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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ROBERT GERGELY, MD,

Plaintiff,

v.

(1) GENERAL ELECTRIC COMPANY;
(2) GE MEDICAL SYSTEMS ULTRASOUND AND PRIMARY CARE DIAGNOSTICS, LLC; and
(3) GE HEALTHCARE AUSTRIA GMBH & CO OG;

Defendants.

Case No.: 8:14-cv-19-CJC-RNB

[Hon. Cormac J. Carney]

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT—JURY TRIAL DEMANDED

Plaintiff Robert Gergely, MD, brings this Second Amended Complaint for Patent Infringement against Defendants General Electric Company ("General Electric"); GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC ("GE Ultrasound"); and GE Healthcare Austria GmbH & Co OG ("GE Healthcare") (collectively "GE"), alleging, based on his own knowledge as to himself and his own actions, and based on information and belief as to all other matters, as follows:

THE PARTIES

1. Dr. Gergely is an individual residing in Los Angeles, California. Dr. Gergely graduated from the Sackler School of Medicine at Tel-Aviv University. He completed his residency in obstetrics and gynecology at Rambam Hospital in Haifa and at Mt. Sinai Medical Center in New York. Dr. Gergely also completed a fellowship in maternal-fetal medicine at Mt. Sinai Medical Center and Cedars Sinai Medical Center in Los Angeles. He has over 20 years of experience specializing in maternal-fetal medicine, and spent approximately ten years as the medical director of the 3D Sonography Center of Beverly Hills. Dr. Gergely is now retired.

2. Defendant General Electric is a corporation organized and existing under the laws of the State of New York with a principal place of business located in Fairfield, Connecticut. General Electric can be served via its registered agent for service of process: CT Corporation; 818 W. Seventh St.; Los Angeles, CA 90017.

3. Defendant GE Ultrasound is a limited liability company organized and existing under the laws of the State of Delaware with a principal place of business located in Wisconsin. GE Ultrasound can be served via its registered agent for service of process: The Corporation Trust Company; Corporation Trust Center; 1209 Orange Street; Wilmington, DE 19801.

4. Defendant GE Healthcare is a corporation organized and existing under the laws of Austria with a principal place of business at Tiefenbach 15, 4871 Zipf, Austria. GE Healthcare is directly or indirectly owned and controlled by General Electric.

JURISDICTION AND VENUE

5. This is an action for infringement of a United States patent arising under 35 U.S.C. §§ 271, 281, and 284-285, among others. This Court has subject matter jurisdiction of the action under 28 U.S.C. §1331 and §1338(a).

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b). GE has transacted business in this district, and has committed and/or induced acts of patent infringement in this district.

7. GE is subject to this Court's specific and general personal jurisdiction due at least to its substantial business in this forum, including: (i) at least a portion of the infringements alleged herein; and (ii) regularly doing or soliciting business, engaging in other persistent courses of conduct, and/or deriving substantial revenue from goods and services provided to individuals in California and in this district.

DR. GERGELY'S INVENTION

8. Dr. Gergely invented a technique for improving the success rate of IVF procedures by using 3D/4D sonography. In particular, he developed a technique in which 3D/4D sonography is used to locate what is known as the "Maximal Implantation Potential" ("MIP") point and to guide an embryo directly to the MIP point for implantation. Dr. Gergely's technique has the benefit of both increasing pregnancy rates and reducing complications such as ectopic pregnancies and multiple births.

9. Dr. Gergely's pioneering work has been widely recognized by the medical community. His results were accepted for publication by Fertility & Sterility. *See* "Three dimensional/four dimensional ultrasound-guided embryo

transfer using the maximal implantation potential point," R. Gergely et al., FERTILITY & STERILITY, Vol. 84, No. 2, August 2005 ("MIP Paper"). Dr. Gergely presented his results at the October 2007 meeting of the American Society for Reproductive Medicine. His results were also accepted for presentation in 2010 at the 26th Annual Meeting of the European Society of Human Reproduction and Embryology. Dr. Gergely's work has been recognized in numerous papers and has also been featured in leading treatises in the field of reproductive technology. *See, e.g.*, MANUAL OF ASSISTED REPRODUCTIVE TECHNOLOGIES & CLINICAL EMBRYOLOGY (Jaybee Brothers Medical Publishers, 2012) at 357 ("Dr. Gergely has found the optimal place in a woman's uterus to implant an embryo for a successful pregnancy. It's not easy to find but the benefits are huge. His method of targeting the 'Maximal Implantation Potential Point' (MIP) . . . considerably increases a woman's chance of achieving a pregnancy, [and] reduces the risk of ectopic pregnancy . . . . The technique literally visualizes a 'bulls-eye' in the uterus—the area with the greatest natural implantation potential for the embryo."); W. Vitek & S. Carson, "Embryo Transfer: Does Position Matter?" in HOW TO IMPROVE YOUR ART SUCCESS RATES: AN EVIDENCE-BASED REVIEW OF ADJUNCTS TO IVF (Cambridge University Press 2011) ("Gergely et al. utilized 3D/4D U/S to define the maximal implantation potential point . . . . [U]tilizing 3D/4D U/S to target the maximal implantation point was associated with a 10% increase in pregnancy rate . . . . Gergely et al. also found that targeting the maximal implantation potential point significantly reduced the ectopic pregnancy rate . . . ."). Dr. Gergely has presented his work at medical conferences in Washington D.C., Hamburg, Moscow, Rome, and New York.

10. GE has also recognized Dr. Gergely's invention. GE prepared a "Case Study" highlighting Dr. Gergely's ultrasound imaging technique for implanting embryos at the MIP point:

GE Healthcare

Case Study

Volume Ultrasound - Discover the Maximal Implantation Potential Point

An ultrasound imaging technique used at the Southern California Reproductive Center Medical Group, Beverly Hills, California, offers promise for the 6.1 million American women and their partners affected by infertility[1]. With in vitro fertilization procedures that include embryo transfer guided by GE's Voluson 730 Expert ultrasound system, Robert Z. Gergely, M.D., and colleagues have documented a clinical pregnancy rate of 36.66 percent in women with an average age of 37.6.

The Southern California Reproductive Center Medical Group is the largest in vitro fertilization (IVF) center west of the Mississippi River. A staff of 40 physicians, nurses, technicians and embryolgists serve 1,000 patients per year.

For the past five years, the Southern California Reproductive Center has improved its IVF success rate by greatly increasing embryo transfer accuracy. Embryo transfer is a critical step in the IVF process, the more accurate the placement, the greater the chance of pregnancy. The goal of transfer is to place the embryo as near as possible to the point nature intended, where the endometrium is thickest and has the greatest blood flow.

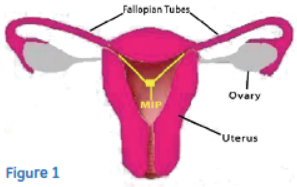

Figure 1

Dr. Robert Z. Gergely has invented a method for finding the Maximal Implantation Potential (MIP) point in each patient and for guiding the embryo directly to it. The MIP point lies at the intersection of two imaginary lines, one starting in each fallopian tube (See Figures 1 & 2). Its location differs slightly for each woman.

Figure 2

Volume Ultrasound is key to accurate delivery

Gergely personally guides all of the center's embryo transfers using GE's Voluson 730 Expert ultrasound system. "Ultrasound-guided embryo transfer has been around since 1985 and has been almost universal for the past three years," Gergely said. "2D ultrasound was used at first, but it only identifies the general area for implantation. Volume Ultrasound pinpoints the ideal spot and significantly improves the likelihood of successful implantation."

In the procedure, 2D ultrasound is used to determine that the patient's bladder is adequately full, important for the acoustic window needed to generate the high-quality 3D image. The 3D mode is then used to display the uterine cavity and identify the MIP point. The physician inserts the transfer catheter, and once the tip enters the uterus, the 4D mode is turned on. This lets Gergely follow the catheter tip in real time.

"I am the eyes of the doctor performing the transfer," Gergely said. "When the catheter tip is directly over the MIP point, I call out, 'Bulls eye,' and the doctor releases the embryo(s)." The ultrasound screen displays the resulting air bubbles as a bright flash (See Figure 3), showing the location of the embryos relative to the MIP point.

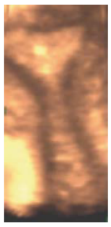

Figure 3

Study documents high rate of success

In a scientific paper released in 2005, Gergely and colleagues documented a 36.66 percent pregnancy rate in IVF procedures using embryo transfer guided by the Voluson system. The study included 1,222 patients, average age 37.6, who received embryo transfers from October 2002 to August 2004[2].

Delivering clinical advantage

Gergely likens his procedure to using a "smart bomb." He and colleagues hope to conduct controlled scientific studies to compare its success rate to those of other embryo transfer procedures. In the meantime, he observes that because of the method's accuracy, doctors can transfer fewer embryos per procedure, reducing the likelihood of multiple births. "Since we are so much more accurate in placing the embryo, we can start reducing the number of embryos we transfer without affecting the pregnancy rate," Gergely said. "We can look to transferring two embryos, or even one."

"The accuracy we achieve is possible only with Volume Ultrasound guidance. Direct visualization of the embryo transfer has enhanced the experience both for the physicians and the patients, who enjoy watching the procedure on the screen. We started out with one doctor guiding transfers using the MIP point. Now, 15 doctors refer patients to our clinic for the procedure. It has definitely increased the pregnancy rate — that's why we bought the machine."

To learn more call us today at 1-888-202-5528.

GE Healthcare
Internet - gehealthcare.com
GE Healthcare
tel 1-866-344-3633
P.O. Box 414
Milwaukee, Wisconsin 53201 U.S.A.

1. Source: National Survey of Family Growth, Centers for Disease Control and Prevention, 1995.
2. Robert Z. Gergely MD, Catherine Marin DeUgarte MD, Hal Danzer MD, Mark Surrey MD, David Hill PhD, Alan H. DeCherney MD, 3D/4D Ultrasound guided embryo transfer using the maximal implantation potential (MIP) point.

General Electric Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation. Contact your GE Representative for the most current information.

11. In the case study, GE acknowledged that "Dr. Robert Z. Gergely has invented a method for finding the Maximal Implantation Potential (MIP) point in each patient and for guiding the embryo directly to it." GE acknowledged that the "ultrasound imaging technique" developed by Dr. Gergely "offers promise for the 6.1 million American women and their partners affected by infertility" and that

"[w]ith in vitro fertilization procedures that include embryo transfer guided by GE's Voluson 730 Expert ultrasound system, Robert Z. Gergely, M.D., and colleagues have documented a clinical pregnancy rate of 36.66 percent in women with an average age of 37.6."

12. On May 17, 2004, Dr. Gergely filed a provisional patent application (No. 60/572,267) with the United States Patent & Trademark Office in order to obtain patent protection for his invention. On May 17, 2005, Dr. Gergely filed a regular patent application claiming priority to his provisional patent application. On January 29, 2008, the United States Patent & Trademark Office duly and legally issued United States Patent No. 7,322,931 (the "931 Patent") for Dr. Gergely's invention, entitled "Sonography Guided Embryo Transfer for In Vitro Fertilization."

13. On November 27, 2007, Dr. Gergely filed a continuation to his May 17, 2005, patent application (now the 931 Patent) claiming priority to his May 17, 2004 provisional patent application. On January 7, 2014, the PTO duly and legally issued United States Patent No. 8,622,887 (the "887 Patent") for Dr. Gergely's invention, entitled "Sonography Guided Embryo Transfer for In Vitro Fertilization."

14. Dr. Gergely is the owner of the 931 and 887 Patents with all substantive rights in and to those patents, including the sole and exclusive right to prosecute this action and enforce the 931 and 887 Patents against infringers, and to collect damages for all relevant times.

GE'S INFRINGEMENT OF U.S. PATENT NOS. 7,322,931 AND 8,622,887

15. GE has infringed the 931 and 887 Patents by using the patented methods to demonstrate ultrasound machines (including at least its Voluson line of ultrasound machines) to customers and potential customers, including at least IVF clinics and doctors and sonographers specializing in IVF procedures.

GE'S INDUCED INFRINGEMENT OF U.S. PATENT NOS. 7,322,931 AND 8,622,887

16. GE has infringed the 931 and 887 Patents by inducing others to use the patented method. GE has specifically encouraged others to use Dr. Gergely's patented method in order to support and promote sales of its ultrasound machines with 3D/4D capabilities (including at least the Voluson line of ultrasound machines) to its customers, including at least IVF clinics and doctors and sonographers specializing in IVF procedures.

17. GE promotes its Voluson products by touting their 4D mode as useful for performing Dr. Gergely's patented method: "**4D Imaging** Mode to help determine the optimal target for transferred embryo placement, known as the maximal implantation potential (MIP) point." *See* http://www.gehealthcare.com/usen/ultrasound/voluson/signature_series/voluson-s8.html#/clinical-expansion. As described above, the Case Study prepared by GE also touts the capability of its Voluson ultrasound machines to be used in practicing Dr. Gergely's invention. GE also runs the "GE Ultrasound Academy," which provides "robust courses" including "instructor-led didactic and hands-on sessions" for its ultrasound products at the GE Healthcare Institute. GE recommends that "in order to accelerate your new product learning curve and for the best learning experience" customers attend a training session "within 3-6 months of your system installation." GE provides a "Voluson Technology Course" which includes "Advanced 3D/4D acquisitions, display and manipulation techniques in Ob/Gyn." GE also offers Voluson education courses at customer sites. Such training includes "in-depth technology review of 3D and 4D techniques . . . and advanced 3D/4D tools and applications." GE also maintains a customer portal (the "VolusonClub") which offers a range of materials such as technical and clinical lectures, and clinical whitepapers to owners of Voluson ultrasound machines.

18. GE "maintains a professional and highly trained sales force that works closely with customers to access their needs and capabilities; offers industry-leading after-purchase service, warranty and technical support that enables users to obtain quick and complete answers from a reliable and dedicated team of GE experts; and ***provides state-of-the-art training and education in the full range of ultrasound applications*** in each specialized field." *See* GE Complaint (Dkt. No. 1) ¶ 24 *in* Case No. 3:12-CV-1488-WQH-WMC (S.D. Cal.) (emphasis added).

19. GE "regularly publishes clinical white papers, technical papers and case studies that address the latest developments in ultrasound technology." GE also claims that it "provides professional education opportunities to doctors and sonographers through the International Academy of Medical Ultrasound, GE's education center that offers lectures, case reports and hands-on practical training in the latest innovations in ultrasound applications. All of these resources are ***critical*** to support purchasers and users of GE's diagnostic ultrasound imaging systems in maintaining patient care at the highest level." *See* GE Complaint (Dkt. No. 1) ¶ 25 *in* Case No. 3:12-CV-1488-WQH-WMC (S.D. Cal.) (emphasis added).

20. Dr. Gergely has been damaged as a result of the infringing conduct by GE and, thus, GE is liable to Dr. Gergely in an amount that adequately compensates Dr. Gergely for GE's infringements, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

GE'S KNOWLEDGE OF U.S. PATENT NOS. 7,322,931 & 8,622,887

21. GE is, and has been, well aware of Dr. Gergely's pioneering work that led to the issuance of the 931 and 887 Patents, including Dr. Gergely's application for, and the issuance of, the 931 and 887 Patents.

22. Jennifer Janowski, GE's OB/GYN Marketing Manager for GE Healthcare Ultrasound, read Dr. Gergely's "very interesting" MIP Paper and

contacted Dr. Gergely in December of 2004 to set up a time to discuss Dr. Gergely's work. Ms. Janowski also expressed interest in featuring Dr. Gergely's work in a GE case study. In January and February 2005, Dr. Gergely provided information to Ms. Janowski to prepare and finalize GE's Case Study featuring his invention.

23. In February 2005, Dr. Gergely met with Ms. Janowski and Michael Podany regarding the proposed Case Study. In March 2005, Dr. Gergely emailed Ms. Janowski and Mr. Podany and raised the issue of compensation for GE's use of his invention:

> In our last meeting here in L.A., three weeks ago, both you and Michael asked me about financial reimbursement for my services.
> I suggested that you (GE) will come up with an intelligent offer for me to consider.
> I have not heard from you in this regard.
> I think it is time to clarify the terms of our business relationship.
> Looking forward to hearing from you.

24. In June of 2005, Dr. Gergely again emailed Ms. Janowski and Mr. Podany, reporting that his paper was scheduled for publication in August of that year. He explained that since their last meeting he had "filed for a global (international) provisionary patent application." He also referred back to his email of March 2005, and made clear that "[i]f we are to continue our business relationship we will need to address these matters."

25. In July of 2005, Dr. Gergely still had not heard back from anyone from GE. Accordingly, he wrote to Ms. Janowski and Mr. Podany and informed them that he was not authorizing GE to use his study to promote GE's ultrasound machines.

26. A few days later, Karl-Heinz Lumpi of GE contacted Dr. Gergely. Mr. Lumpi introduced himself as being in charge of GE's Voluson operation based

in Austria. Mr. Lumpi responded that although he was "sorry that I was so late involved in the process" he was "really happy now reading and hearing about the great work" Dr. Gergely was doing in IVF. He explained that GE was "very interested in working closer with you from the product development point of view." Nevertheless, Mr. Lumpi informed Dr. Gergely that GE would not provide monetary compensation for his work.

27. In August 2005, Ms. Janowski again contacted Dr. Gergely and sought permission to move ahead publishing the case study. Dr. Gergely again responded that he would not authorize GE to use his work without appropriate compensation.

28. Dr. Gergely continued to update GE regarding his work, and to seek appropriate compensation from GE. For example, in December of 2006, Dr. Gergely emailed GE explaining his success with his procedure and attaching a copy of his paper "Three dimensional/four dimensional ultrasound-guided embryo transfer using the maximal implantation potential point," Fertility & Sterility, Vol. 84, No. 2, August 2005. He also noted that he would be presenting his procedure at the next ASRM (American Society for Reproductive Medicine) meeting in October 2007. In January of 2007, Dr. Gergely emailed GE, attaching another paper. In the email, Dr. Gergely wrote: "Please look at this paper (attached.) Of interest to us are the last 3 paragraphs. Obviously, 3D/4D is the way to go for Embryo Transfer. Yes, my paper got quoted and our center mentioned. **The rapidly growing market (of in Vitro Fertilization) is ripe for GE/Voluson**. When are you planning to seriously start marketing your excellent product to the IVF community?" Mr. Lumpi of GE responded by email, noting that the "attached paper is very interesting" and that they "know IVF is a very interesting market and we will focus more on it in the near future." In October 2007, Dr. Gergely presented his work at the ASRM meeting. He personally met with GE's senior ultrasound representatives, including Mr. Lumpi. He presented his invention, and

offered to license it, to GE during that meeting. GE refused to agree to pay Dr. Gergely any compensation for his invention.

29. After his 931 Patent issued, Dr. Gergely again contacted GE. For example, in 2010, Dr. Gergely again wrote to Mr. Lumpi and offered to license his patented technology to GE. Dr. Gergely expressly informed GE that his method was covered by his patent: "*NOTE: The technique described above is protected by the following patents: Sonography Guided Embryo Transfer for In Vitro-Fertilization. United States Patent No. 7,322,931. European Patent Application No. 0575835.7.*"

30. GE has refused to pay Dr. Gergely a royalty for its use of his patented technology. In response to his inquiries, GE acknowledged Dr. Gergely's "contribution in the academic area of IVF/Fertility." But GE took the position that Dr. Gergely must seek compensation for the use of his patented technology from the individual doctors and sonographers using GE's ultrasound equipment to practice his patented invention rather than GE.

ADDITIONAL ALLEGATIONS REGARDING GE'S DIRECT INFRINGEMENT OF U.S. PATENT NOS. 7,322,931 AND 8,622,887

31. GE has directly infringed the patents-in-suit by performing medical procedures on actual patients that are covered by one or more claims of each patent-in-suit.

32. GE has done so at least by employing application specialists and/or *per deim* contractors or proctors who perform medical procedures on actual patients in connection with training GE customers on how to use GE's ultrasound equipment. GE's agents (for example, its own application specialists or sonographers or doctors that it has specifically engaged) have directly performed Dr. Gergely's patented method on patients. They have done so while teaching sonographers or doctors how to perform the MIP procedure while demonstrating or teaching the use of its ultrasound machines.

33. GE advertises job positions for Ultrasound Applications Specialists whose responsibilities include (a) providing "pre-sale product demonstrations (or clinical trial support)," (b) ongoing post-sale customer support including "***on site clinical in-servicing,"*** (c) "***on site clinical applications training***," and (d) demonstrating the full range of product features including "potential uses, product capabilities, and benefits to customers as needed." *See* http://www.ge.com/careers /opportunities (emphasis added).

34. GE advertises that it conducts "**In-depth, hands-on training**" and that it "offers Voluson education courses at our facilities or ***on-site at your location.***" *See* http://www.gehealthcare.com/usen/ultrasound/voluson/ international/community.html (emphasis added). GE's training includes "technical and clinical lectures as well as ***hands-on scanning under the supervision of product experts.***" *Id*. (emphasis added).

35. It is a regular practice in the medical profession for manufacturers of medical equipment (including, specifically, ultrasound equipment) to send their agents to work with doctors or other medical technicians (including, for example, sonographers) who will be using the equipment, in order to train them in, or in order to demonstrate, the uses of the medical equipment. It is a regular practice for such agents to be directly involved in performing medical procedures on actual patients using the medical equipment (including, specifically, ultrasound equipment) during such training or demonstrations.

36. GE also directly infringes the patents-in-suit under the doctrine of equivalents. GE does so by using Dr. Gergely's patented method on patient volunteers (also known as simulated patients) and/or obstetric models. *See*, e.g., http://www3.gehealthcare.com/en/Education/ Product_Education_ Clinical/ Ultrasound/Voluson_Technology_Course (advertising that GE conducts "hands-on scanning" in small groups, using "volume datasets and obstetric models.").

JURY DEMAND

Dr. Gergely requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure of any issues so triable by right.

PRAYER FOR RELIEF

Dr. Gergely requests that the Court find in its favor and against GE, and that the Court grant Dr. Gergely the following relief:

a. Judgment that one or more claims of United States Patent Nos. 7,322,931 and 8,622,887, either literally and/or under the doctrine of equivalents, by GE;

b. A permanent injunction enjoining GE and its officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in active concert therewith from infringing and inducing infringement of the 931 and 887 Patents;

c. Judgment that defendants account for and pay to Dr. Gergely all damages to and costs incurred by Dr. Gergely because of GE's infringing activities and other conduct complained of herein;

d. That GE's infringements be found to be willful, and that the Court award treble damages for the period of such willful infringement pursuant to 35 U.S.C. § 284;

e. That Dr. Gergely be granted pre-judgment and post-judgment interest on the damages caused by GE's infringing activities and other conduct complained of herein;

f. That this Court declare this an exceptional case and award Dr. Gergely its reasonable attorney's fees and costs in accordance with 35 U.S.C. § 285; and

g. That Dr. Gergely be granted such other and further relief as the Court may deem just and proper under the circumstances.

Dated: May 12, 2014

Respectfully submitted,

/s/ Bob Muller

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