UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

WUXI HISKY MEDICAL TECHNOLOGIES CO., LTD., *Plaintiff,* v. ECHOSENS SA and ECHOSENS NORTH AMERICA, INC., *Defendants.*	Civil Action No. 17-11242 **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Wuxi Hisky Medical Technologies Co., Ltd. ("Plaintiff" or "Hisky") brings this complaint for patent infringement against Defendants Echosens SA and Echosens North America, Inc. ("Echosens North America") (collectively, "Defendants" or "Echosens").

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271 *et seq.*, by Hisky against Echosens for infringement of United States Patent No. 9,554,771 ("the '771 patent"). A true and accurate copy of the '771 patent is attached as Exhibit A.

THE PARTIES

2. Plaintiff Hisky is a company organized and existing under the laws of the People's Republic of China with a principal place of business located at Room B401, 530 Plaza, University Science Park, Taihu International Science & Technology Park, Wuxi, Jiangsu, China 214135.

3. On information and belief, Defendant Echosens SA is a limited liability corporation organized and existing under the laws of France with a principal place of business at 30 Place D'Italie 75013 Paris, France.

4. On information and belief, Defendant Echosens North America is a limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at 1050 Winter Street, Waltham, Massachusetts 02451.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has jurisdiction over Echosens. On information and belief, Echosens North America maintains its principle place of business within Massachusetts and has committed one or more acts of infringement of the '771 patent within Massachusetts and this judicial district. Echosens North America and Echosens SA, directly or through Echosens North America, offer for sale, sell, and/or import infringing products in the United States and this judicial district. These infringing products have been, and continue to be, purchased and used by consumers in this judicial district. Hisky believes, and on that basis alleges, that Echosens derives substantial revenue from the sale of infringing products in this judicial district, expects its actions to have consequences in this judicial district, and derives substantial revenue from its acts in interstate and international commerce. Thus, a substantial part of the events giving rise to Hisky's claims occurred and continues to occur in this judicial district.

7. On information and belief, Echosens purports to be the world's leading provider of non-invasive medical devices dedicated to the assessment of chronic liver diseases.

8. On information and belief, Echosens manufactures liver diagnostic devices under the FibroScan® product line brand, including, for example, the FibroScan® line of products, and more specifically, the FibroScan® 502 Touch and FibroScan® 530 Compact (collectively, "Accused FibroScan Products").

9. On information and belief, Echosens maintains an established, wide-reaching international sales and distribution network that sells and distributes the Accused FibroScan Products directly or through intermediaries to customers located in the United States and this judicial district. For example, Echosens's established network includes over 40 distributors (exclusive of any local sub-distributors). Echosens actively markets its products and services in the United States, which it considers a major market, including this judicial district. Echosens asserts that "[w]herever you are, Echosens is able to provide you with its products and services."

10. On information and belief, Echosens North America plays an integral role in maintaining Echosens's established distribution network in the United States. Echosens North America was established in 2015 and provides the United States market with direct support for the Accused FibroScan Products. Echosens North America sells and distributes the Accused FibroScan Products in the United States, including this judicial district. Echosens North America also provides comprehensive customer support services from this judicial district, including services relating to sales and marketing, operator training and certification, technical service, medical affairs and research, and product development.

11. Venue for this civil action in this District is proper under 28 U.S.C. §§ 1391 and 1400(b). On information and belief, Echosens North American resides in this District, and has committed acts of infringement and has a regular and established place of business in this District. Venue is proper for Echosens SA under 28 U.S.C. § 1391(c)(3).

FACTUAL BACKGROUND

12. Hisky is a rapidly growing high-tech medical device company that specializes in developing, manufacturing, and marketing medical equipment for non-invasive liver diagnosis.

13. Since its founding in 2010, Hisky has focused on research and development of cutting-edge acoustic and transient elastography technology in the healthcare industry. Hisky has research and development centers in Wuxi, China and Beijing, China.

14. Hisky offers a wide range of specialized, sophisticated, and affordable liver diagnostic systems for its customers worldwide. Hisky has pioneered FibroTouch, an innovative and widely-used solution for liver fibrosis and steatosis diagnosis that is capable of making quantitative detection and assessment of liver fibrosis and hepatic steatosis with low frequency shear wave technology. FibroTouch has greatly contributed to the prevention and early detection and treatment of chronic liver disease.

15. On January 31, 2017, the United States Patent and Trademark Office (USPTO) duly and legally issued the ’771 patent, entitled Method and Device for Detecting Elasticity of Viscous Elastic Medium,” to the listed inventor Jinhua Shao of Beijing, China, and other co-inventors in China. Hisky is the assignee and owner of the ’771 patent.

16. The ’771 patent relates to a non-destructive method and device for detecting an elasticity of a viscoelastic medium. For example, the method and device involve driving an ultrasonic transducer probe with low-frequency vibration to produce an elastic wave in a viscoelastic medium, transmitting an ultrasonic wave to the viscoelastic medium, collecting an ultrasonic echo returned from the viscoelastic medium, calculating a propagation velocity of the elastic wave according to an effective ultrasonic echo, and calculating the elasticity of the viscoelastic medium according to the calculated propagation velocity.

17. On information and belief, the Accused FibroScan Products utilize a vibration-controlled transient elastography to assess liver tissue stiffness.

18. On information and belief, the Accused FibroScan Products include a mechanical vibrator and a custom-designed ergonomic transducer, which produce an elastic wave that travels through the skin and into the liver.

19. On information and belief, the Accused FibroScan Products utilize ultrasound to track the elastic wave and to calculate its velocity. For example, the Accused FibroScan Products measure ultrasound attenuation corresponding to a decrease in amplitude of ultrasound waves as they propagate through the liver.

20. On information and belief, the Accused FibroScan Products correlate the calculated velocity with an elasticity of the liver.

CLAIM FOR RELIEF

Infringement of U.S. Patent No. 9,554,771

21. Hisky incorporates by reference each and every allegation set forth in paragraphs 1-20 as if fully set forth and restated herein.

22. On information and belief, Echosens has infringed and continues to infringe at least claims 1-3 and 5-12 of the ’771 patent under 35 U.S.C. § 271(a), (b) and (c), either literally or under the doctrine of equivalents, by making, using, offering for sale, selling, and/or importing in the United States at least the Accused FibroScan Products.

23. On information and belief, Echosens’s Accused Products contain each limitation of each asserted claim of the ’771 patent. By way of example only, Echosens’s Accused Products meet all requirements of claim 6:

6. A device for detecting an elasticity of a viscoelastic medium, comprising:

a vibrator producing a vibration;

an ultrasonic transducer probe driven by the vibrator with the vibration so as to produce an elastic wave to be propagated in the viscoelastic medium;

a control apparatus connected with the ultrasonic transducer probe and the vibrator respectively, and configured to control the ultrasonic transducer probe to transmit an ultrasonic wave to the viscoelastic medium and to collect through the ultrasonic transducer probe an ultrasonic echo returned from the viscoelastic medium and corresponding to the transmitted ultrasonic wave, the control apparatus being further configured to select an effective ultrasonic echo from the ultrasonic echo according to a duration of the vibration and physical parameters of the viscoelastic medium, and to calculate a propagation velocity of the elastic wave in the viscoelastic medium according to the effective ultrasonic echo, and to calculate the elasticity of the viscoelastic medium according to the propagation velocity of the elastic wave, wherein the ultrasonic transducer probe stops vibrating and the elastic wave is propagated in the viscoelastic medium at a moment corresponding to the effective ultrasonic echo; and

a pressure sensor array mounted between and contacted with the ultrasonic transducer probe and the vibrator, wherein the control apparatus further comprises a pressure signal collecting circuit connected with one of a computer, a microprocessor and a microcontroller through a communication interface, and wherein the control apparatus detects with the pressure sensor array a pressure applied to the viscoelastic medium by the ultrasonic transducer probe and a verticality of the ultrasonic transducer probe relative to the viscoelastic medium, and wherein the control apparatus is further configured to start to detect the elasticity of the viscoelastic medium in response to the detected pressure and the detected verticality satisfying preset conditions.

24. By way of example only, Echosens's FibroScan 502 Touch is a "device for detecting an elasticity of a viscoelastic medium."

Exhibit B, FibroScan 502 Touch Leaflet at PDF 4.

25. The FibroScan 502 Touch includes "a vibrator producing a vibration," and the vibrator includes "an ultrasonic transducer probe driven by the vibrator with the vibration so as to produce an elastic wave to be propagated in the viscoelastic medium." In particular, the FibroScan 502 includes a custom-designed ergonomic transducer that

generates a controlled vibration, which "induces a mechanical shear wave" that propagates in the liver.

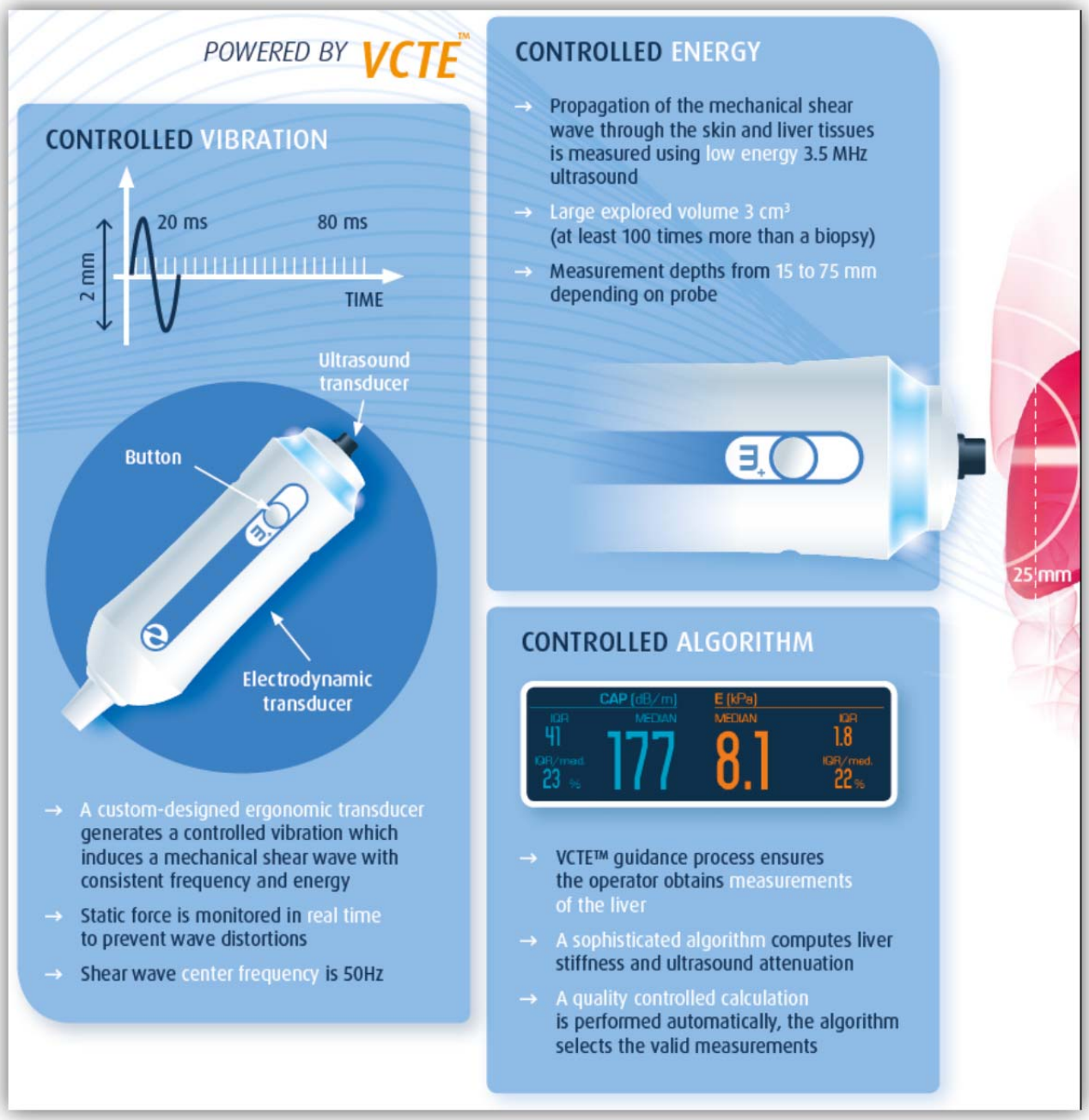


Exhibit B, FibroScan 502 Touch Leaflet at PDF 4.

Technological Characteristics
FibroScan® uses transient elastography for the non-invasive measurement of liver shear wave speed. A mechanical vibrator produces low-amplitude elastic waves that travel through the skin and intercostal space into the liver. Ultrasound is used to track the shear wave and to measure its speed, which is correlated with the elasticity of the liver.

Exhibit C, FibroScan 502 Touch 510(k) Summary, at 2.

26. The FibroScan 502 Touch device includes a control apparatus, including both hardware and software, to be connected with the probe, where the vibrator is located. *See, e.g.*, Exhibit B, FibroScan 502 Touch Leaflet at PDF 12-13:

27. The control apparatus in the FibroScan 502 Touch controls "the ultrasonic transducer probe to transmit an ultrasonic wave to the viscoelastic medium."

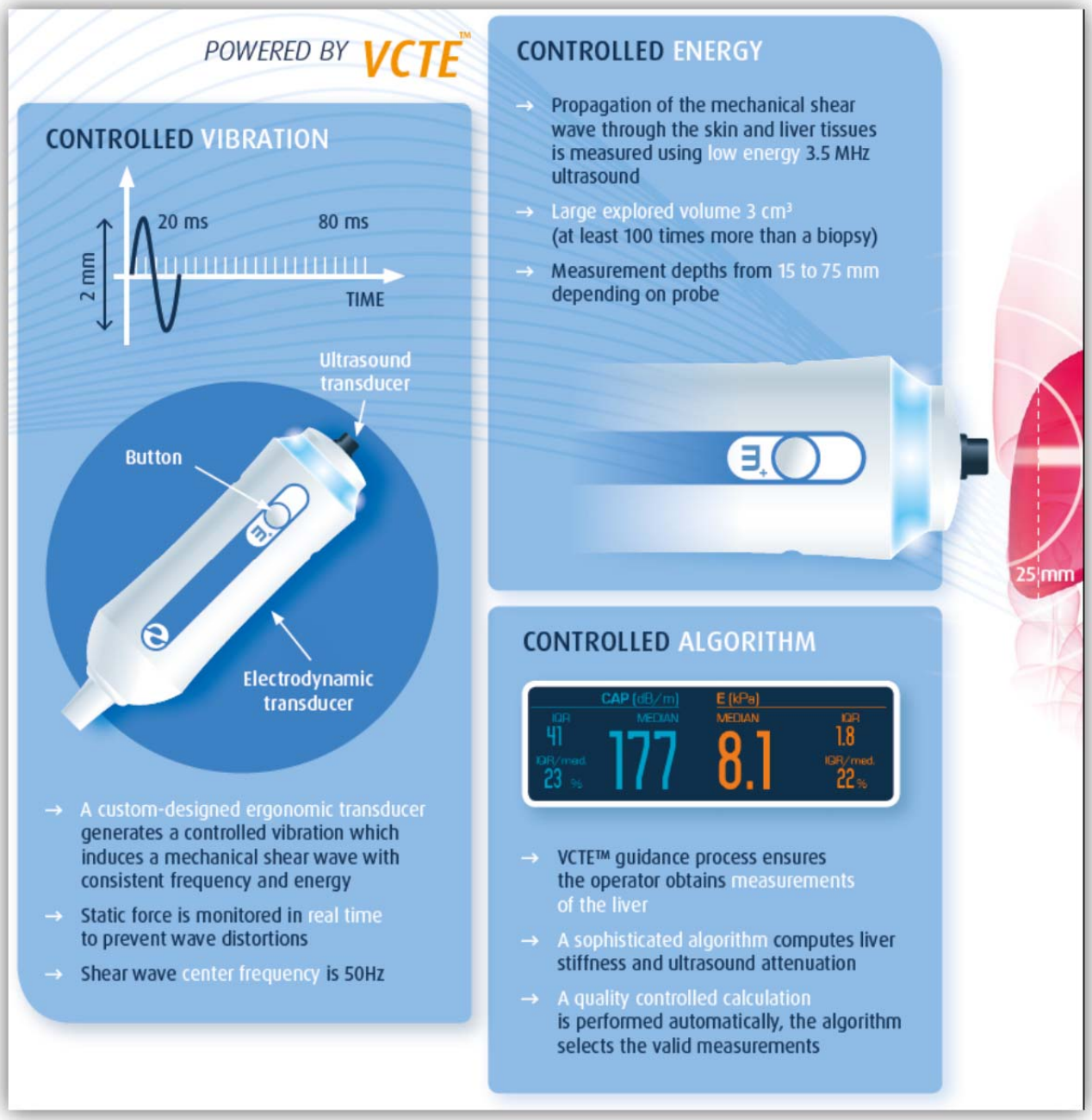
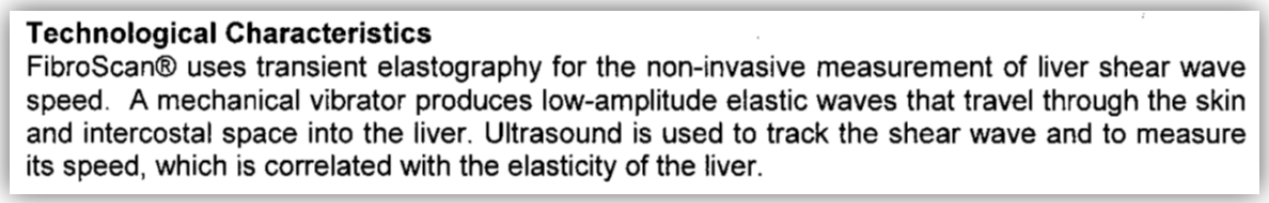


Exhibit B, FibroScan 502 Touch Leaflet at PDF 4.

28. The control apparatus in FibroScan 502 Touch collects "through the ultrasonic transducer probe an ultrasonic echo returned from the viscoelastic medium and corresponding to the transmitted ultrasonic wave." *See, e.g.*, Exhibit C, FibroScan 502 Touch 510(k) Summary, at 2:



Technological Characteristics
FibroScan® uses transient elastography for the non-invasive measurement of liver shear wave speed. A mechanical vibrator produces low-amplitude elastic waves that travel through the skin and intercostal space into the liver. Ultrasound is used to track the shear wave and to measure its speed, which is correlated with the elasticity of the liver.

29. On information and belief, the control apparatus in FibroScan 502 Touch is also "configured to select an effective ultrasonic echo from the ultrasonic echo according to a duration of the vibration and physical parameters of the viscoelastic medium," "wherein the ultrasonic transducer probe stops vibrating and the elastic wave is propagated in the viscoelastic medium at a moment corresponding to the effective ultrasonic echo." Accused FibroScan Products have demonstrated an improvement on the speed of scan. In particular, earlier models of FibroScan products prior to 2014 required 5-10 minutes from boot-up to the first scan image being displayed on the monitor, and about 5-6 seconds for each additional image to be displayed. According to Echosens, their newer models, e.g., FibroScan 502 Touch, take about 1 minute to complete a scan. *See, e.g.*, Exhibit D, Echosens's Free Scan Promotion. It also has been observed that the Accused FibroScan Products take about 1 second between consecutive images (as opposed to 5-6 seconds on the older models). Based on information and belief, these improvements in speed are due to the selection for calculation of effective ultrasonic echo that correspond to a moment when the ultrasonic transducer probe stops vibrating and the shear wave is still propagating in the liver.

30. The control apparatus in FibroScan 502 Touch calculates "a propagation velocity of the elastic wave in the viscoelastic medium according to the effective ultrasonic echo."

Exhibit E, FibroScan 502 Brochure at 2 ("Liver equivalent stiffness"). *See also* Exhibit C, FibroScan 502 Touch 510(k) Summary, at 2:

Technological Characteristics
FibroScan® uses transient elastography for the non-invasive measurement of liver shear wave speed. A mechanical vibrator produces low-amplitude elastic waves that travel through the skin and intercostal space into the liver. Ultrasound is used to track the shear wave and to measure its speed, which is correlated with the elasticity of the liver.

31. The FibroScan 502 Touch includes "a pressure sensor array mounted between and contacted with the ultrasonic transducer probe and the vibrator, wherein the

control apparatus further comprises a pressure signal collecting circuit connected with one of a computer, a microprocessor and a microcontroller through a communication interface, and wherein the control apparatus detects with the pressure sensor array a pressure applied to the viscoelastic medium by the ultrasonic transducer probe and a verticality of the ultrasonic transducer probe relative to the viscoelastic medium, and wherein the control apparatus is further configured to start to detect the elasticity of the viscoelastic medium in response to the detected pressure and the detected verticality satisfying preset conditions." For example, a YouTube video at https://www.youtube.com/watch?v=H2ZiSZg6Dfc, which appears to be published by Echosens's official YouTube account, discusses applying pressure to a patient's skin and illumination of the probe light when suitable pressure is detected, whereupon an operator is instructed to trigger at least 10 consecutive measurements.

32. On information and belief, the accused FibroScan 530 Compact product operates the same way as the accused FibroScan 502 Touch product with respect to the relevant features and therefore also infringes the '771 patent. *See, e.g.*, Exhibit F, FibroScan 530 Compact Brochure, at p. 3 ("The FibroScan 530 Compact offers the same dual function capabilities and examination experience that you have come to expect from the FibroScan 502 Touch."); Exhibit G, Printout from Echosens's webpage at http://www.echosens.us/fibroscan-compact-530 ("Expanding innovation, the FibroScan® 530 Compact offers mobility with the same experience and consistent results that you have come to expect from the FibroScan® 502 Touch.").

33. On December 17, 2014, Echosens submitted a request to the State Intellectual Property Office of China, seeking to invalidate Hisky's Chinese patent, No.

200910235731.3 (the "Chinese '731 patent"). The Chinese '731 patent is the foreign counterpart to the '771 patent. Based on information and belief, and the actions taken by Echosens on the Chinese '731 patent, Echosens had knowledge of the '771 patent as of at least December 17, 2014, and, with knowledge of the '771 patent, has continued to knowingly infringe the '771 patent by selling and offering for sale in the United States the Accused FibroScan Products.

34. Echosens's infringement of the '771 patent has been and continues to be willful. Upon information and belief, Echosens has been aware of the '771 patent since on or about December 17, 2014. Echosens has acted and is continuing to act in an egregious and wanton manner by continuing to infringe the '771 patent when it knew or should have known that its actions constituted infringement. Echosens therefore has willfully infringed and continues to willfully infringe the '771 patent.

35. Based on information and belief, Echosens has induced and continues to induce others to infringe claims 1-3 and 5-12 of the '771 patent. Based on the actions taken by Echosens with respect to the Chinese '731 patent, Echosens had knowledge of the '771 patent as of at least December 17, 2014. With knowledge of the '771 patent, Echosens has induced and continues to induce others to directly infringe the '771 patent. For example, Echosens induces customers, including doctors, medical centers, and hospitals, and clinics[1] to directly infringe claims 1-3 and 5-12 of the '771 patent by providing materials, training aids, instructions for recommended use, a certification program, and instructional videos to those customers, which show the customers how use the Accused FibroScan Products in the infringing manner set forth in paragraphs 23-32,

[1] *See, e.g.*, Exhibit H, List of Medical Centers in Massachusetts with FibroScan systems.

supra. Echosens also induces distributors, sub-distributors, and intermediaries[2] to directly infringe the apparatus claims of the ’771 patent by inducing them to offer for sale and sell the Accused FibroScan Products in the United States. Echosens’s induces these distributors, sub-distributors, and intermediaries to offer for sale and sell the Accused FibroScan Products through distribution and sales agreements, comprehensive customer support services, and services relating to sales and marketing. These acts also constitute contributory infringement of method claims 1, 2, 3, and 5, as Echosens sells, offers for sale, and imports the Accused FibroScan Products for use in practicing the patented methods. On information and belief, no substantial noninfringing use exists for the Accused FibroScan Products.

36. Echosens does not have a license or permission to use the ’771 patent.

37. As a result of Echosens’s infringement of the ’771 patent, Hisky has been irreparably injured. Unless such infringing acts are enjoined by this Court, Hisky will continue to suffer additional irreparable injury.

38. As a result of Echosens’s infringement of the ’771 patent, Hisky has suffered, and continues to suffer, damage.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Hisky asks this Court to enter judgment in its favor against Echosens and grant the following relief:

A. a declaration that Echosens infringes the ’771 patent under 35 U.S.C. § 271(a) and/or (b) and a final judgment incorporating the same;

B. an award of enhanced damages as a result of Echosens’s willful infringement of the ’771 patent as provided by 35 U.S.C. § 284;

[2] *See, e.g.*, Exhibit I, List of Sales Representative in Massachusetts.

C. equitable relief under 35 U.S.C. § 283, including but not limited to, an injunction that enjoins Echosens and all persons and entities acting in concert with Echosens, from infringing the ’771 patent;

D. an order and judgment permanently enjoining Echosens and all persons and entities acting in concert with Echosens, from infringing the ’771 patent;

E. an award to Hisky of actual damages sufficient to compensate Hisky for Echosens’s acts of patent infringement of the ’771 patent, together with prejudgment and post judgment interest under 35 U.S.C. § 284;

F. a judgment holding that this is an exceptional case under 35 U.S.C. § 285 and awarding Hisky its reasonable attorney fees, costs, expenses, and interest; and

G. any further relief that this Court deems just and proper.

JURY DEMAND

Under Rule 38 of the Federal Rules of Civil Procedure, Hisky hereby demands trial by jury of all issues so triable by a jury in this action.

Dated: July 6, 2017

By: */s/ Christopher S. Schultz*

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