrane. This is especially helpful when the cavity is distorted by small intracavitary or intramural pathology or when the uterine cavity lacks axial symmetry . . . the Minerva Endometrial Ablation System uses bipolar RF electrical current at a frequency of 480 kHz to ionize argon (AR) gas, which is fully contained and circulating within a sealed silicone membrane covering the plasma formation array (PFA)."[92]

- Minerva Operator Manual at MSI00001987: "Intracavitary moisture is not removed during the energy delivery process. Argon gas is fully contained within the Minerva Disposable Handpiece silicone membrane and is not released into the uterine cavity during the ablation procedure."[93]
- HDD Pneumatics at MSI00002337: "The perforation detection subsystem . . . verifies that no other cavity leak exists, *such as a perforation in the plasma membrane*."[94]

As I discuss further below, Minerva's design operates in a different way to exploit and benefit from the

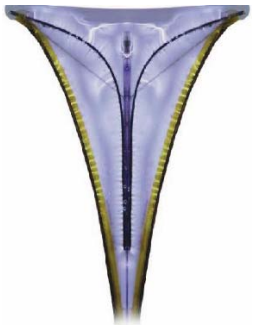
[92] D.I. 87, Ex. 10.

[93] D.I. 87, Ex. 12.

[94] D.I.87, Ex. 82.

presence of a moisture layer between the exterior of its sealed silicone membrane and the uterine wall.[95]

127. Plasma Argon Gas. In Minerva's design, there is only a single return electrode (of a first polarity) on the outer surface of the membrane.[96] The other electrode (of opposite polarity) is located inside the non-permeable silicone membrane.[97] The inner electrode never makes contact with the uterine tissue. Prior to and during the ablation, the Minerva EAS pumps an inert Argon gas into the sealed silicone membrane. The inner electrode ignites the Argon within the membrane, turning it into a glowing blue plasma:[98]



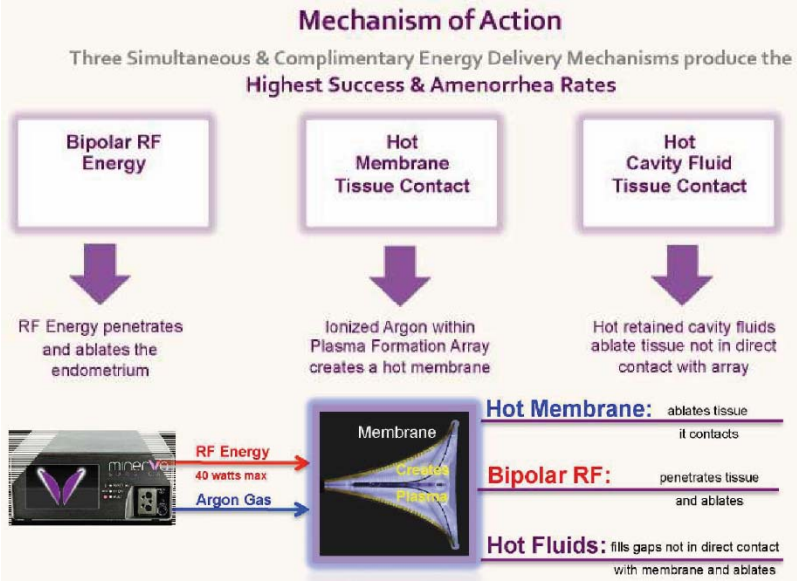
[95] *See also* my previous declaration in this case describing the operation of Minerva's device.

[96] D.I. 87, Ex. 12 (Minerva Operator Manual) at MSI00001986 ("A single tissue contacting electrode resides on the outer surface of the membrane.").

[97] D.I. 87, Ex. 12 ("[T]he expanded frame acts as the internal electrode inside the membrane.").

[98] D.I. 87, Ex. 12 at MSI00001986-87 ("Argon gas inside the membrane is ionized by the RF energy delivered by the internal electrode . . . The heat generated from the ionized argon plasma allows for the controlled transfer of energy to the uterus for the purpose of endometrial tissue ablation."); also D.I.87, Ex. 10 (Pre-Training Study Manual) at MSI00004508-09.

The plasma forms filaments of electricity that emanate a visible blue light. These filaments can be seen by the naked eye in Minerva videos that show its PFA in operation.[99] Minerva's EAS ablates tissue using hot membrane tissue contact, hot cavity fluid tissue contact, and also RF energy mechanisms of action as illustrated below:[100]



128. Primary Thermal Mechanism. Due to the physics of the Minerva device, once the plasma is ignited, the filaments seek out and heat points along the inside of the sealed silicone membrane that are adjacent to tissue that requires additional ablation.[101] That heat is conducted through the sealed silicone

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[99] MSI00001654 (D.I. 87, Ex. 7) (PFA in operation); MSI00120135 (D.I. 87, Ex. 19) (PFA in saline); and MSI00002251 (D.I. 87, Ex. 15) (PFA in egg white).

[100] D.I. 87, Ex. 10 (Pre-Training Study Manual) at MSI00004499 & 4507.

[101] Truckai Decl., ¶¶ 21-30.

membrane and heats the adjacent uterine tissue. This heating is demonstrated in the attached video of the Minerva PFA in operation heating egg white.[102] Minerva's distal end uses a thermally-conductive silicone membrane to uniformly heat the uterine tissue.[103]

129. In my opinion, a POSITA would not understand the common specification to teach or disclose any plasma formation mechanism. I am not aware of any other endometrial ablation device (including the NovaSure product) that uses anything like the plasma formation mechanism used by Minerva's EAS design.

130. Secondary Thermal Mechanism. In the process of ablating the tissue, the moisture layer builds up along the exterior of Minerva's sealed silicone membrane and along the tissue/membrane interface as described or illustrated by the documents below:

- MSI00168258 (D.I. 24): video attached as Exhibit 16 to the Cohn Declaration at 16-22 seconds.
- D.I. 87, Ex. 10 (Pre-Training Study Manual) at MSI00004500: Minerva's system "does not proactively evacuate the liquid contents from the uterine cavity. These liquids remain in the uterine cavity, are heated by the membrane, and used to ablate the endometrial tissue that is not in direct contact with the membrane. *This is especially helpful when the cavity is distorted by small intracavitary or intramural pathology or when the uterine cavity lacks axial symmetry.*"

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[102] MSI00002251, (D.I. 87, Ex. 15)(egg white video).

[103] D.I. 87, Ex. 10 (Pre-Training Study Manual) at MSI00004500.

- D.I. 87, Ex. 12 (Minerva Operator Manual) at MSI00001987: "Intracavitary moisture is not removed during the energy delivery process.") and MSI00001989 ("The combination of the heat conducted through the membrane wall from the plasma to adjacent endometrial tissue, retained heated intra-cavitary moisture that fills gaps around the surface of the array, and a small amount of bipolar RF current traveling through the target tissue (and resultant heat), results in the ablation endometrial tissue.").

131. Minerva's PFA heats the moisture layer in the interstices of the tissue, thereby facilitating a more uniform ablation, and using roughly 40 Watts.[104]

132. In contrast to Minerva's maximum output of 40 watts, the common specification describes how an:

> EEPROM within the RF generator system converts the length and width to a set power level according to the following relationship:
>
> P=LxWx5.5
>
> Where P is the power level in watts, L is the length in centimeters, W is the width in centimeters, and 5.5 is a constant having units of watts per square centimeter.[105]

Thus, for an ablation area of 6.5cm in length and 4.5cm in width (for example), the invention described

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[104] D.I. 87, Ex. 10 (Pre-Training Study Manual) at MSI00004500 ("creating a uniform and reproducible ablation") and MSI00004517 ("system operates at a max power output of 40 watts").

[105] 15:67-16:6.

in the common specification would require 160 watts (6.5 x 4.5 x 5.5).

133. Tertiary Mechanism. Small amounts of RF current from the filaments that emanate from the internal electrode pass across the dielectric silicone membrane by a phenomenon known as capacitative coupling. These filaments are attracted to a low impedance area where the tissue needs further ablation. While the energy is not large, it is important in treating tissue needing further ablation and in adding to the uniformity of the ablation. This is the "scanning" phenomenon described in Minerva's PFA patents that contributes greatly to the uniformity of the ablation.

134. Because the Minerva device uses its patented plasma formation technology to ablate the tissue and also uses a relatively small amount of RF current to control the depth of ablation, it also more evenly ablates the tissue using only a quarter of the power of the NovaSure device. Consequently, Minerva's device does not generate nearly the same level of steam as the NovaSure product, and therefore (unlike the NovaSure) steam does not need to be actively evacuated during the procedure. In other words, no moisture transport system as described in the Moisture Transport Patents is needed. This is illustrated in a side-by-side video of both devices.[106] With Minerva's PFA, the heated liquid layer is retained and used productively to gently ablate the millions of tiny internal folds of uterine tissue.

I. Minerva's Patented PFA Technology

135. Here I incorporate by reference the facts set out by Mr. Truckai regarding Minerva's PFA patents.

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[106] D.I. 87, Ex. 25

I have confirmed that during prosecution of its PFA patents, Minerva's disclosed the entire common specification by virtue of disclosing the '520 patent to the Patent Office.

136. Exhibit D to this Report includes claim charts comparing a claim of each of the Minerva's PFA patents to Minerva's EAS. In my opinion, Minerva's EAS practices the claims cited in Exhibit D.

137. In my opinion, Minerva's EAS embodies each of the three Minerva PFA patents included in Exhibit D.

J. A POSITA Would Not Find Written Description Support For the Full Scope of the Asserted Moisture Transport Claims In the Common Specification

1. Lack of Written Description

138. In my opinion, a POSITA reading the common specification would not find that the inventors were in possession of the full scope of the Asserted Moisture Transport Claims. The disclosures of the common specification fail to reasonably convey to a POSITA that the inventors had possession of the subject matter that Plaintiffs' assert falls within the scope of the asserted claims, for all of the above reasons which I summarize below, and therefore the Asserted Moisture Transport Claims are invalid.

139. A POSITA would understand the common specification to disclose that the inventors had possession of only a species of RF applicator head with a *permeable* or *absorbent* tissue contacting surface into which moisture is drawn in order to prevent formation of a moisture layer along the exterior surface of the device (i.e., the moisture transport system). The

common specification describes in detail the numerous reasons why the failure to "prevent" or "eliminate"

* * *

DEFINITIONS

> **Plasma**. In general, this disclosure may use the terms "plasma" and "ionized gas" interchangeably. A plasma consists of a state of matter in which electrons in a neutral gas are stripped or "ionized" from their molecules or atoms. Such plasmas can be formed by application of an electrical field or by high temperatures. In a neutral gas, electrical conductivity is non-existent or very low. Neutral gases act as a dielectric or insulator until the electrical field reaches a breakdown value, freeing the electrons from the atoms in an avalanche process thus forming a plasma. Such a plasma provides mobile electrons and positive ions, an acts as a conductor which supports electrical currents and can form spark or arc. Due to their lower mass, the electrons in a plasma accelerate more quickly in response to an electric field than the heavier positive ions, and hence carry the bulk of the current.

There is no equivalent disclosure of even a plasma in the common specification of the Moisture Transport Patents; much less any description or enabling disclosure for how to harness the use of such a plasma into the distal end of an endometrial ablation device.

167. I further observe that Minerva's accused PFA design uses a non-permeable (i.e., fluid tight) balloon to enclose the Argon gas. This use of a non-permeable balloon designed to *retain* the moisture layer, and that primarily relies on a *thermal* ablation, is not enabled and is indeed *contrary* to the teachings of the common

specification. As I note above, the common specification repeatedly disparages and teaches away from each of these features. Yet, due to the physics of its plasma formation array (e.g., the "scanning" mechanism whereby the plasma filaments actually seek out the less ablated tissue as described in Minerva's PFA patents), Minerva's PFA is able to achieve what is in my opinion a gentle, even and well-controlled delivery of energy, which is customized to the patient's uterus, in contravention of the teaching in the common specification that thermal techniques were less subject to control. Thus, this further informs my opinion that the common specification of the Moisture Transfer Patents lacks an enabling disclosure.

3. A POSITA Would Understand That Minerva's "Scanning" Mechanism Was Not Predictable.

168. The fact that Mr. Truckai was surprised by the physics of how his plasma formation array was able to achieve a more gentle and even ablation further supports my opinion that a POSITA would have had to engage in undue experimentation to enable the full scope of the Asserted Moisture Transport Claims. As Mr. Truckai relates, the "scanning" mechanism described in detail in his PFA Patents was an unpredictable benefit of how the plasma filaments would very rapidly seek out the low-impedance paths through the target tissue.[126] I agree based on my experience that this would not have been a predictable result at the time based on Mr. Truckai's novel use of plasma formation technology to ablate tissue through a thin-walled dielectric membrane. I understand my

[126] Truckai Decl., ¶¶ 30, 36, 41; *see, e.g.*, columns 11-12 and Figs. 9A-D of U.S. Pat. No. 8,372,068.

opinions in this regard relate to *Wands* factor number 7.

169. I further note that Mr. Truckai describes other discoveries in the course his PFA development, such as:[127]

> In one aspect of the invention, FIG. 10 is a circuit diagram representing the steps of the method in FIGS. 9A-9D which explains the discovery that return electrode 205 can have a small surface area and not be subject to significant heating. In
>
> * * **

O. Conclusions Regarding the Asserted Pressure Sensor Patent

262. Thus, the Asserted '183 Patent Claims are invalid because they (i) fail to meet the written description requirement; and independently because they (ii) fail to meet the enablement requirement.

XI. RESERVATIONS OF RIGHTS

263. Although I have cited particular evidence in this report, I have done so to assist in understanding my conclusions and the bases for them. This report does not discuss every piece of evidence that could be used to support by conclusions. Accordingly, 1 may affirm, update, or modify my opinions based on such other evidence as necessary.

264. I may make additions or modifications to my conclusions in the future, based on new evidence that is presented to me. For trial, I may prepare diagrams,

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[127] The '068 Patent at 12:47-50.

charts, and other demonstratives to illustrate my conclusions or the technology at issue.

Dated: June 30, 2017

/s/ Robert Tucker
Dr. Robert Tucker, Ph.D., M.D.

[1] 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 and Counterdefendants,

vs.

MINERVA SURGICAL, INC.,

Defendant and Counterclaimant.

HIGHLY CONFIDENTIAL –
ATTORNEYS' EYES ONLY

Videotaped Deposition of
CSABA TRUCKAI
Wednesday, October 25, 2017
1:02 p.m.

650 Page Mill Road
Palo Alto, California

Janis Jennings, CSR No. 3942, CCRR, CLR

[2] VIDEOTAPED DEPOSITION OF CSABA TRUCKAI, taken on behalf of the Plaintiffs and Counterdefendants, at WILSON, SONSINI, GOODRICH & ROSATI, LLP, 650 Page Mill Road, Palo Alto, California, beginning at 1:02 p.m. on Wednesday, October 25, 2017, before Janis Jennings, Certified Shorthand Reporter No. 3942, CLR, CCRR.

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WITNESS: CSABA TRUCKAI

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[8] PALO ALTO, CALIFORNIA; WEDNESDAY, OCTOBER 25, 2017; 1:02 A.M.

THE VIDEOGRAPHER: Good afternoon. We are on the video record on October 25, 2017, and the time is 1:02. My name is Reynaldo Abesamis Jr.; I'm the legal videographer. And the court reporter today is Janis Jennings.

This is the beginning of disc labeled No. 1 for the deposition of Csaba Truckai in the matter of Hologic, Inc., versus Minerva Surgical. The case number is 15-1031-SLR-SRF. We are located today at I Wilson Sonsini in Palo Alto, California, 94304.

Counsel, please identify yourself for the record, beginning with the questioning attorney.

MR. RAJANI: Assad Rajani, Arnold & Porter Kaye Scholer, on behalf of the plaintiffs.

MS. ELSON: Vera Elson of Wilson Sonsini Goodrich & Rosati on behalf of defendant Minerva Surgical.

Also, in the caption, the initials of the judge you read are incorrect. It's no longer Sue Robinson. It's Judge Bataillon.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness.

* * *

[41] BY MR. RAJANI:

Q. How are you aware of that?

MS. ELSON: Instruction not to answer. Privileged.

BY MR. RAJANI:

Q. What do you understand is the current challenge on the validity of the patents-in-suit?

MS. ELSON: Same objection. Instruction not to answer. Privileged.

THE WITNESS: I'm taking my counsel advice.

MR. RAJANI: And I want to make clear: Your objection is that what his understanding is of the current attack on the validity of the patents-in-suit is privileged?

MS. ELSON: If you can answer that question without revealing the substance of any attorney-client communication, you may do so.

Objection. Form. Legal conclusion.

THE WITNESS: Repeat the question, please, one more time.

BY MR. RAJANI:

Q. What is your understanding of the current basis for the challenge of the validity of Hologic's patents-in-suit?

MS. ELSON: Same instruction.

[42] THE WITNESS: I don't think it very simply can be answered. It's a number of issues.

BY MR. RAJANI:

Q. What are those issues?

MS. ELSON: Overly broad. Objection. Form. Legal conclusion.

THE WITNESS: Again, I'm not a legal expert. That's why I'm – it's difficult, you know, to say without you asking specific questions regarding what are those items.

BY MR. RAJANI:

Q. You just said it was a number of issues; right?

MS. ELSON: Same objection.

THE WITNESS: That's my understanding.

BY MR. RAJANI:

Q. What's your understanding of what those issues are?

A. I would have to make – sorry.

MS. ELSON: No. Go ahead. I was just going to give the same objection.

If you can answer that question without revealing the substance of any attorney-client communication, you may do so.

THE WITNESS: I can't answer.

[43] BY MR. RAJANI:

Q. Are you aware if Hologic's patents-in-suit have been challenged as not enabled?

MS. ELSON: Same objection.

THE WITNESS: Explain. What does it mean "enabled"?

BY MR. RAJANI:

Q. You don't know what it means to not enable?

MS. ELSON: Objection. Form. Legal conclusion.

THE WITNESS: It's a legal term. I'm not a lawyer. So if you explain to me what does it mean, then I will answer.

BY MR. RAJANI:

Q. I'm asking if you have an understanding as to what "enablement" is.

MS. ELSON: Objection. Legal conclusion.

THE WITNESS: I would just have to guess.

MS. ELSON: I have to ask for a pause. I'm suddenly not getting the realtime. Can we go off the record a moment?

MR. RAJANI: Sure.

THE VIDEOGRAPHER: We are going off the record, and the time is 1:41.

(Off the record.)

[44] THE VIDEOGRAPHER: We are now going back on the record, and the time is 1:43.

BY MR. RAJANI:

Q. Mr. Truckai, are you aware that your declaration is being cited in support of Minerva's invalidity arguments in this case?

MS. ELSON: If you can answer that question without revealing the substance of any attorney-client communications, you may do so. Otherwise, I instruct you not to answer.

THE WITNESS: Actually, I don't know its use. I don't know how it is being used.

BY MR. RAJANI:

Q. You prepared Exhibit 1, your declaration, and you're not sure how its being used in the case?

MS. ELSON: Asked and answered.

BY MR. RAJANI:

Q. Go ahead and answer.

MS. ELSON: Same – same instruction. If you can answer that question without revealing the substance of any attorney-client communication, you may do so. Otherwise, I instruct you not to answer.

THE WITNESS: I am taking my counsel advice.

///

[45] BY MR. RAJANI:

Q. You didn't ask if your declaration was related to the invalidity of the patents-in-suit?

MS. ELSON: Instruction not to answer.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Have you ever discussed the invalidity of Hologic's patents-in-suit with anyone?

MS. ELSON: Same instruction not to answer. Privileged.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Let's go to page 1 of your declaration, paragraph 2. The last sentence refers to a copy of your CV; right?

A. I'm sorry?

Q. The last sentence refers to your CV; correct?

A. Which part are you talking about? I'm sorry.

Q. Paragraph 2, the last sentence.

A. Yes.

Q. "A copy of my CV."

A. That's right.

THE VIDEOGRAPHER: Counsel, I'm going to [46] ask that you turn off your cell phone. It's causing some interference, some static.

MS. ELSON: Mine?

THE VIDEOGRAPHER: Both of you.

MS. ELSON: Mine was muted.

THE VIDEOGRAPHER: I'm going to turn off mine too.

THE WITNESS: I could put on airplane mode

MR. RAJANI: I think he's saying interference, so I'll just turn mine off.

I'm going to mark as Exhibit 2 a document titled "Csaba Truckai," and it's Bates-labeled MSI00299668 through 669.

(Exhibit 2 marked for identification.)

BY MR. RAJANI:

Q. This is a copy of your CV; right?

A. Yes.

Q. When Novacept was formed, you were Novacept's vice president of R&D; right?

A. Correct.

Q. In what year was Novacept formed?

A. It's not a simple answer. So the company was started in 1993 as Envision Surgical System. Envision Surgical System.

Q. Envision?

[47] A. E-n-v-i-s-i-o-n.

Then the company changed its name to Acuvasive.

Q. How do you spell that?

A. A-c-u-v-a-s-i-v-e, I believe, but I have to check.

Q. Okay.

A. I know we pronounce it "Acuvasive."

Q. Do you know when you became Novacept's vice president of R&D?

A. When we changed the name to Novacept.

Q. And is it at the time of the name change you became the vice president of R&D?

A. Yes.

Q. Do you know approximately when that was?

A. I would have to guess. 1995, '96, something like that.

Q. You also became Novacept's president; correct?

A. Later on, yes.

Q. When was that?

A. I don't recall the precise date.

Q. Did you remain Novacept's president until 2000?

A. Until 1999; December, I believe.

[48] Q. In March of 2000 you joined Novacept's board of directors?

A. No. I was on the board prior to that.

Q. How much earlier were you on the board of directors of Novacept?

A. Since Envision. So Envision, Acuvasive and continuation of Novacept. So I was – if you're looking at the company, the company started as Envision Surgical System. Through the name changes, I was always on the board.

Q. Did you remain on Novacept's board of directors until it was acquired by Cytyc, C-y-t-y-c, in 2004?

A. I was.

Q. You're a founder of Minerva; correct?

A. Yes.

Q. You founded Minerva in 2008; correct?

A. I believe so.

Q. Who named it Minerva?

MS. ELSON: Objection. Form.

THE WITNESS: I think it was the CFO at the time came up with the name.

BY MR. RAJANI:

Q. Do you know why the company was named Minerva?

[49] A. Because Minerva is a goddess, you know, for woman. So since the company purpose is to develop a product which helps and improve woman healthcare, that's why we ended up having the name Minerva.

Q. Was there a particular type of product that Minerva had in mind at its – strike that.

Was there a particular type of product that the company had in mind at its founding?

MS. ELSON: Objection. Form.

THE WITNESS: Endometrial ablation product.

DEPOSITION REPORTER: One more time.

THE WITNESS: Endometrial ablation product.

BY MR. RAJANI:

Q. So is it fair to say that you began developing Minerva's endometrial ablation product as soon as it was founded?

MS. ELSON: Objection. Form.

THE WITNESS: It's not a simple answer to that.

BY MR. RAJANI:

Q. Explain it to me.

A. In 2006 we formed a company, and we were looking at all kind of different technologies. The company was Arqos, and – but that was just IP holding company. So we were developing a orthopedic [50] product, and part of the development was – I would call it collateral damage. You know, we discovered –

DEPOSITION REPORTER: "I would call it –

THE WITNESS: Collateral. You know –

MR. RAJANI: Collateral damage.

DEPOSITION REPORTER: Oh.

THE WITNESS: – invention, collateral invention. We realized that the technology has multiple applications, including the endometrial ablation field.

BY MR. RAJANI:

Q. What was the name of the company formed in 2006 that you just mentioned?

A. Argos.

Q. How do you spell that?

A. A-r-q-o-s.

Q. Is Argos listed in Exhibit 2?

A. It was really – it had no employees, so it was an IP holding company. And Argos split into multiple companies. We split the IP into multiple fields. It was a true IP holding company.

Q. Was it an LLC?

A. That's correct.

MS. ELSON: Objection – objection. Form.

[51] THE WITNESS: That's correct.

BY MR. RAJANI:

Q. Were there other members of Argos?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. Who?

A. John Shadduck, Bruno Strul. I have to look at the names. The company is no longer in existence, so . . .

Q. What was Bruno's last name?

A. Strul.

Q. How do you spell that?

A. S-t-u-r-l [verbatim].

Q. S-t-u-r-l? Okay.

So is it fair to say that you began developing Minerva's endometrial ablation product prior to Minerva being formed?

A. No –

MS. ELSON: Objection. Form.

THE WITNESS: No, it's not.

BY MR. RAJANI:

Q. Why do you say that?

A. Because we developed many technologies, and the technology eventually which is Minerva has [52]

nothing got to do with Arqos technology, really. It wasn't part – you know, it was just us developing the orthopedic product. We realized that, you know, there are other things that are beyond Arqos.

Q. You were the president of Minerva at its founding in 2008?

A. Yes.

Q. You were the president of Minerva until May 2011; correct?

A. It sounds about right.

Q. And that was when Mr. Clapper took over?

A. Correct.

Q. As the president of Minerva, what were your job responsibilities at a high level?

MS. ELSON: Objection. Form.

THE WITNESS: Give general direction to the company, put the management team in place, raise the sufficient funds, and just like many startup company, you know, do whatever it takes.

BY MR. RAJANI:

Q. With respect to the endometrial ablation product that Minerva was working on, as the president of Minerva, did you have any specific responsibilities – strike that.

As the president of Minerva, did you have [53] any specific job responsibilities with respect to its endometrial ablation product?

MS. ELSON: Objection. Form.

THE WITNESS: The company is an endometrial ablation company, so not precisely. I'm trying to –

what – I mean, I – I describe my function of the company. It's a single-product company, so its not like, you know . . .

BY MR. RAJANI:

Q. Thanks for clarifying. So the job responsibilities you just described earlier, all of those relate to Minerva's endometrial ablation product; correct?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. You were also the CEO of Minerva until May 2011; right?

A. Correct. So I have them the same time, the president and the CEO.

Q. As the CEO what were your job responsibilities?

MS. ELSON: Objection. Form.

THE WITNESS: Same as the president.

///

[55] Q. So you were not an employee of Minerva at its founding?

MS. ELSON: Objection. Form.

THE WITNESS: I was a consultant CEO.

BY MR. RAJANI:

Q. You have never been an employee of Minerva?

A. I was always a consultant CEO.

Q. Your understanding is you have never been an employee of Minerva?

A. I have never received a salary from Minerva as a normal employee.

Q. Did you consider yourself an employee of Minerva at any time?

MS. ELSON: Objection. Form.

THE WITNESS: I was a consultant. Consultancy.

BY MR. RAJANI:

Q. You're currently a member of Minerva's board of directors?

A. Yes, I am.

Q. How long have you been on Minerva's board?

A. Since inception.

Q. And your title is currently director at Minerva?

A. Board –

[54] BY MR. RAJANI:

Q. Is it fair to say that your job as president and CEO included managing the company?

MS. ELSON: Objection. Form.

THE WITNESS: That was my primary responsibility.

BY MR. RAJANI:

Q. Is it fair to say that as president and CEO your job included setting the strategic direction of the company?

A. Yeah. Somewhat. That is one of the functions.

Q. And as Minerva's CEO and president, is it fair to say that your job included implementing that strategic direction?

MS. ELSON: Objection. Form.

THE WITNESS: My job was to execute the company plan.

BY MR. RAJANI:

Q. Did you bill by the hour when you served as president and CEO of Minerva?

A. Yes.

Q. So you billed those hours through Hermes, H-e-r-m-e-s, Innovations, LLC?

A. Correct.

[56] MS. ELSON: Objection. Form.

THE WITNESS: Board of directors, member of the board of directors.

BY MR. RAJANI:

Q. Do you have any – excuse me – do you have any written agreement with Minerva by which you have agreed to serve on its board of directors?

A. I – actually, I am not sure. I don't think so.

Q. Do you understand that one of your duties as a member of the board is to hire and fire CEOs?

MS. ELSON: Objection. Form.

THE WITNESS: Yeah.

BY MR. RAJANI:

Q. Do you understand that one of your duties as a member of the board is to assess the direction of Minerva's business?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. Do you understand that as a member of Minerva's board of directors you owe a fiduciary duty to Minerva?

MS. ELSON: Objection. Form. Legal conclusion.

[57] THE WITNESS: Yes.

BY MR. RAJANI:

Q. How often does Minerva's board of directors meet?

A. Every two to three months.

Q. When the board of directors meets, do you attend in person?

MS. ELSON: Objection. Form.

THE WITNESS: Not all the time.

BY MR. RAJANI:

Q. How often would you say you attend in person?

MS. ELSON: Same objection.

THE WITNESS: I would say most of the time, but I don't have a precise count.

BY MR. RAJANI:

Q. Who – who presents at these meetings?

A. The –

MS. ELSON: Objection. Form.

And I would just caution the witness not to reveal any attorney-client communications. If you can otherwise answer the question, go ahead.

THE WITNESS: Company management.

BY MR. RAJANI:

Q. Is it only the CEO who presents, or is

[58] there more than one person that presents?

A. Company –

MS. ELSON: Same – same instruction.

THE WITNESS: Company management.

BY MR. RAJANI:

Q. Is it more than one person from company management that presents?

A. Yes.

MR. RAJANI: I am going to mark as Truckai Exhibit 3 a document titled "Minerva Surgical Board of Directors Meeting," and it is labeled MSI00298766 through MSI00298845.

(Exhibit 3 marked for identification.)

MR. RAJANI: And I'll also mark as Truckai Exhibit 4 another document titled "Minerva Surgical Board of Directors Meeting," and this one is labeled MSI00298846 through MSI002- – 298953.

(Exhibit 4 marked for identification.)

MR. RAJANI: Here you go.

BY MR. RAJANI:

Q. Are Exhibits 3 and 4 examples of slides that are presented during board of directors meetings?

A. It appears so.

Q. Do you have any reason to believe that they [59] are not the slides presented at board of directors meetings?

MS. ELSON: Objection. Form.

THE WITNESS: I don't know. I haven't reviewed them, so I can't comment on them.

BY MR. RAJANI:

Q. Do you want to take some more time to look at them?

A. Sure.

MR. RAJANI: Oh, and I can represent to you that these were produced by Minerva, as shown by the Bates numbers at the bottom corner.

BY MR. RAJANI:

Q. And let me actually ask you to go to just the cover of Exhibit 3. The document has a date of Tuesday, April 18, 2017; right?

A. Correct.

Q. Do you specifically remember attending this meeting?

A. I have to review the material.

Q. Go ahead.

A. I think so, but if you are looking at the board and you have multiple board meetings and the subject matter is pretty much the same, so very – very repeat – very repeated information. So [60] probably I was. If not, I called in.

Q. And we can speed this along. Do you remember the specifics of what was said or wasn't said at any – at either the meeting on April 18th, 2017 or February 14th, 2017?

MS. ELSON: And I'm just instructing the witness –

Well, let me put it this way, Counsel. Would you care to rephrase that question to exclude any privileged communications?

BY MR. RAJANI:

Q. I will just start with – I am only asking for a "yes" or "no," whether you remember the specifics of what was discussed at either of those meetings.

A. Somewhat. Not everything. I mean, I would have to refresh, go back, look at the board meeting minutes and . . .

Q. Let's go to the second page of Exhibit 3. The Bates number ends in 767 in the bottom corner, and the title of the slide is "Agenda."

Do you see that?

A. Yeah. Yes, I can.

Q. On what topics are board members briefed when the board of directors meets?

[61] MS. ELSON: Objection. Form.

THE WITNESS: On all, but in various extent, so it changes board meetings to board meetings. So even though you have the agenda, this one doesn't describe how much time we spent on each subject.

BY MR. RAJANI:

Q. And just before when you said "On all," you were referring to all of the nine topics listed on the agenda?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. Topic No. 3 reads, "IP Lawsuit Update."

Do you see that?

A. Yes, I can.

Q. Without going into what the substance of that update is, why is – why are members of the board given an IP lawsuit update?

MS. ELSON: I'll instruct the witness not to answer. Privileged.

BY MR. RAJANI:

Q. Do you understand as a member of the board why you would be given updates as to IP lawsuits?

MS. ELSON: Instruction not to answer. [62] Privileged.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Who presents the legal updates at the Minerva board meetings?

MS. ELSON: Same – same instruction. Privileged.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Does Mr. Clapper provide that update, or is it someone else in management?

MS. ELSON: Same instruction. Privileged.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Has the board ever discussed Minerva's legal strategy in this case?

MS. ELSON: Same instruction. Privileged.

THE WITNESS: I'm taking my – my counsel legal advice.

BY MR. RAJANI:

Q. As a member of the board, do you ever provide any comments about this litigation?

MS. ELSON: Same instruction. Privileged.

THE WITNESS: I'm taking my counsel legal advice.

[63] BY MR. RAJANI:

Q. Do you currently have an ownership interest in Minerva by virtue of owning company stock?

MS. ELSON: Objection. Form.

THE WITNESS: Yes, I do.

BY MR. RAJANI:

Q. You own approximately 6 percent of Minerva's stock?

MS. ELSON: Objection. Form.

THE WITNESS: Probably you know better than I do. I don't know.

BY MR. RAJANI:

Q. You're not sure how much you own?

A. No.

Q. Do you own any shares of Minerva where your ownership interest has not yet vested?

MS. ELSON: Objection. Form.

THE WITNESS: I may have some warrants, so . . .

DEPOSITION REPORTER: "I may have some –

THE WITNESS: Warrants. Warrants.

BY MR. RAJANI:

Q. What is that?

MS. ELSON: Objection. Form.

THE WITNESS: It's a stock where you have [64] the right to buy it at a certain price.

BY MR. RAJANI:

Q. Like an option?

A. It's like a – it's not an option. It's a warrant.

Q. How do you spell that word?

A. W-a-r-r-a-n-t.

Q. And through – how did you come to – do you own any warrants for Minerva stock?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. How did you come to own those?

MS. ELSON: Objection. Form.

THE WITNESS: That was a financing, and prior to financing the company, they made some bridge funds, and a note came with a warrant.

BY MR. RAJANI:

Q. So this is something you would have received at the time when Minerva was founded?

A. No.

MS. ELSON: Sorry. I didn't get my objection in. Objection. Form.

Go ahead.

///

[65] BY MR. RAJANI:

Q. When did you receive those warrants?

A. 2011, I would say.

Q. Do you invest in Minerva through any of your other businesses?

MS. ELSON: Objection. Form.

THE WITNESS: No. It's in my own money.

BY MR. RAJANI:

Q. Are you an investor in Vivo Capital?

A. No, I am not.

Q. You're a founder and managing member of Hermes, H-e-r-m-e-s, Innovations LLC; right?

A. Correct.

Q. Is it your company?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. How much of the company do you own?

MS. ELSON: Objection. Form.

THE WITNESS: It's an LLC. It's an equal distribution to members.

BY MR. RAJANI:

Q. Did you say it was an equal distribution?

A. I don't know precisely what the distribution structure is, but, you know, the [66] members are equal.

Q. Has Hermes provided Minerva services regarding Minerva's intellectual property?

A. Yes.

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. What kind of services has it provided?

MS. ELSON: And if you can answer that question without revealing the substance of any attorney-client communication, you can do so. Otherwise, I instruct you not to answer.

THE WITNESS: We license certain patents to Minerva.

BY MR. RAJANI:

Q. Is that the only work Hermes has done with Minerva?

MS. ELSON: Same instruction.

THE WITNESS: Hermes also provided CFO service and IP service, which comes with the – licensing the patent to the company.

BY MR. RAJANI:

Q. Does Hermes provide any services regarding whether any inventions are patentable?

MS. ELSON: I instruct you not to answer. [67] Privileged.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. That's what you said at your last deposition, so I would assume that the privilege is waived. What did you mean in your prior testimony?

A. That we license –

MS. ELSON: Same instruction. You don't have to answer. Privilege.

BY MR. RAJANI:

Q. Are you going to answer?

A. I'm taking my counsel advice.

Q. Has Hermes provided any services to anyone relating to Hologic's patents-in-suit?

MS. ELSON: Same instruction not to answer. Privilege.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Has Hermes provided any services to anyone relating to the NovaSure device?

MS. ELSON: If you can answer that question without revealing the substance of any attorney-client communications, you may do so. Otherwise, I instruct you not to answer.

THE WITNESS: No.

[68] BY MR. RAJANI:

Q. With respect to Hermes providing any services to anyone regarding Hologic's patents-in-suit, can you answer that question without disclosing any attorney-client communications?

MS. ELSON: I'm sorry.

MR. RAJANI: Let me ask the question again.

MS. ELSON: Yeah.

THE WITNESS: Yeah.

BY MR. RAJANI:

Q. Has Hermes provided any services to anyone relating to Hologic's patents-in-suit?

MS. ELSON: And if you can answer that question without revealing the substance of any attorney-client communications, you may answer that question. Otherwise, I instruct you not to answer.

THE WITNESS: I can't answer.

BY MR. RAJANI:

Q. Has Hermes provided any services to anyone relating to this lawsuit?

MS. ELSON: Again, if you can answer that question without revealing the substance of any attorney-client communications, you may answer that question. Otherwise, I instruct you not to answer.

* * *

[73] Am I pronouncing that correctly?

A. Correct.

Q. M-e-d-r-e-s.

Has Medres –

DEPOSITION REPORTER: I'm sorry.

MR. RAJANI: M-e-d-r-e-s.

DEPOSITION REPORTER: Thank you.

BY MR. RAJANI:

Q. Has Medres been involved in any way with the design of any alternate Minerva handles?

MS. ELSON: Objection. Form.

THE WITNESS: First, I don't know that there is an alternate design, and I'm not aware if Medres, you know, would do any of that.

BY MR. RAJANI:

Q. Okay. Let's go to page 19 of your declaration, which was Exhibit 1.

MS. ELSON: I'm sorry. Page 19 or paragraph 19?

MR. RAJANI: Page 19, paragraph 49.

MS. ELSON: Thank you.

BY MR. RAJANI:

Q. The second sentence of paragraph 49 reads:

"One year later, on November 10, 2000, my co-inventors and I filed U.S. [74] Application No. 09/710,102, which was later issued as U.S. Patent No. 6,554,780 (the 780 patent)."

Do you see that sentence?

A. Yes, I can.

MR. RAJANI: I am going to mark as Truckai Exhibit 5 a document that's Bates-labeled HOL-MIN_145183 through 145190.

(Exhibit 5 marked for identification.)

BY MR. RAJANI:

Q. And if you can take a look at it and tell me if you recognize the document.

MS. ELSON: Thank you.

Sorry. This is Exhibit –

MR. RAJANI: 5.

MS. ELSON: 5.

BY MR. RAJANI:

Q. And if it helps you, the page in which I'm interested is the one ending in 186 titled "Assignment."

Have you seen this assignment before?

MS. ELSON: Objection. Form.

THE WITNESS: I'm pretty sure I did, but I'm not – I can't recall. It's been a long time.

///

[75] BY MR. RAJANI:

Q. Does your signature appear on the page ending in 187?

A. Yes, that's my statement. Probably I reviewed it at the time.

Q. Did you sign this assignment in Exhibit 5 under penalty of perjury?

A. Yes.

MS. ELSON: Objection. Form. Legal conclusion.

THE WITNESS: I signed this with my understanding of the declaration, yeah, the assignment.

BY MR. RAJANI:

Q. You signed it knowing that it was under penalty of perjury; right?

MS. ELSON: Objection. Form. Legal conclusion.

THE WITNESS: I'm assigned it as a assigner of the patent, so I'm representing that I'm one of the co-inventor of the patent.

BY MR. RAJANI:

Q. I'm trying to understand what your understanding was when you signed the document. Did you understand that by signing it you were signing [76] it under penalty of perjury?

MS. ELSON: Objection. Form. Legal conclusion.

THE WITNESS: Again, I'm – the only thing I'm saying is that I signed it because I was one of the co-inventor.

MR. RAJANI: I'm going to object as nonresponsive.

BY MR. RAJANI:

Q. What did you do before signing this document?

MS. ELSON: Objection. Form.

THE WITNESS: Could you be more specific?

BY MR. RAJANI:

Q. Before you were ready to sign this assignment, did you do anything to determine whether you would or wouldn't sign the document?

MS. ELSON: Objection. Form.

THE WITNESS: We reviewed the patent.

BY MR. RAJANI:

Q. And at this point it would have been a patent application that you would have reviewed?

A. That's what I meant.

DEPOSITION REPORTER: I'm sorry?

THE WITNESS: That's what I meant.

[77] BY MR. RAJANI:

Q. And did you certify that you reviewed and understood the contents of that application? Right?

MS. ELSON: Objection. Form.

THE WITNESS: Yes, I understood it.

BY MR. RAJANI:

Q. And the application number is listed here on the page ending 186 as application number 09/710,102; right?

MS. ELSON: Objection. Form.

THE WITNESS: That's correct.

BY MR. RAJANI:

Q. Let's go back to – let's go to the first paragraph of the assignment. It has the names of a number of the inventors listed on the first line; right?

A. Correct.

MS. ELSON: Objection. Form.

THE WITNESS: Correct.

BY MR. RAJANI:

Q. And on the next line where it says "Assignors," in all capitals, do you see where it says, "have invented certain new and useful improvements as described and set forth in the below-identified application for United States [78] Letters Patent."

Do you see that part of the sentence?

A. Yes, I can.

Q. And you understood that as part of signing this assignment you attested that you believed that you invented the subject matter described in the application?

A. Co-invented.

Q. Do you still believe your statements in Exhibit 5 to be true today?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. Okay. Let's go back to your declaration, which is Exhibit 1.

A. Okay.

Q. Page 1.

A. Page?

Q. Page 1.

All right. Do you see a section heading A titled "The Moisture Transport Prototypes and Patents" towards the bottom of the page?

A. Yes, I can.

Q. And just generally, in this section of your declaration, are you describing your prototyping [79] work at Novacept?

MS. ELSON: Objection. Form.

THE WITNESS: That's what it describes.

BY MR. RAJANI:

Q. And you turned in your lab notebooks when you left Novacept; right?

A. Yes.

Q. Do you still have copies of any documents, like lab notebooks or other documents, reflecting this prototyping work that you did at Novacept?

A. No, I don't.

Q. Is it fair to –

A. Everything I had, I provid- – I gave to the company when I left as an employee.

Q. Is it fair to say that you haven't seen any documents reflecting the prototyping work that you did at Novacept since you left Novacept?

MS. ELSON: Objection. Form.

THE WITNESS: It's – that's a correct assumption.

BY MR. RAJANI:

Q. Let's turn to page 4 of your declaration, paragraph 8. In the last sentence it says:

"I believed at the time (as I still do today) that it is highly undesirable to [80] use more electric current than necessary inside the human body."

Do you see that sentence?

A. Yes, I can see it.

Q. At the time did you have in mind a certain amount of electric current that you considered unsafe in the human body?

MS. ELSON: Objection. Form.

THE WITNESS: There are general guidelines for that, but you want to use as little as is humanly possible.

DEPOSITION REPORTER: "Use" –

THE WITNESS: As little energy as is humanly possible.

BY MR. RAJANI:

Q. Why?

MS. ELSON: Objection. Form.

THE WITNESS: If anything goes wrong, with more energy, you do more damage. So you are trying to minimize the potential damage can cause by, you know, the device.

BY MR. RAJANI:

Q. But did you have in mind any particular threshold of energy that you considered to be unsafe at the time?

[81] MS. ELSON: Objection. Form.

THE WITNESS: Again, the guidance says that, you know, you have to do less than 400 watts per second delivered, so it's a limit, you know, per the FDA, so –

DEPOSITION REPORTER: I need that again. The guidance says that, you know, you have to do per hundred watts per second" –

THE WITNESS: The FDA guidance is 400 watts per second energy delivered or power delivered to the patient. That's a limit set by the FDA. So anything below that is safe. Nevertheless, you want to use as little as is humanly possible. You do less harm in certain cases.

BY MR. RAJANI:

Q. At the time did you have in mind a particular amount of electric current that was necessary to perform ablation?

MS. ELSON: Objection. Form. Vague and ambiguous.

THE WITNESS: Based on the experimentation and product development at Novacept, we came up with the energy requirement to perform the procedure.

DEPOSITION REPORTER: To –

THE WITNESS: Perform the procedure.

[82] BY MR. RAJANI:

Q. Let's stay on page 4 of your declaration, paragraph 8. It's the one that begins, "To summarize."

Do you see that?

A. I'm sorry?

Q. Do you see the paragraph that begins, "To summarize"?

A. Oh, yes.

Q. Okay. In the summary paragraph you're noting that the presence of a moisture layer would – and I'll direct you to iii – "interfere with how the system controlled the depth of ablation."

Do you see that?

A. Yes, I can.

Q. In your view, does the presence of a moisture layer interfere with how the system controls depth of ablation?

MS. ELSON: Objection. Form.

THE WITNESS: The way the NovaSure system, so at the time I meant here very specifically a direct RF device that the electrodes did actively conducting the tissue, yes. So the answer is yes.

///

[83] BY MR. RAJANI:

Q. So the reference to the system –

A. Its a reference to the NovaSure system.

Q. Let's just remind each other not to cut each other off.

A. I'm sorry.

Q. It makes it a lot harder for the reporter.

So the problem regarding depth of ablation occurred because the NovaSure system controlled depth of ablation by monitoring impedence; right?

MS. ELSON: Objection. Form. Vague and ambiguous.

THE WITNESS: Could you repeat that. I mean –

BY MR. RAJANI:

Q. Sure.

A. – you put too many things together there, and –

Q. Sure. I assure you its the fault of the question.

Did the NovaSure system control depth of ablation by monitoring the impedence of the tissue?

MS. ELSON: Objection. Form.

THE WITNESS: It's a partial. We monitor the impedence, but together with the power density [84] and with the moisture transport we control the depth of ablation. If it didn't have moisture transport, it didn't control it.

BY MR. RAJANI:

Q. Are there other ways in which you could monitor or terminate ablation rather than monitoring impedence of the tissue?

MS. ELSON: Objection. Form. Hypothetical.

THE WITNESS: I mean, its been known to the art that people, for example, used temperature sensors in the prior art or other means to see how far the tissue – or just they just used time, depending – dependent on the type of energy delivered. So its very hard to answer just like that.

BY MR. RAJANI:

Q. Was it – strike that.

You mentioned temperature. Is it your understanding that it was possible to terminate the delivery of RF energy when the temperature of the tissue reaches a particular temperature?

MS. ELSON: Objection. Form. Hypothetical.

THE WITNESS: I can't – I want to answer, [85] but I can't because you – it's very vague, so it depends how you doing it.

BY MR. RAJANI:

Q. What would you need to know to determine if you could use temperature to dictate when the delivery of RF energy would stop?

MS. ELSON: Objection. Form. Hypothetical.

THE WITNESS: I mean, it is many different ways, and I – it's been done in the prior art. I mean, they do it in cardiac ablation and other areas. It depends on the very specific procedure and conditions.

So, again, I'm – if you want me to explain how, for example, cardiac ablation works, I can do that; or the way they did liver ablation, I can do that. But, again, it depends, you know, on the particular device. So it's device- and procedure- and condition-dependent.

BY MR. RAJANI:

Q. Did any of the prototypes that you worked on at NovaSure use thermocouple or other temperature sensors to monitor the depth of ablation?

A. Not as I recall. We tried to map, you know, the ablation depth. So, again, your question, [86] it has to be a little bit more specific, you know, in what regard.

Q. Do you recall ever using a temperature sensor or thermocouple to monitor the depth of ablation when you were developing the prototypes at Novacept?

MS. ELSON: Objection. Form.

THE WITNESS: Yes, but we able to only monitor the temperature when we turned the RF off – off, because the RF introduces noise, and you can't measure – you couldn't measure at that time temperature.

BY MR. RAJANI:

Q. So you were trying to measure temperature –

A. But we couldn't in realtime. We couldn't in realtime.

Q. Who did that testing?

MS. ELSON: Objection. Form.

THE WITNESS: I was one of the person who did it. I tried to do that too, but others.

BY MR. RAJANI:

Q. Why were you trying to use temperature – why were you trying to monitor the temperature during the time that RF energy was on?

[87] MS. ELSON: Objection. Form.

THE WITNESS: So during the ablation, could I measure in realtime was the depth of heating –heated zone within the tissue. So I assured that the temperature sensor was inserted into the tissue. It was not on the surface. It was in the tissue in a certain depth.

DEPOSITION REPORTER: I'm sorry. "So during the ablation could I measure in realtime was the depth of heating – heat in zone within the tissues so I assured that the temperature" –

THE WITNESS: So during the ablation, we were not able to measure the temperature below the surface of the tissue, what we try to treat, because of the radio frequency noise is introduced into the radio – into the thermocouple.

BY MR. RAJANI:

Q. Is that when you decided to use the monitor impedence instead?

MS. ELSON: Objection. Form. Mischaracterizes.

THE WITNESS: No. It was a process of development, you know. We tried many things, so . . .

BY MR. RAJANI:

Q. How long would you say that you spent [88] testing the temperature sensor?

MS. ELSON: Objection. Form.

THE WITNESS: I don't remember. It was 20-some – 20 years ago, so . . .

BY MR. RAJANI:

Q. Is it hard to recall something 20 years ago?

MS. ELSON: Objection. Form. Argumentative.

THE WITNESS: You do remember certain things. In some respect, I will not. Precise dates, hours – I mean, I don't think you can expect anyone to remember, you know, how many days, hours, you know, twenty years ago spent on something. We spent time on it.

BY MR. RAJANI:

Q. Let's go to page 12 of your declaration.

Do you see the section heading C in the middle of the page titled The Development of Minerva's Accused Device"?

A. Yes, I can see it.

Q. And is it fair to say that this section of your declaration describes the development of Minerva's EAS? Right?

A. This describes the Minerva PFA, better to [89] say, which is an integral part of the device.

Q. What you mean to say it doesn't describe the entire endometrial ablation system; it more specifically describes the development of Minerva's PFA?

MS. ELSON: Objection. Form.

THE WITNESS: It described the device but more focused on the PFA.

BY MR. RAJANI:

Q. Let's go to page 14 of your declaration, paragraph – actually, let's go to page 15, paragraph 41. You write:

"To summarize, my team and I had to perform numerous experiments during the development phases described above to eventually arrive at the final, working design of Minerva's PFA."

Do you see that?

A. Yes, I can.

Q. So the numerous experiments that you're referring to in this sentence refers to the development of the Minerva PFA; right?

A. Minerva PFA and – yes.

Q. These aren't the experiments that were necessary to create the NovaSure prototypes; right?

[90] MS. ELSON: Objection. Form.

THE WITNESS: Part – part of the NovaSure device. I mean, this is the – the primary – the primary experiments were to develop the plasma formation within the Minerva device.

DEPOSITION REPORTER: "Within the" –

THE WITNESS: Plasma formation.

DEPOSITION REPORTER: "Within the" -

THE WITNESS: Within the – the Minerva PFA. Plasma formation array.

BY MR. RAJANI:

Q. So these were – these were not the primary experiments that were needed to develop the NovaSur device; right?

MS. ELSON: Objection. Form.

THE WITNESS: The – again, the primary experiments, you know, started, way back, you know, when we were looking at the orthopedic device, and,

again, we just realized that, you know, this is something very usable in other fields. So it's a long process. Many things have to be resolved. So if, you know, you be – if you ask more specific, you know, I can tell you what you're looking for.

BY MR. RAJANI:

Q. Yeah. So let's go back to paragraph 41. [91] In the first line you are referring to performing numerous experiments. Do you see that?

A. Uh-huh.

Q. Are those experiments that you're describing related to the development of Minerva's PFA or the Novacept device?

A. This is –

MS. ELSON: Objection. Form.

THE WITNESS: This is Minerva device. Did I say Novacept?

BY MR. RAJANI:

Q. I couldn't quite tell, but you've clarified. Thank you.

So, to be clear, you don't believe that these are the experiments that were necessary to create NovaSure; right?

MS. ELSON: Objection. Form.

THE WITNESS: Just could you repeat it one more time.

BY MR. RAJANI:

Q. Yeah.

A. So these are –

Q. The numerous experiments that you referenced in paragraph 41 –

A. Yes.

[92] Q. – those are not the experiments that you believed were necessary to create the NovaSure prototypes; right?

A. These experiments that perform specifically for the Minerva device.

Q. I see. Let's go to page 23 of your declaration. I'll direct you to paragraph 60.

A. 21?

Q. Page 23, paragraph 60. The second sentence of paragraph 60 reads, "Fully aware that the '183 patent" –

A. I'm sorry. Could I have it one more time.

Q. Second sentence –

A. Uh-huh.

Q. – reads:

"Fully aware that the '183 patent claims the use of a 'pressure sensor' as its solution for monitoring for perforations in the uterus, we at Minerva decided to develop our own solution based on the use of a flow meter."

You see that; right?

A. Yes, I can.

Q. What do you mean when you say "fully aware" in this sentence?

[93] A. Since I was a co-inventor, I was aware of the existence of the NovaSure patent or Novacept at the time in the company.

Q. So the sentence said that, you know, "fully aware of the '183 patent"; the second half, it says, "we at Minerva decided to develop our own solution."

Did Minerva decide to use what you referred to here as a flow meter because the '183 patent recited a pressure sensor?

MS. ELSON: Objection. Form.

THE WITNESS: No. We were aware of the problems using the pressure sensor. There is – there was lots of issues with the pressure sensor, and those issues, you know, created lots of problems in the field – you know, failed treatments, etc., etc., so you know, to use –

DEPOSITION REPORTER: I'm sorry. "Lots of problems in the field."

THE WITNESS: In the field –

DEPOSITION REPORTER: And then –

THE WITNESS: – with physicians where they – its called a failed treatment. They weren't able to treat the patient because the pressure sensor false- – falsely detected a perforation, and there was no perforation.

[94] BY MR. RAJANI:

Q. So Minerva decided to develop its own solution using what you call a "flow meter" because of problems it was seeing in the field?

MS. ELSON: Objection. Form.

THE WITNESS: Because we were aware of the shortcomings of other devices which is using pressure sensor and, you know, our goal was to develop a new technology which is more sensitive and provides the – the user, the physician, a better method detecting perforation.

BY MR. RAJANI:

Q. And so Minerva was fully aware that the '183 patent claimed a pressure sensor; right?

MS. ELSON: Objection. Form.

THE WITNESS: I was aware and my co-workers, yes.

BY MR. RAJANI:

Q. How were your co-workers aware of that?

A. Because I described to them the issues which is in the field at the time, you know, with the – the NovaSure product that, you know, many times they are unable to repair from the ablation because the pressure sensor faultly declares that you have a perforation. And one of the goals and [95] what they set is that we have to come up with a better, more reliable method to detect perforation, which is very important.

Q. Let's turn to page 6 of your declaration, paragraph 12. And the last sentence of paragraph 12 reads, Our refined prototype" –

DEPOSITION REPORTER: I'm sorry. Can you start that again.

BY MR. RAJANI:

Q. "Our refined prototype, on which the disclosures in the MT Provisional and the '072 application were based, used a handle with distal and proximal grips pivotally attached at a pivot point rather than the earlier syringe-like handle."

You wrote this sentence?

A. Yes.

Q. Did you use the phrase "pivotally attached at a pivot point" when you were designing this prototype?

MS. ELSON: Objection. Form.

THE WITNESS: I mean, that was the device we used. Actually, there was lots of issue with that one too because the size of handle we ended up [96] with, it was very uncomfortable for the female users.

MR. RAJANI: I am going to object as nonresponsive.

BY MR. RAJANI:

Q. My question is: Did you use the phrase "pivotally attached at a pivot point" at the time when you were designing the prototype?

MS. ELSON: Objection. Form.

THE WITNESS: At the time when I designed a NovaSure device, I don't know how I called it. But if I describe it now, that's the way I would describe it in technical terms.

BY MR. RAJANI:

Q. Who was designing the handle, the NovaSure handle, at the time?

MS. ELSON: Objection. Form.

THE WITNESS: It's – it was a number of us.

BY MR. RAJANI:

Q. Who?

A. Russ Sampson, myself, Stephanie Squarcia. I mean, there are a number of people who contributed.

Q. Do you see the phrase in the last line that [97] I just read referring to "the earlier syringe-like handle"?

A. Yes.

Q. Is it fair to say that the early NovaSure prototype used a syringe-like handle to open and close the applicator head?

A. No.

Q. So what is this reference to "the earlier syringe-like handle"?

A. We made a conceptual design, which actually was put into the patent too. It's just a potential embodiment, but it never had the force, you know, to open or close the device. So it was a conceptual version which we made actual prototype of, but it was unfunctional. And on that one, that was only me. Nobody else.

Q. And do you consider that – strike that. What do you mean by "conceptual version"? As opposed to what?

A. I used to go and try to raise money to venture capital companies, so, you know, we had to do something, and the easiest version was, you know to modify the existing syringe-type device. So we didn't have the funds to, you know, design very quickly,. mold, et cetera. so it was a svrinae-tvoe

[99] MS. ELSON: Objection. Form.

THE WITNESS: Our invention really which we were going for is the moisture transport. Any handle could do it.

MR. RAJANI: I think we need to change the media, so let's go ahead and take a break.

THE VIDEOGRAPHER: This now marks the end of disc labeled No. 1 of the video deposition of Csaba Truckai. We are now going off the record. The time is 2:57.

(Off the record.)

THE VIDEOGRAPHER: This now marks the beginning of disc labeled No. 2 in the video deposition – deposition of Csaba Truckai. We are now going back on the record, and the time is 3:07.

BY MR. RAJANI:

Q. Mr. Truckai, you understand that you're still under oath?

A. Yes, I do.

Q. When we just broke, we were speaking about some of the early designs involving a syringe-like handle. Do you recall that?

MS. ELSON: Objection. Form.

THE WITNESS: Yes, we talked about that.

MR. RAJANI: Let me mark as Truckai [98] device which we took and we modified. But it was never functional.

Q. So do you consider the earlier syringe-like handle to be part of what you invented?

MS. ELSON: Objection. Form.

THE WITNESS: The handle is less important in the early invention. The early invention, what we had is a moisture transport. It's not talking about – really about the handle. The handle does- – it's not important.

MR. RAJANI: I'm going to object as nonresponsive.

BY MR. RAJANI:

Q. My question is whether you considered the earlier – strike that.

Did you consider the conceptual embodiment with the syringe-like handle to be one of your inventions?

MS. ELSON: Objection. Form. Asked and answered.

THE WITNESS: I mean, we never considered this an invention, the handle.

BY MR. RAJANI:

Q. Okay. You never considered this to be a part of the invention? [100] Exhibit 6 a copy of the '348 patent.

(Exhibit 6 marked for identification.)

BY MR. RAJANI:

Q. You're familiar with this document?

A. I've seen this document.

Q. Are you a named inventor on this patent?

A. My name is on the patent.

Q. Can you turn to the drawings that start about five pages in. The drawing has Figure 1 and Figure 2 side by side. Do you see those?

A. Yes, I can.

Q. What type of handle is depicted in Figures 1 and 2?

A. This drawing is a direct representation of the syringe type of handle.

Q. And was it your testimony that you did try to build this type of handle?

MS. ELSON: Objection. Form.

THE WITNESS: We built it, but it never really performed.

BY MR. RAJANI:

Q. When you say "it never really performed," what do you mean by that?

A. It wasn't really able to perform, you know, in a device. You know, it – you know, it worked as [101] a mockup device at the time. And the handle for us wasn't an important part of the invention. The invention is the moisture transport array, so we weren't really focusing on the handle. It was just a embodiment. It could have been five different types of embodiment.

MR. RAJANI: I'm going to object to the last portion of your response as nonresponsive.

BY MR. RAJANI:

Q. Do you consider this to be – strike that.

Do you consider the mockup that you made with the syringe-like handle to be a prototype of the NovaSure device?

MS. ELSON: Objection. Form.

THE WITNESS: No.

BY MR. RAJANI:

Q. Why not?

A. Because we never built one like this which functioned.

Q. So the only prototypes that you are including are the ones that have which function?

A. Which perform the moisture transport function.

Q. So if there was an earlier prototype you made that didn't perform a particular type of [102] moisture transport, you don't consider that to be a prototype of

the NovaSure device; right? MS. ELSON: Objection. Form.

THE WITNESS: So for you to understand what we had at the time, I mean – repeat, please, one more time your question. I'm trying to answer it.

BY MR. RAJANI:

Q. I'm trying to understand what you're defining as a prototype. And earlier you mentioned that you don't consider the syringe-type handle -¬the mockup that you made with the syringe-type handle to be a prototype of the NovaSure device; is that fair?

MS. ELSON: Objection. Form.

THE WITNESS: No, because we didn't care about the handle. We really didn't focus on the handle at all. We didn't even have a handle. All the prototypes we built, you know, that was little screws and nuts which, you know, moved the array open. That's what we used. We didn't have a handle.

BY MR. RAJANI:

Q. Let's turn to Figure 22 of the '348 patent. Figure 22 depicts a different type of handle; right?

[103] A. Yes.

Q. And, in your view, is this the pivotally attached handle?

A. Yes.

Q. Why?

A. Point –

MS. ELSON: Objection. Form.

THE WITNESS: Sorry. Point 166 is the pivot point.

BY MR. RAJANI:

Q. Does Minerva's handle have a proximal and a distal handle too?

MS. ELSON: Objection. Form.

THE WITNESS: Could you –

MS. ELSON: Vague and ambiguous.

THE WITNESS: Could you define what's proximal and distal?

BY MR. RAJANI:

Q. Do you understand what a proximal and a distal handle are?

MS. ELSON: Objection. Form. Vague and ambiguous.

THE WITNESS: In the Minerva device or in the NovaSure device or –

///

[104] BY MR. RAJANI:

Q. Do you – I'll clarify.

A. I'm sorry.

Q. I'll clarify.

Do you understand what the terms "distal" and "proximal" grips mean?

A. What my understanding is, proximal is closer to me; distal is farther from me. But, you know, since, you know, so many different types of handles out there in the world, you know, I cannot give you more precise information besides – I know the words, but I don't know what you're referring to.

Q. Does Minerva's EAS handpiece have grips?

MS. ELSON: Objection. Form.

THE WITNESS: It has members that you can hold with your hand.

BY MR. RAJANI:

Q. And are there two grips?

MS. ELSON: Same objection.

THE WITNESS: One moving, one stationary.

BY MR. RAJANI:

Q. Which one do you consider to be stationary?

MS. ELSON: Objection. Form.

THE WITNESS: The one which, you know,

* * *

[129] describing very well, you know, how our UIT systems work, so I think this has important relevant information about it.

BY MR. RAJANI:

Q. Can you go to the page that ends in the Bates number 5310.

A. Which one? I'm sorry. What number?

Q. 531, the last three digits.

Do you see a comment in the margin?

A. "This need to be modified for real system simplified diagram."

Q. Did you author that comment?

A. I'm not sure.

Q. Do you know who did?

A. I'm not sure.

Q. Who first provided a copy of Exhibit 7 to you?

MS. ELSON: Object- – I'm going to instruct not to answer. Privileged.

BY MR. RAJANI:

Q. Who first – strike that.

Do you specifically recall receiving this document in 2009?

A. No, yes. But if you asked me, you know, a couple of years ago, I wouldn't be able to [130] remember, so...

Q. I'm not sure I understood your answer. Let me ask it again.

Do you specifically recall receiving this document in 2009?

MS. ELSON: Objection. Form.

THE WITNESS: I remember that – I remember that I received it, but I didn't remember precisely the time until I looked.

BY MR. RAJANI:

Q. Do you specifically recall discussing this document with anyone in 2009?

MS. ELSON: Assuming you can answer that without revealing attorney-client communications, you can answer that question.

THE WITNESS: Mr. Akos Toth.

BY MR. RAJANI:

Q. And you specifically remember discussing this document with Mr. Toth in 2009?

A. No, I don't remember.

Q. How do you remember you discussed it with him, then?

A. Because anything got to do with the UIT, it's – it was his invention, you know, his work platform, and he, you know, did actly [verbatim].

[131] DEPOSITION REPORTER: It was his what platform?

THE WITNESS: His invention.

DEPOSITION REPORTER: "His" –

THE WITNESS: That was his work.

BY MR. RAJANI:

Q. So you don't remember specifically discussing this document with Mr. Toth; right?

A. This document, it was discussed at the time with multiple people, so I'm pretty sure it was more than just Akos Toth. The entire R&D team, you know, reviewed this. This is – this is a document not for one person. But for fact, since he was there, the primary inventor on the UIT, you know – for fact I can tell you that he was involved with it.

He generated, you know, the diagram in this exhibit.

MR. RAJANI: I'm going to mark as Truckai Exhibit 8 a document –

MS. ELSON: 8 or 9?

MR. RAJANI: 8. Did I – I think it's 8. The last one was 7.

MS. ELSON: Oh, okay.

MR. RAJANI: It's a document labeled MSI0029738 through 297551.

(Exhibit 8 marked for identification.)

[132] BY MR. RAJANI:

Q. Are you the author of Exhibit 8?

MS. ELSON: Objection. Form.

THE WITNESS: Nope.

BY MR. RAJANI:

Q. Was Exhibit 8 produced from your files?

MS. ELSON: Objection. Form.

And if the answer would reveal any attorney-client privilege, I instruct you not to answer.

THE WITNESS: I can't answer. I will take my counsel advice on that.

BY MR. RAJANI:

Q. You're telling me that whether this came from your files is privileged?

MS. ELSON: That wasn't the question.

BY MR. RAJANI:

Q. Was Exhibit 8 produced from your files?

MS. ELSON: To the extent you are asking about production that involves attorney involvement, I instruct him not to answer.

THE WITNESS: So on that level I am taking my counsel advice.

MR. RAJANI: And your understanding is that if this document, Counsel, was produced from his [133] files, because it was in a production, it's all of a sudden privileged, whether or not it came from his files?

MS. ELSON: I'm not going to argue with you, Counsel.

MR. RAJANI: I'm not trying to argue. I'm trying to find the basis of these objections, which are so off-base, but . . .

MS. ELSON: That's your view.

BY MR. RAJANI:

Q. Who authored Exhibit 8?

A. As you can see, the first author, X1, it's Akos Toth. It says, "Initial Release." Then you can see the – the revisions, so you can see the first revision was Akos Toth, and then X4 is Ron Hundertmark.

Q. You are reading from the first page of this exhibit; right?

A. That's right. It says, "Change Record."

Q. And those names are under the column "Responsible Person"; right?

A. That's correct.

Q. Are you assuming the person that's responsible is also the author of the document? A. Because of the quality system that's [134] required. That's the fact.

DEPOSITION REPORTER: Because of the what system?

THE WITNESS: The quality system. The person who responsible for the revision is the author of the document.

BY MR. RAJANI:

Q. Do you recall – prior to your preparing for this declaration, did you have an independent memory of this particular document?

MS. ELSON: Objection. Form.

THE WITNESS: I can tell you every single document was sent to me, so, yes, product specification is a very important document. And as you can see, there are multiple revisions, so it's not just one document. This is the fourth revision of that document.

MR. RAJANI: I'm going to object as nonresponsive.

BY MR. RAJANI:

Q. Let me try and phrase it a different way.

Before you started preparing the declaration as Exhibit 1, did you have an independent memory of this particular document that's marked as Exhibit 8?

MS. ELSON: Objection. Form. Asked and [135] answered.

THE WITNESS: Again, the only thing I can tell you, that every single document which was product – was product-specification-related was -¬ended up at me. And this is the fourth edition, and I'm pretty sure there are other editions, you know, on that, so...

BY MR. RAJANI:

Q. Did you see any of the other editions when you were looking through your email to prepare for your declaration?

MS. ELSON: Objection. Form.

THE WITNESS: I have to look again to be sure.

BY MR. RAJANI:

Q. Do you recall when you were looking through it whether you saw any other versions, just sitting here today?

MS. ELSON: Same objection.

THE WITNESS: I have to look and confirm. There are a number of editions. So, you know, you asking me which edition you talking about it, is very difficult for me to say if, you know, X1, X- -¬yeah, as you can see.

///

[136] BY MR. RAJAN I :

Q. Do you recall seeing multiple versions of this document when you were looking through your emails to prepare for this declaration?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. Can you go to the page ending in 547 in this document. Do you know who authored the redlines on that page?

A. This – this entire document, it was altered by Ron Hundertmark.

Q. Do – is it your understanding that Mr. Hundertmark is the one who drafted the redlines, made the changes that are reflected?

A. So the way you have to read this document, it says at the bottom here its X4. Then you can see here – on the revision X4 you can see it was done by Ron Hundertmark, and then you can see the changes, which is described: various, format, clarity, edit, additional –

DEPOSITION REPORTER: "Which is described" –

THE WITNESS: Which are described under the "Description of Change." It's on the front page.

* * *

[173] DEPOSITION REPORTER: Oh.

BY MR. RAJANI:

Q. So in paragraph 29 you say:

"A relatively small amount of RF current (as compared to the NovaSure) flows between the single internal electrode and the second external 'return' electrode on the exterior of the PFA."

Do you – do you believe that statement is accurate?

A. It is accurate.

Q. Okay. Is that the only direction in which the RF current can flow in the Minerva EAS?

A. No.

Q. And I can be a little bit more specific.

Is there any RF energy being sent in the other direction from the external electrode through – to the internal electrode?

A. This is radio frequency. Just, you know, the polarities changing all the time.

Q. Is that a function of it being an alternating current?

A. It's a function of an alternating current.

Q. So the internal electrode could also serve as the return electrode?

[174] MS. ELSON: Objection. Form.

THE WITNESS: I mean, you can use terms, but we are talking about two electrodes, period. One is on the outside, and one is on the inside, the polarity of the electrodes alternating.

BY MR. RAJANI:

Q. And are you aware that the parties in this case are disputing what the term "pressure sensor" means?

MS. ELSON: Objection. Form.

Let me instruct – if you can exclude any –

MR. RAJANI: I can – let me withdraw the question.

MS. ELSON: Okay.

BY MR. RAJANI:

Q. I'm just asking for a "yes" or no as to whether you are aware that the parties have proposed competing constructions of what the term "pressure sensor" means.

MS. ELSON: And objection. Form. Legal conclusion.

You can answer that question, but just I caution you not to reveal the substance of any attorney-client communication.

[175] THE WITNESS: I don't know precisely what the argument – the legal argument is.

BY MR. RAJANI:

Q. Let's go to paragraph 57 of your declaration. The last sentence of paragraph 57 reads:

"In 1999, I personally understood a pressure sensor to be a device that directly detects a force per unit area at its input."

What do you mean by "directly detects a force per unit"?

MS. ELSON: I'm sorry.

MR. RAJANI: Last sentence of paragraph 57.

MS. ELSON: I apologize. Go ahead.

BY MR. RAJANI:

Q. What do you mean in that sentence by "directly detects a force per unit area"?

A. It means that the pressure you apply to the pressure sensor measure the pressure.

Q. That's what you mean by "directly detects a force"?

A. Yes.

Q. How do you recall what you personally understood a pressure sensor to be in 1999?

[176] A. How do – I'm sorry.

Q. How did you – how did you remember what you personally understood a pressure sensor to mean in 1999?

A. Before 1999 – after '99 I used pressure sensor for many applications. I know what's pressure and sensor is. It's very common in the medical US industry to measure pressure.

Q. Let's go to paragraph 55 of your declaration. The last sentence reads:

"That device was only a pressure sensor consistent with my understanding of a pressure sensor (. . . a device that detects a force per unit area at its input and outputs a corresponding value)."

Is this consistent with your understanding of what a pressure sensor was in 1999?

MS. ELSON: Objection. Form.

THE WITNESS: That's correct. And that's what I referred before to.

BY MR. RAJANI:

Q. This reference in paragraph 55 doesn't refer to directly detecting a force per unit area, does it?

A. No, but its stating that its a device

* * *

[201] I, JANIS JENNINGS, CSR No. 3942, Certified Shorthand Reporter, certify:

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was duly sworn by me;

That the testimony of the witness, the questions propounded, and all objections and statements made at the time of the examination were recorded stenographically by me and were thereafter transcribed;

That the foregoing pages contain a full, true and accurate record of all proceedings and testimony.

Pursuant to F.R.C.P. 30(e) (2) before completion of the proceedings, review of the transcript [ ] was [X] was not requested.

I further certify that I am not a relative or employee of any attorney of the parties, nor financially interested in the action.

I declare under penalty of perjury under the laws of California that the foregoing is true and correct.

Dated this 2nd day of November 2017.

/s/ Janis Jennings
JANIS JENNINGS, CSR NO. 3942
CLR, CCRR

[202] DEPOSITION ERRATA SHEET

Esquire Litigation Services Assignment No. J0670065
Case Caption: HOLOGIC, INC., et al., vs. MINERVA SURGICAL, INC.

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

Signed on the __ day of _____, 20__.

_____

CSABA TRUCKAI

[202] DEPOSITION ERRATA SHEET

Esquire Litigation Services Assignment No. J0670065
Case Caption: HOLOGIC, INC., et al., vs. MINERVA SURGICAL, INC.

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

Signed on the 07 day of November, 2017.

/s/ Csaba Truckai
CSABA TRUCKAI

[203] DEPOSITION ERRATA SHEET

Page No. 114 Line No. 23 Change to: specifically talk about the flow control section

Reason for change: correct sentence

Page No. __ Line No. __ Change to: _____

Reason for change:

Page No. __ Line No. __ Change to: _____

Reason for change:

Page No. __ Line No. __ Change to: _____

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Reason for change:

Page No. __ Line No. __ Change to: _____

Reason for change:

SIGNATURE: _____ DATE: _____

Csaba Truckai

From: Michael Regan
Sent: Sunday, January 30, 2011 3:52 PM
To: Anderson, Ted L
Cc: Mary Edwards; Csaba Truckai; Eugene Skalnyi
Subject: RE: cMinerva Case Update to MAB

Hi Dr Anderson:

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 2-4 week post treatment hysterectomy. Discussions to date with FDA indicate that we won't he required to do "delayed hysterectomy' cases. 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.

I appreciate your insights and the review of our clinical protocol which you provided in a separate email.

Take Care Mike

From: Anderson, Ted L [mailto:ted.anderson@Vanderbilt.Edu]
Sent: Thursday, January 27, 2011 7:55 AM
To: Michael Regan
Subject: RE: Minerva Case Update to MAB

looks good.

How long after treatment is the hysterectomy done?

Have you looked at hysterectomy about 2-4 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.

I have one sort of global question. I envision major "patent infringement" disputes for this device vs Novasure. How is this being dealt with or how do you plan you will be able to deal with it?

Ted L. Anderson, MD, PhD, FACOG, FACS
Director, Division of Gynecology and Gynecologic Surgery
Department of Obstetrics and Gynecology
Vanderbilt University Medical Center
Nashville, TN 37232
tel: 615-343-6710
fax: 615-343-8881
ted.anderson@vanderbi lt.edu

From: Michael Regan [michaelr@minervasurgical.com]
Sent: Wednesday, January 26, 2011 7:01 PM
To: Andrew Brill; Anderson, Ted L; Donald Galen MD (drgalen@drgalen.com); Adolf Gallinat; Amy Garcia; Richard Gimpelson MD (epabernathy@hotmail.com)
Cc: Csaba Truckai; Mary Edwards; Carol Anne Yarbrough; Dominique Filloux
Subject: Minerva Case Update to MAB

Dear Drs. Brill, Anderson, Galen, Galinat, Garcia, and Gimpleson

We just want to update you on our latest series of peri-hysterectomy cases last week. We are happy to report that we completed 4 additional cases in Hungary at two sites. This brings the cumulative peri-hysterectomy experience to 7 cases. We hope to have the formal pathology report within the next two weeks. In the meantime, the attached files and gross pathology observations noted below give an indication of the results. We were fortunate to have Dr Gallinat proctor these cases which helped tremendously with the new user learning curve.

Procedural observations and potential future improvements:

-perforation detection system works well if we can keep the blood out of the tubing (we need to install a small blood capturing container)

-we are investigating methods to minimize tip profile during insertion through the cervix

-auto inflation in device vs in controller may be preferred because device can be removed multiple times in a procedure

-length setup is cumbersome to know where the device is set (investigating a number in “window” to make reading the number easier)

-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

-we are looking into software to prompt the user to reposition device if power is below 40W within the first 1-20 seconds of the ablation

Pathology Pictures and gross measurements:

D103

- Highest serosal temp was 36.72 (range 33.98 – 36.72)
- AnteriorTC came loose and did not record temp appropriately
- Closest distance of thermal injury to serosa at right cornu 15.5mm
- Depth of thermal injury (all maximum measurements)
    1. Right cornu anterior – 4.9mm
    2. Right cornu posterior – 4.5mm
    3. Lt cornu anterior – 4.9mm
    4. Lt cornu posterior – 4.3mm
    5. Fundus – 5.0mm
    6. Anterior Right Corpus – 5.0mm
    7. Anterior Left Corpus – 4.3mm
    8. Posterior Right Corpus – 4.1mm
    9. Posterior Left Corpus – 3.8mm

10. Anterior LUS – 4.2mm
11. Posterior LUS – 3.6mm
12. Right Corpus sidewall – 4.1mm
13. Left Corpus side wall – 3.9mnn

From: Dave Clapper
Sent: Tuesday, November 10, 2015 6:10 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Thanks. And by the way, Hologic filed a Complaint for Patent Infringement (lawsuit) on Friday at 5 pm. I can give you the details later. We anticipated something along these lines, and have been working on a response with an IP litigation group for the last 6 months. Our response is "In the can" so to speak. More later.

Dave Clapper
President and CEO
Minerva Surgical

From: <Glaser>, Erik Glaser <erik.glaser@smith-nephew.com>
Date: Tuesday, November 10, 2015 5:09 PM
To: Dave Clapper <daveclapper@minervasurgical.com>
Subject: RE: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Ahh ..yes . . . that's our code word . . . access code 3160290 . . . 1.888.858.6043

From: Dave Clapper [mailto:daveclapper@minervasurgical.com]
Sent: Tuesday, November 10, 2015 8:07 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Thank you. Two quick things: Is Athena interchangeable with Minerva. Two, can you provide a dial-in #\pass code for the call? Couple of our people will be calling in remotely.

Dave

Sent from my iPhone

On Nov 10, 2015, at 3:15 PM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

Dave . . . wanted to send along some questions to help guide tomorrow's call

- ? Why is there a contraindication of hysteroscopic myomectomy prior to the Minerva procedure?
- ? Why are there variations in QOL results between Athena Single Arm and Pivotal studies?
- ? We've reviewed AEs across both Minerva and NovaSure . . . why are there difference in AE data? Let's review the nature and classification of the AEs

These will naturally lead into other discussion points but wanted to give you preliminary view of what the team is thinking

Look forward to the call Erik

From: Dave Clapper [mailto:daveclapper®minervasurgical.com]
Sent: Wednesday, November 04, 2015 4:10 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Ok. I think we have this worked out. Eugene moved his flight back to 5 pm eastern, which should give us plenty of time. How does that sound?

Dave Clapper
President and CEO
Minerva Surgical

From: <Glaser>, Erik Glaser <erik.glaser@smith-nephew.com>
Date: Wednesday, November 4, 2015 9:49 AM
To: Dave Clapper <daveclapper@minervasurgical.com>
Subject: RE: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

I am thinking that we should move the call from next week for the convenience of everyone . . . our CMO is completely out of pocket until 2 pm et and several people are out next Friday.

So maybe at AAGL? I know Mira will have a suite that should hold up to 8 . . . I think she'll be there with 3 of her team . . . sounds like up to 3-4 from the Minerva team? Or we wait until after AAGL

From: Dave Clapper [mailto:daveclapperminervasurgical.com]
Sent: Wednesday, November 04, 2015 12:45 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Any amount of time we can move the meeting up, even 15 minutes will be valuable.

Sent from my iPhone

On Nov 4, 2015, at 8:32 AM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

Dave . . . trying to figure out a way to make this work on the 11t" . . . our CMO can't make 12 pm et (he's one of the folks in Europe)

If we stick with 2 pm et on the 11th . . . and get Dr. Skalnyi for-30 minutes . . . will he be in transit to the airport? In other words, probably not the best environment for a call?

From: Dave Clapper [mailto:daveclapper@minervasurgical.com]
Sent: Tuesday, November 03, 2015 9:38 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

It will work, however Dr Skalnyi has a flight at 2:38, so well only have him for 25 minutes or so.

Sent from my iPhone

On Nov 3, 2015, at 7:13 PM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

Appreciate the follow up. . .any way to push the 2 pm et slot? I know there's a lot to line up. . .I should be able to get everyone at 2

Sent from my iPhone

On Nov 3, 2015, at 7:35 PM, Dave Clapper <daveclapper@minervasurgical.com> wrote:

Just heard back from the entire Minerva team. Noon eastern time will allow all of us to be on the call for at least an hour. Would this work?

Sent from my iPhone

On Nov 3, 2015, at 1:01 PM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

Thanks Dave . . . let's tentatively book 2 pm eastern time on the 11th . . . I'm still checking calendars here . . . some folks are in Europe and want to make sure the time zones are accurate!

From: Dave Clapper [mailto:daveclapperminervasurgical.co m]
Sent: Tuesday, November 03, 2015 1:59 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Hi Erik. I'm catching a flight from DC back to the west coast today.

2pm Eastern on the 11th works.

I'll double check on the AE lists tomorrow when I'm back in the office. I'm 99% sure that we eliminated Attachment 1. All of the AE's are listed in the charts or narrative that you have in the report. Virtually all

AE's following Ablations occur within the first 30 days and most in the first 24 hours. I'll recheck tomorrow.

Depending on your list of questions, I'm anticipating that I will be on the call, plus VP Med Affairs - Eugene Skalnyi MD, CRO - Jan McComb PhD, and possibly VP's of Ops and RD.

We don't have a rep in Boston yet, so I'm not planning a visit there anytime soon.

Dave

Sent from my iPhone

On Nov 3, 2015, at 10:19 AM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

Thanks Dave . . . please see below

- ? I'm looking into the 11th for potential times for management call . . . would 2 pm et work for you/your team? I'm still confirming internal schedules but should know shortly . . . also wanted to confirm who from your team would participate . . . assume CMO and head of clinical to participate? Anyone else (you of course)
- ? Unfortunately, I won't be at AAGL due to travel conflicts
- ? Wanted to get back to you on your funding proposal . . . it sounds potentially intriguing but obviously the devil is in the details . . . want to try and catch up on that after AAGL? Are you potentially in Boston in the near future? Would be great to discuss F2F

Lastly, a couple follow on questions regarding the 1 yr. pivotal report

? Bottom of page 22 and top of page 23 . . . there is a reference to an Attachment 1 (containing listing of AEs) . . . we can't seem to find the attachment 1 . . . did we miss it?

? Reference table VII.B.2. . . it shows post-op AEs @ 4 weeks . . . do you also have AEs at 1 year? Did we perhaps miss the 1 year AE data?

-----Original Message----

From: Dave Clapper [mailto:daveclapper@minervasurgical.com]
Sent: Monday, November 02, 2015 4:54 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" ¬Minerva Pivotal Study One Year Report

The 11th would be best. We could meet at AAGL. Will you be attending anyway? We have several other meetings at AAGL which is par for the course, so I'm not concerned about that. Let me know if anytime in the 11th could possible work. If not, possibly early on the 13th, like 10 am eastern might work.

Sent from my iPhone

> On Nov 2, 2015, at 3:46 PM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

>

>OK . . . let me see about schedules . . . would it make sense to connect at

AAGL? Would need to find a suitable location that would not raise eye brows.

>-----Original Message------

>From: Dave Clapper [mailto:daveclapper@minervasurgical.com]

>Sent: Monday, November 02, 2015 2:17 PM
>To: Glaser, Erik
>Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

> Hi Erik. The 12 or 13th wont work. And AAGL is the next week, 16, 17, & 18. Yikes!! Any chance of making something work on the 11th??

> Sent from my iPhone

>>On Nov 2, 2015, at 1:31 PM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

>>

>>Dave,

>>

>>Waned to follow up regarding management call. Unfortunately, due to some travel conflicts, I can't get our team together until next week . . . so could you suggest some convenient dates/times for late next week (12th or 13th) and into the week of the 16th for a management call with your team?

>>

>>I figure an hour should be good? We'll prepare a list of questions to send to you beforehand in preparation to run the call efficiently.

>>

>>Many thanks for your help.

>>Best,

>>

>>Erik

>>

>>-----Original Message-----

>>From: Dave Clapper
[mailto:daveclapper@minervasurgical.com]
>>Sent: Wednesday, October 28, 2015 9:40 PM
>>To: Glaser, Erik
>>Subject: Confidential “DRAFT” - Minerva Pivotal Study One Year Report

>>

>>Erik, attached please find a Confidential “DRAFT” copy of the Minerva Pivotal Study One Year Report. I wanted to get this over to your team for review, while we are still triple checking the data, running statistical significance analysis, and proof reading - proof reading - proof reading! There will very likely be some minor changes and additions to this report before we send it into the FDA. Happy reading, and I hope your team likes the data as much as we do!!

>>Let me know if you have any questions.

>>Dave

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.

EXHIBIT 1
JOINT STATEMENT OF UNCONTESTED FACTS

I. PARTIES

1. Plaintiff Hologic, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752.

2. Plaintiff Cytyc Surgical Products, LLC ("Cytyc") (together with Hologic, Inc., "Hologic") is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Cytyc is a wholly-owned subsidiary of Hologic, Inc.

3. Defendant Minerva Surgical, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 101 Saginaw Drive, Redwood City, CA, 94063.

II. PATENTS-IN-SUIT

A. U.S. Patent No. 6,872,183 ("the '183 Patent")

4. The '183 Patent is entitled "System and Method for Detecting Perforations in a Body Cavity."

5. The '183 Patent was issued by the United States Patent and Trademark Office ("USPTO") on March 29, 2005.

6. The '183 Patent expires on November 10, 2020.

7. The '183 Patent claims priority to Provisional Application No. 60/164,482, filed November 10, 1999 (i.e., the '183 Priority Date). Original Utility Application No. 09/710,102, filed November 10, 2000, issued as U.S. Patent No. 6,554,780 ("the '780 Patent"). Application No. 10/400,823, filed March 27, 2003, was a continuation of Application No. 09/710,102, and issued as U.S. Patent No. 6,743,184 ("the '184 Patent"). Application No. 10/852,684, filed May 24, 2004, was a continuation of Application No. 10/400,823, and issued as U.S. Patent No. 6,872,183 ("the '183 Patent"). The '780, '184, and '183 Patents all share a common specification. Only the claims of each are different.

8. Russel M. Sampson, Mike O'Hara, Csaba Truckai, and Dean T. Miller are the named inventors of the '183 Patent.

9. Hologic, Inc. is the owner by assignment of the '183 Patent.

10. Hologic, Inc. acquired the '183 Patent from Cytyc on January 15, 2016.

11. Csaba Truckai assigned his interest in the '183 Patent to Novacept, Inc. on February 9, 2001.

12. In February 2001, Csaba Truckai assigned his interest in U.S. Application No. 09/710,102, an application to which the '183 Patent claims priority, to Novacept, Inc.

B. U.S. Patent No. 9,095,348 ("the '348 Patent")

13. The '348 Patent is entitled "Moisture Transportation System for Contact Electrocoagulation."

14. The '348 Patent was issued by the USPTO on August 4, 2015.

15. The '348 Patent expires on November 19, 2018.

16. The '348 Patent claims priority to Provisional Application No. 60/084,791, filed May 8, 1998 (i.e., the '348 Priority Date). Original Utility Application No. 09/103,072, filed June 23, 1998, issued as U.S. Patent No. 6,813,520 ("the '520 Patent"). Application No. 10/959,771, filed October 6, 2004 was a divisional of Application No. 09/103,072, and issued as U.S. Patent No. 7,604,633 ("the '633 Patent"). Application No. 12/581,506, filed October 19, 2009, was a continuation of Application No. 10/959,771, and issued as U.S. Patent No. 8,506,563 ("the '563 Patent"). Application No. 13/962,178, filed August 8, 2013, was a continuation of Application No. 12/581,506, and issued as U.S. Patent No. 9,095,348 ("the '348 Patent"). The '520, '633, '563, and '348 Patents all share a common specification. Only the claims of each are different.

17. Cytyc listed Csaba Truckai, Russel Mahlon Sampson, Stephanie Squarcia, Alfonso Lawrence Ramirez, and Estela Hilario as named inventors on the face of the '348 Patent.

18. Hologic, Inc. is the owner by assignment of the '348 Patent.

19. Hologic, Inc. acquired the '348 Patent from Cytyc on January 15, 2016.

20. Csaba Truckai assigned his interest in the '348 Patent to Novacept, Inc. on August 5, 1998.

21. In August 1998, Csaba Truckai assigned his interest in U.S. Application No. 09/103,072, an application to which the '348 Patent claims priority, to Novacept, Inc.

22. Certain persons at Minerva had knowledge of the '348 Patent prior to the filing of the original Complaint.

III. THE NOVASURE SYSTEM

23. Menorrhagia, also known as Abnormal Uterine Bleeding or AUB, is menstrual bleeding that is abnormally heavy in amount and/or duration.

24. Endometrial ablation is a transcervical surgical technique in which the lining of the uterus is destroyed with the goal of preventing further bleeding.

25. Mr. Truckai and others at Novacept, Inc. developed the NovaSure system.

26. In 1993, Csaba Truckai co-founded Novacept, Inc.

27. Novacept, Inc. received FDA premarket approval for commercial distribution of the NovaSure system on September 28, 2001.

28. Novacept, Inc. assigned to Cytyc Corp. its patent rights including continuation applications.

29. Hologic markets and sells the NovaSure system throughout the United States and in interstate commerce.

IV. MINERVA AND THE MINERVA ENDOMETRIAL ABLATION SYSTEM ("MINERVA EAS")

30. Both the Minerva EAS and the NovaSure system are indicated for use on premenopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.

31. The Array Opening Indicator of the Minerva EAS contains a Black Indicator Line that can move relative to rows of black dots depending on the degree of expansion of the Plasma Formation Array.

32. Csaba Truckai was involved in the development of the Minerva EAS.

33. Csaba Truckai is a founder of Minerva.

34. Minerva was founded in 2008.

35. Minerva received FDA premarket approval for commercial distribution of the Minerva EAS on July 27, 2015.

36. Minerva began commercial distribution of the Minerva EAS in August 2015.

37. Minerva markets and sells the Minerva EAS throughout the United States and in interstate commerce.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

1:15CV1031

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

v.

MINERVA SURGICAL, INC.,
Defendant.

ORDER

In conformity with the Memorandum Opinion issued this date,

IT IS ORDERED:

1. The parties' motions for oral argument (D.I. 354 and D.I. 359) are denied.

2. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion to strike argumentative exhibits (D.I. 346) is denied.

3. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion to bifurcate (D.I. 374) is denied.

4. The parties' motions to preclude or strike expert testimony (D.I. 279, 290, and 317) are denied.

5. Defendant Minerva Surgical, Inc.'s motion to dismiss (D.I. 275) is denied.

6. Defendant Minerva Surgical Inc.'s motion for partial summary judgment (D.I. 277) is denied.

7. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion for a summary judgment of no invalidity (D.I. 287) is granted.

8. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion for a summary judgment of infringement (D.I. 288) is granted.

9. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion for summary judgment with respect to assignor estoppel (D.I. 289) is granted.

10. The action will proceed to trial for a determination of damages and willfulness in connection with the patent claim and for a determination of the parties' state-law claims and counterclaims.

DATED this 28th day of June, 2018.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

1:15CV1031

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

v.

MINERVA SURGICAL, INC.,
Defendant.

VERDICT

We, the jury, find by a preponderance of evidence, as follows:

I. PATENT DAMAGES

- As instructing in Instructions Nos. 13 to 22, we find Hologic is entitled damages for: (answer YES to only one)
  - ○ _X_ Lost profits (Answer question I.a)

    OR
  - ○ ___ Only a Reasonable Royalty (Answer question I.b)

I.a If you find that Hologic is entitled to lost profits answer the following:

- ○ For lost profits of $4,200,529.75 and,
- ○ For royalties for sales not included in lost profits $587,138.48, a royalty of 8 %

I.b If you find that Hologic is entitled to only a Reasonable Royalty:

- For a reasonable royalty $_____, a royalty of __%.

II. WILLFUL INFRINGEMENT

- As instructed in Instruction No. 23, we find Minerva's infringement of the '348 patent was

  ___ Willful

  _X_ Not willful

III. MINERVA'S COUNTERCLAIMS

A. Breach of Contract

- On Minerva's claim for breach of contract, as instructed in Instruction No. 35, we find in favor of

  ___ Minerva or _X_ Hologic

B. Lanham Act

- On Minerva's claim of false advertising under the Lanham Act, as instructed in Instruction No. 33, we find in favor of

  ___ Minerva or _X_ Hologic

If you found in favor of Hologic your deliberations are at an end.

If you found in favor of Minerva, answer the following:

- What is the amount of money required to compensate Minerva for any actual injury?

  $_____

- What is the amount of additional profits Hologic gained as a result of the false advertising?

  $_____

- Was Hologic's conduct willful?

  ____ Yes

  ____ No

Your deliberations are at an end. Please have your foreperson sign and date this form .

DATED this 27 day of July, 2018.

[redacted]
FOREPERSON

JURORS:

[redacted]

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