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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

KARL STORZ ENDOSCOPY AMERICA, INC.,

Plaintiff,

v.

FEMSUITE, LLC,

Defendant.

Case No.: C:08-cv-03210 VRW

NOTICE OF MOTION, MOTION AND MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED OR, IN THE ALTERNATIVE, TO STAY PROCEEDINGS

Hearing Date: December 11, 2008
Hearing Time: 2:30 p.m.
Courtroom 6, 17th Floor

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on _____, 2008, or as soon thereafter as the matter may be heard, in the courtroom of the Honorable Vaughn G. Walker, United States District Judge, United States District Court, 450 Golden Gate Avenue, San Francisco, California 94102, defendant, FemSuite, LLC ("FemSuite"), by and through its undersigned counsel, will and hereby does move this Court for an Order dismissing this action without leave to amend pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted or, in the alternative, for an order staying this proceeding until FemSuite has obtained clearance from the Food and Drug Administration ("FDA") to sell its FemEye Two medical device in the United States. This motion is based upon this Notice of Motion and Motion, FemSuite's Memorandum of Points and Authorities below, all affidavits and exhibits submitted herewith and any and all other matters presented to the Court.

STATEMENT OF RELIEF THE MOVANT SEEKS

FemSuite brings this motion on the ground that the Complaint fails to identify any activities that may render FemSuite liable for patent infringement under 35 U.S.C. § 271. The allegations in the Complaint, even if taken as true, therefore do not state a claim upon which relief can be granted. Accordingly, FemSuite respectfully requests dismissal. FemSuite's accused FemEye Two device qualifies as a Class II medical device under Section 515 of the Food, Drug and Cosmetic Act ("FDCA") and must be cleared by the FDA prior to being commercially marketed and sold in the United States. FemSuite has not applied for, let alone received, such clearance. As a result, FemSuite has not offered for sale or sold the FemEye Two in the United States. Moreover, FemSuite's activities

with respect to the FemEye Two are protected from plaintiff's claims of patent infringement by the "Safe Harbor" provision of the patent statute, 35 U.S.C. § 271(e)(1). Hence, at a minimum, the case should, in the alternative, be stayed until the FDA has cleared the FemEye Two for sale in the United States.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

On July 3, 2008, plaintiff Karl Storz Endoscopy-America, Inc. ("KSEA") filed its complaint herein against San Francisco-based FemSuite, LLC ("FemSuite") alleging past, present and future infringement by FemSuite of U.S. Patent No. 5,166,787 ("the '787 patent"). *See* Declaration of Dean G. Bostock ("Bostock Decl.") submitted herewith, attaching the Complaint as Exhibit A, ¶¶ 8-14. The '787 patent relates to an endoscope with a video device for imaging and recording object fields within the human body. *See id.* Ex. B.[1] The patent expires in less than two years, on June 28, 2010.

The Complaint alleges "upon information and belief" that FemSuite: (i) "has offered to sell and continues to offer to sell the FemEye Two medical device via one or more Internet websites"; (ii) "has offered to sell, and continues to offer to sell, the FemEye Two medical device at industry trade shows in the United States"; and (iii) "is actively preparing to sell medical devices that would infringe the '787 patent". *Id.* at ¶¶ 9-13. KSEA prays for judgment that FemSuite has infringed the '787 patent and a "declaratory judgment that FemSuite's sales of medical devices … would infringe the `787 patent." *Id.* at p. 4.

All of FemSuite's alleged past and present activities which form the basis for KSEA's patent infringement claim are exempt from liability pursuant to the "Safe

[1] A copy of the '787 patent was attached as an exhibit to the Complaint but is submitted herewith as a separate exhibit for ease of reference.

Harbor" provision of 35 U.S.C. § 271(e)(1), as interpreted by the Supreme Court and the Federal Circuit. Indeed, Section 271(e)(1)'s "exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA." *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (emphasis in original). Moreover, KSEA's claim for patent infringement based on what FemSuite plans to do with the FemEye Two hysteroscope ("FemEye Two") in the future is premature. The FemEye Two has not been approved by the FDA, may never be approved by the FDA, and if approved, may be approved in a configuration yet to be determined. Thus, none of the allegations set forth in KSEA's complaint are ripe for any relief and should not be adjudicated by this Court. Accordingly, defendant moves for dismissal or, in the alternative, a stay of this case until the FemEye Two may be cleared for sale in the United States.

II. STATEMENT OF THE ISSUE

The issue presented is whether KSEA has stated a claim upon which relief can be granted when all of the alleged infringing activities which serve as the basis of KSEA's claim are statutorily exempt from liability?

III. STATEMENT OF RELEVANT FACTS

The accused FemEye Two device is a disposable hysteroscope containing channels for the entry and egress of fluids, as well as the insertion of certain instrumentation. *See* Bostock Decl., Ex. C. KSEA attached this document as Exhibit B to the complaint and alleges that this page indicates that FemSuite has offered the FemEye Two device for sale. *See* Bostock Decl., Ex. A, ¶ 9. KSEA neglects, however, to submit the page of FemSuite's website stating that the FemEye Two device is "currently under development" or the page of the website stating that the FemEye Two device is "[i]n the pipeline". *See* Bostock Decl., Ex. D. As explained below, FemSuite has not

commercially sold or offered for sale the FemEye Two. The complaint does not allege that FemSuite has received Food & Drug Administration ("FDA") approval to sell the FemEye Two device, a prerequisite for marketing such a device.

The complaint relies primarily on the allegations that FemSuite features the FemEye Two on the FemSuite website and that FemSuite took a version of the device to two industry trade shows. *See* Bostock Decl., Ex. A, ¶¶ 9-12. According to KSEA, these activities amount to an offer for sale under the patent statute. *Id.* There is no allegation in the complaint, or evidence in the exhibits thereto, that any price was ever quoted by FemSuite for the FemEye Two device. *Cf. MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1376 (Fed. Cir. 2005) (for infringement under the offer for sale provision of the patent statute, a price must be quoted).

IV. ARGUMENT

Under Fed. R. Civ. P. 12(b)(6), a party may move the court to dismiss an action when the plaintiff fails to state a claim upon which relief can be granted. *See* FED. R. CIV. P. 12(b)(6) (2008). A claim will be dismissed under Rule 12(b)(6) if it appears beyond doubt that the pleader can prove no set of facts in support of the claim that would entitle the pleader to relief. *See SmileCare Dental Group v. Delta Dental Plan*, 88 F.3d 780, 783 (9th Cir. 1996). "All allegations of material fact are taken as true and construed in the light most favorable to the plaintiff." *Id*. at 782-83. Here, taking each of its allegations as true, KSEA has failed to state a claim upon which this Court can grant relief. That is, even if KSEA could show that FemSuite has conducted infringing activities that fall within the purview of 35 U.S.C. § 271(a), such activities, by operation of law, are exempt from liability under 35 U.S.C. § 271(e)(1). Thus, the complaint should be dismissed pursuant to Rule 12(b)(6).

In the alternative, the Court should stay this case until FemSuite may receive approval from the FDA to actually market the FemEye Two product.

A. Count I Fails To State A Claim Upon Which Relief Can Be Granted Because FemSuite's Activities Relating To The FEMEYE TWO Are Exempt From Infringement Liability Under 35 U.S.C. § 271(e)(1)[2]

1. The 271(e)(1) Safe Harbor

While it is generally an act of patent infringement to make, use, offer to sell, or sell any patented invention during the term of the patent therefor, Congress enacted an exemption to this general rule, codified in 35 U.S.C. § 271(e)(1). This section of the patent statute provides that:

> [i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

See Merck, 545 U.S. at 202; 35 U.S.C. § 271(e)(1). This exemption under Section 271(e)(1) "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA." *Merck*, 545 U.S. at 202 (emphasis in original). The Supreme Court has held that this exemption also applies to medical devices (such as the FemEye Two) that are subject to FDA approval. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

Notably, the Court of Appeals for the Federal Circuit has held in a prior case that activities, such as those of FemSuite identified in the complaint herein, are protected by the safe harbor provision of Section 271(e)(1). In *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992), Ventritex "displayed its [new]

[2] By this Motion, FemSuite does not concede infringement and, in fact, believes that the FemEye Two does not infringe any claim of the `787 patent as set forth below.

defibrillator at seven medical conferences, at which the device was demonstrated to physicians and to some non-physicians." *Id.* at 1521. Telectronics alleged that the new defibrillator being tested by Ventritex would infringe several patents of Telectronics. *Id.* at 1521-22. Ventritex countered that its activities were covered by the Safe Harbor of Section 271(e)(1). *Id.* at 1521. The district court agreed with Ventritex and granted summary judgment of non-infringement. *Id.* The Federal Circuit affirmed the Safe Harbor protection because "such demonstrations constitute an exempt use reasonably related to FDA approval . . .". *Id.* at 1523.[3] The activities of FemSuite complained of by KSEA herein are the same as those of Ventritex. More particularly, KSEA alleges that FemSuite manufactured prototype devices and displayed and demonstrated the prototypes at trade shows. *See* Bostock Decl., Ex. A, ¶¶ 10-12.[4] As a result, KSEA has failed to state a claim upon which relief can be granted and the complaint must be dismissed.

2. FemSuite's Past And Present Activities Are Exempt

KSEA alleges that FemSuite has offered to sell and continues to offer to sell the FemEye Two on its website and offered to sell the FemEye Two at the American College of Obstetrics and Gynecology ("ACOG") trade shows in May 2007 and 2008. *See id.* at ¶¶ 9, 11-12. In *Intermedics*, this Court was confronted with similar allegations by

[3] Ventritex "present[ed] clinical trial data at a cardiology conference, report[ed] clinical trial progress to investors, analysts and journalists, and describe[ed] clinical trial results in a private fund-raising memorandum . . .". *Id.* at 1523. The Federal Circuit found all of these activities protected under the safe harbor on the basis that they "fall under the category of dissemination of the data developed for FDA approval." *Id.* at 1523-24.

[4] "Congress obviously knew that companies that were trying to position themselves to enter the commercial market in a significant way immediately after a patent expired would engage in a range of business activities (like raising capital, establishing mechanisms for product distribution, etc.) for uses other than simply generating data for the FDA." *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1278 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993).. Thus, the exemption "is not lost simply as a result of a showing that the defendant has engaged in non-infringing acts whose 'uses' fall outside those permitted by the statute." *Id.* Likewise, as this Court recognized, a *de minimis* infringing act does not remove the device from the exemption of Section 271(e)(1). *Id.* at 1287-89.

Plaintiff Intermedics and found that the § 271(e)(1) exemption applied. More particularly, Intermedics alleged, *inter alia*, that defendants demonstrated their medical device (the "Cadence") at various scientific trade shows and that such uses constituted acts of infringement that were not reasonably related to obtaining FDA approval. The district court noted that "Plaintiff's argument presupposes that demonstrating the cadence at trade shows is an otherwise infringing act under § 271(a)." *Intermedics*, 775 F. Supp. at 1285. The court indicated that the "the mere demonstration or display of an accused product, even in a obviously commercial atmosphere, does not constitute an infringing use under § 271(a)." *Id.* at 1286.[5]; *see also Telectronics*, 982 F.2d at 1522-25.

In *Intermedics*, it was undisputed that the defendants displayed and demonstrated the Cadence at several medical conferences. The court found that defendants' demonstrations and displays did not constitute § 271(a) acts of infringement:

> At most, these demonstrations "advertised" the existence and features of the cadence to potential customers. Moreover, major contingencies would have to be overcome before any such potential customers might actually consummate a purchase. Most obviously, the FDA would have to issue its approval of the device for general commercial marketing. Such approval is in no sense a foregone conclusion. And how long it might take the FDA to make its determination was (and is) quite unpredictable.

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[5] The district court noted that while there is little case law directly addressing whether a trade show demonstration constitutes an act of infringement, the few cases that have confronted the issue have required some activity culminating in a sale:

> The *Celotex* case held that a single demonstration of an allegedly infringing product, which did not lead to a sale of the product, did not constitute a direct infringement of plaintiff's patent. The court relied, in part, on the holding in *Kaz Manufacturing Co., Inc. v. Chesebrough-Ponds, Inc.*, 317 F.2d 679 (2d Cir. 1963), that the use of a patented product for the purpose of advertising defendant's product is not a § 271(a) act of infringement.
>
> *Brennan v. Mr. Hanger, Inc.*, 479 F. Supp. 1215 (S.D.N.Y. 1979) also held that the mere display of an allegedly infringing product does not constitute an "in-fringing use" under § 271(a). Both the *Celotex* and *Brennan* courts relied, in part, on the fact that the demonstration activity complained of did not culminate in a sale of the accused product.

Intermedics, 775 F. Supp. at 1285 (internal citations omitted).

Intermedics, 775 F. Supp. at 1286. The district court also noted that the gap between the possibility that defendants' trade show activity generated general commercial interest in the Cadence and the "actual harm to an interest protected by plaintiff's patent is far to [*sic*] wide to justify a finding that the demonstration activity should cost defendants the benefits of § 271(e)(1)." *Id.* at 1289.

Moreover, the display of the FemEye Two on FemSuite's website, even if for commercial purposes that are unrelated to FDA approval, does not constitute an act of infringement under § 271(a). *See Intermedics*, 775 F. Supp. at 1281 ("the fact that this non-infringing activity reveals a commercial 'purpose' unrelated to obtaining FDA approval cannot provide a basis for denial of the exemption."). Indeed, as acknowledged in *Intermedics*, such commercial activities are important means for a defendant to position itself to enter the marketplace if its product ever receives FDA approval. *See Id.* at 1281 ("[t]he fact that these non-infringing activities evidence a business 'purpose' or motive that is unrelated to obtaining FDA approval has no bearing on our resolution of this matter.")

The fact that FemSuite has also manufactured prototypes of the FemEye Two does not add any life to KSEA's claims. In *Intermedics*, the court found that "where it is undisputed that most of the Cadences have been used to generate data for the FDA, the fact of manufacture, by itself, does not deprive defendants of the statutory exemption." *Id.* at 1282. KSEA cannot dispute that the FemEye Two has not been cleared by the FDA for sale in the United States. In turn, all of FemSuite's alleged infringing activities to date have consisted entirely of research and development and clinical evaluation of the FemEye Two relating to obtaining this FDA clearance. Thus, FemSuite's right to the safe harbor under § 271(e)(1) is not lost by its manufacture of FemEye Two prototypes.

KSEA further alleges that "upon information and belief, FemSuite is actively preparing to sell medical devices that would infringe the `787 patent". *See* Bostock Decl., Ex. A, ¶ 13. Even assuming this allegation to be true, "actively preparing to sell" the FemEye Two does not constitute an infringing activity under § 271(a) because it is not the "making," "using," "selling" of a patent invention. *See Intermedics*, 775 F. Supp. at 1277-78. This allegation, thus, also fails to add any life to KSEA's claim for infringement.

3. FemSuite's Potential Future Activities Are Not Relevant

KSEA's Complaint also requests a declaratory judgment of future infringement based on the allegation that FemSuite "will soon sell medical devices that infringe the `787 patent." Bostock Decl., Ex. A, ¶ 14. Although a patentee may seek a declaration of infringement against a future infringer, the court's decision to exercise jurisdiction over such a claim is discretionary. *See Telectronics*, 982 F.2d at 1526. The question is whether there is a substantial controversy of sufficient immediacy and reality. *See Medimmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007). This question is analyzed in the context of the facts as they existed when the Complaint was filed. *Telectronics*, 982 F.2d at 1527.

At the commencement of this suit on July 3, 2008, and indeed at present, the FemEye Two device is in the research and development stage and undergoing clinical evaluations. *See* Declaration of Jerry Sanders ("Sanders Decl."), ¶¶ 2, 5-7. FemSuite has not applied for, let alone received, clearance from the FDA to market and sell the FemEye Two in the United States. *Id.* at ¶ 5. Once the application is submitted, there is no way of knowing with any certainty when FDA clearance will be granted. *See id.*; *see also Intermedics*, 775 F. Supp. at 1289 (obtaining FDA approval "could take years"). Moreover, the FDA could require FemSuite to make changes to the device as a condition

of approval, which could drastically change or eliminate KSEA allegations of infringement. *See* Sanders Decl., ¶ 5.

The Federal Circuit addressed similar facts in *Telectronics* and affirmed the district court's ruling "that the case lacked sufficient immediacy and reality to meet the actual controversy requirement . . .". 982 F.2d at 1527. The Court based its decision on the fact that potential FDA approval was not imminent and that there "was no certainty that the device when approved would be the same device that began clinical trials," noting that Ventritex could and "in fact did modify its device during clinical trials." *Id.* at 1527. Given the presence of such uncertainties in the instant case, it is not clear that there will ever be a case or controversy between KSEA and FemSuite that arises under federal patent law.

Furthermore, ruling on a declaratory judgment when defendants are protected from infringement under § 271(e)(1) would undermine Congress' intent of offering a safe harbor to companies to develop and testing their new products:

> At least for relatively small start-up companies like Ventritex, where much of the business and technical work essential to survival is done by a small group of people, the promise by Congress of a safe haven could prove to be completely illusory if the courts permitted competitors to proceed full bore with expensive, resource-draining, and personnel-distracting litigation in the form of actions for declaratory relief. It makes little sense, and thus we assume would be inconsistent with Congress' intent, to protect companies like Ventritex from suit for actual patent infringement but leave them fully exposed to declaratory relief actions whose gravamen and burdens are much the same.

Intermedics, 775 F. Supp. at 1290.

While recognizing the interest of patentees in sustaining their full protection of rights, Section 271(e)(1) nonetheless elevates "the health care interests of the public above the pecuniary interests of the patent holders" by assuring public access to new medical

products immediately following a patent's expiration. *See Intermedics*, 775 F. Supp. at 1276-77 ("Congress clearly decided that it wanted potential competitors to be able to ready themselves, fully, during the life of the patent, to enter the commercial marketplace in a large scale way as soon as the relevant patents expired.").

B. In The Alternative, FemSuite Requests A Stay Pending The Commencement Of FemSuite From Any Potentially-Infringing Conduct

This Court "has broad discretion to stay proceedings as an incident to its power to control its own docket." *Clinton v. Jones*, 520 U.S. 681, 683 (1997) (citing *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)). A stay "is appropriate when it serves the interests of judicial economy and efficiency." *Rivers v. Walt Disney Co.*, 980 F. Supp. 1358, 1360 (C.D. Cal. 1997). When considering a motion to stay, the Court considers the following three factors:

1. potential prejudice to the non-moving party;
2. hardship and inequity to the moving party if the action is not stayed; and
3. the judicial resources that would be saved by avoiding duplicative litigation if the cases are in fact consolidated.

Id.

A stay would be particularly appropriate in this case. Although a FemEye Two prototype device was present at the ACOG conferences in New Orleans and San Diego, the design of the device has not been finalized. *See* Sanders Decl., ¶¶ 6-7. No FemEye Two devices been sold, and no orders have been accepted for the device. *Id*. at ¶¶ 9-11. Absent any such sales or orders, Storz has not been damaged by FemSuite.

A stay is also appropriate because FemSuite is months, if not years, from introducing the FemEye Two product. The FemEye Two is an endoscopy camera that requires Food & Drug Administration ("FDA") approval before it can be sold by FemSuite. *Id*. at ¶¶ 2-3. As the design of the FemEye Two is not yet final, FemSuite has not even applied for FDA approval for this device. *Id*. at ¶ 2. Moreover, even after an application for FDA approval is filed, it is not known when the FDA will act upon the application. *See Intermedics*, 775 F. Supp. at 1289 ("the [FDA] approval process could take years.").

It is also clear that the final FemEye Two product design will not infringe the '787 patent. If an independent claim of a patent is not infringed, all claims depending therefrom are likewise not infringed. *See, e.g., Wolverine World Wide, Inc. v. Nike, Inc.*, 38 F.3d 1192, 1199 (Fed. Cir. 1994) (citing *Wahpeton Canvass Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989)). The '787 patent has one independent claim (claim 1) and fifty-one dependent claims (claims 2-52). As a result, if claim 1 is not infringed, then neither are claims 2-52 infringed.

Claim 1 of the '787 patent recites as follows

> An endoscope comprising an elongated shaft having a distal end and a proximal end, an illumination unit and a video unit arranged at the distal end of said shaft and connected by a transmission system to a supply unit arranged at the proximal end of said shaft, said video unit comprising a lens adapted to acquire images of an object field illuminated by said illumination unit and at least one image recorder which is adapted to record and transmit images acquired by said lens, said video unit being movable between a first position adjacent the distal end of said shaft, **in which an outer contour of a cross section of said video unit lies substantially within an outer contour of a cross section of said distal end of said shaft during introduction and withdrawal of said endoscope** into and out of a cavity to be examined, and at least a second position in which the outer contour of the cross section of said video unit lies substantially without the outer contour of a cross section of the distal

> end of said shaft after completion of the introduction of said endoscope into said cavity, and actuating means for causing said video unit to move between said first position and at least said second position.

Bostock Decl., Ex. B, cols. 11-12 (emphasis added).

As the highlighted language states, the cross section of the video unit must lie substantially within the cross section of the shaft. FemSuite is purposefully designing the final FemEye Two product such that the outer contour of the video unit will not lie substantially within the cross section of the endoscope shaft during insertion mode. *See* Sanders Decl., ¶ 7. As a result, the final FemEye Two product will not infringe the '787 patent. *See PSN Ill., LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1167-68 (Fed. Cir. 2008) (no infringement unless accused products incorporates each element of the claim). Similarly, the outer contour of the video unit on the FemEye Two device at the ACOG conferences did not lie substantially within the cross section of the endoscope shaft. *See* Sanders Decl., ¶ 7.

In view of the above, the three elements for obtaining a stay are met in this case. As no FemEye Two devices have been sold, and in any event none can be sold prior to FDA approval, Storz will not be prejudiced by a stay. Contrariwise, absent a stay, both parties hereto will be prejudiced by incurring significant legal fees and expenses that will all be for naught because the FemEye Two product that may be introduced in the future will not have the same design as the device complained of in Storz's complaint. As a result, the third element justifying a stay is also met. It would be a waste of judicial resources at this time to conduct an entire patent infringement case on a device that has not yet been sold, that cannot be sold, prior to FDA approval, and the design of which has

not been finalized. In view of the foregoing, FemSuite requests that this case be stayed until such time as FDA approval may be obtained for the FemEye Two product and the product is commercially offered for sale.

V. CONCLUSION

In view of the foregoing, defendant respectfully requests that the Court dismiss plaintiff's Complaint or, in the alternative, stay the proceedings until FDA clearance has been obtained for the accused device.

Dated: September 5, 2008

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY and POPEO, P.C.,

/s/ Allison K. Young
Allison K. Young
Attorneys for Defendant, FemSuite, LLC