UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

REGENLAB USA LLC, Plaintiff, v. ESTAR TECHNOLOGIES LTD., ECLIPSE AESTHETICS LLC, HEALEON MEDICAL, INC., Defendants.	Civil Action No. 1:16-cv-8771 COMPLAINT **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff RegenLab USA LLC ("RegenLab" or "Plaintiff") brings this action against Defendants Estar Technologies Ltd. ("Estar"), Eclipse Aesthetics LLC ("Eclipse"), and Healeon Medical, Inc. ("Healeon") (collectively, "Defendants") and alleges as follows:

STATEMENT OF THE CASE

1. This is an action for patent infringement in violation of the Patent Laws of the United States, 35 U.S.C. § 271 *et seq*., and seeking injunctive relief and damages under 35 U.S.C. §§ 283 – 285, arising from the Defendants' unauthorized use of RegenLab's patented technology in connection with Defendants' making, using, actively inducing others to use, importing, offering to sell, and/or selling infringing products.

2. RegenLab brings this action to protect its reputation as an innovator, retain control over its intellectual property, prevent its technology from being unlawfully exploited by Defendants, and to avoid irretrievably lost sales.

3. RegenLab hereby seeks: (1) injunctive relief against Defendants' continued unauthorized, improper and willful commercial use and exploitation of its patented technology; and (2) all damages arising from Defendants' past and present infringement, including all statutory damages, and RegenLab's attorneys' fees and costs for having to bring this suit to enforce its rights.

PARTIES

4. RegenLab is a Limited Liability Company organized and existing under the laws of Delaware and having a place of business at 575 Madison Avenue, New York, NY 10022-2511.

5. RegenLab is an affiliate of Regen Lab SA, a corporation organized and existing under the laws of Switzerland and having a place of business at En Budron B2, 1052 Le Mont-sur-Lausanne, Switzerland. RegenLab, along with Regen Lab SA, is known throughout the world as a technology innovator and provider of medical and pharmaceutical products, which are distributed under the famous REGENLAB® brand. REGENLAB® and the products sold under this brand are known worldwide to be synonymous with superior technology and quality.

6. Upon information and belief, Estar is a corporation organized and existing under the laws of Israel and having a place of business at 15 Hamerkava St., Holon 5885111, Israel.

7. Upon information and belief, Estar is a manufacturer and distributor of medical and pharmaceutical products, including the infringing products at issue in this litigation.

8. Upon information and belief, Eclipse is a Limited Liability Company organized and existing under the laws of the State of Texas and having a place of business at 13988 Diplomat Dr., Ste. 180, Dallas, TX 75234-8833.

9. Upon information and belief, Eclipse is a distributor of Estar's medical and pharmaceutical products, including the infringing products at issue in this litigation.

10. Upon information and belief, Eclipse is affiliated with Estar.

11. Upon information and belief, Healeon is a corporation organized and existing under the laws of the State of California and having a place of business at 1111 Rancho Conejo Blvd., #204, Newbury Park, CA 91320.

12. Upon information and belief, Healeon is a distributor of Estar's and/or Eclipse's medical and pharmaceutical products, including the infringing products at issue in this litigation.

13. Upon information and belief, Healeon is affiliated with Eclipse.

JURISDICTION AND VENUE

14. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338. This Court also has diversity jurisdiction under 28 U.S.C. § 1332 because RegenLab and Defendants are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

15. Defendants have been doing business in this District, and have and are advertising, distributing, offering for sale, and selling products that infringe RegenLab's patent rights to persons located within this District.

16. Estar markets its products through physical sales and its operation of an interactive website, available at www.estar-medical.com. Estar's website is publicly accessible to consumers in New York and those throughout the U.S.

17. Eclipse markets and sells its products through physical sales and its operation of an interactive website, available at www.eclipseaesthetics.com. Eclipse's website is publicly accessible to consumers in New York and those throughout the U.S. Eclipse attends tradeshows

in New York and sells its products to consumers in New York, including the infringing products at issue in this litigation.

18. Healeon markets and sells its products through physical sales and its operation of an interactive website, available at www.healeonmedical.com. Healeon's website is publicly accessible to consumers in New York and those throughout the U.S. Upon information and belief, Healeon sells its products to consumers in New York, including the infringing products at issue in this litigation

19. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants: (1) transact business within this District; (2) contract to supply goods or services in this District; (3) have committed a tortious act within this District; (4) have committed a tortious act causing injury to RegenLab within this District; (5) regularly do or solicit business, or engage in other persistent course of conduct, or derive substantial revenue from goods used or consumed or services rendered, in this District; (6) expect or should reasonably expect their acts to have consequences in this District and derive substantial revenue from interstate or international commerce; (7) have systematic and continuous contacts with this District; (8) continue to transact and do business in this District; and (9) have websites and social media accounts that are accessible in this District.

20. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and/or 1400(b). A substantial part of the wrongful events giving rise to this action took place in this District and RegenLab has suffered harm in this District.

FACTS COMMON TO ALL CLAIMS FOR RELIEF

Background of Estar's Relationship to RegenLab

21. In 2006, Regen Lab SA signed a worldwide exclusive distribution agreement with

"A.P. Yamasaki and partners" for the commercialization of Regen Lab SA's platelet rich plasma therapy products. Mr. Yamasaki was the CEO of a company called Veritas based in Japan, which became a distributor for Regen Lab SA pursuant to the distribution agreement.

22. On information and belief, after becoming a distributor for Regen Lab SA, Veritas began working with Estar to develop a competing product called "Mycells."

23. Upon information and belief, Estar developed the Mycells product by copying RegenLab's patented technology.

24. Upon information and belief, Mr. Yamasaki's partners in the 2006 distribution agreement included Dr. J. Kubota in Japan and Dr. J. Otto in England.

25. Both Dr. J. Kubota and Dr. J. Otto were collaborators with Regen Lab SA, were sponsored and paid by Regen Lab SA, and conducted research using Regen Lab SA's equipment.

26. Upon information and belief, Estar developed the Mycells product with the help of Dr. J. Kubota and Dr. J. Otto using Regen Lab SA's clinical results.

27. Upon information and belief, Dr. J. Kubota and Dr. J. Otto presented Regen Lab SA's clinical results during the IMCAS congress in Bangkok in July 2009. This presentation was misleading because the clinical results were presented as if they were obtained using the Mycells product. Regen Lab SA never authorized such use of its clinical results by Estar, Dr. J. Kubota, or Dr. J. Otto.

28. On or about October 2008, Regen Lab SA learned that Veritas had become a Japanese distributor of Estar's Mycells product, which copied RegenLab's patented technology.

29. On or about June 2009, Regen Lab SA met with Estar and informed Estar that the Mycells product infringed its patent rights. Despite this, Estar continued to promote and sell infringing products, including those at issue in this litigation.

Background of Eclipse's Relationship to RegenLab

30. In January 2011, Eclipse became the U.S. distributor for Regen Lab SA's platelet rich plasma therapy products. The distribution agreement acknowledges Regen Lab SA's patent rights in the technology at issue in this litigation.

31. In April 2013, the U.S. Food and Drug Administration ("FDA") issued a cease and desist letter resulting from Eclipse's "off label" promotion of Regen Lab SA's products, including for cosmetic uses, which could significantly affect safety and/or effectiveness. According to the FDA, Eclipse was responsible for misbranding the products and, as a result, was liable for fraudulent promotional activities.

32. Shortly after the FDA letter in April 2013, Regen Lab SA terminated the distribution agreement with Eclipse due to Eclipse's serious breaches of U.S. regulations for the promotion of medical devices.

33. Regen Lab SA explained to the FDA that Eclipse was never authorized to use "off label" promotion and that it was not compliant with Regen Lab SA's own standards. Having taken this information into account, the FDA considered the matter closed.

34. As a consequence of its unlawful activities, Eclipse was forced to: i) acknowledge its breaches with the FDA; ii) take corrective actions; and iii) inform customers of its breaches, which it did in May 2013.

35. In communications to customers in May 2013, as well as in draft FDA communications sent to Regen Lab SA in April 2013, Eclipse acknowledged its breaches, even stating that "Eclipse Aesthetics acknowledges the off label brochures were circulated and is taking immediate action to correct and furthermore prevent future deficiencies."

36. Following termination of the distribution agreement between Regen Lab SA and Eclipse, Regen Lab SA incorporated RegenLab USA LLC (Plaintiff) to market and distribute its products in the U.S.

37. RegenLab hired Ms. Amy Batra and Mr. Sanjay Batra in July 2013. Ms. Batra was RegenLab's Office Manager and Mr. Batra was RegenLab's General Manager. Ms. Batra's and Mr. Batra's responsibilities included managing the marketing and distribution of RegenLab's products, and they were given special knowledge of RegenLab's technology and strategic plans.

38. In July 2013, Mr. Batra informed Regen Lab SA that Eclipse had introduced a competing product in the U.S. called "Eclipse PRP." Mr. Batra noted that the Eclipse PRP product "is a disaster and no physician will prefer it."

39. At or around October to November 2013, Regen Lab SA discovered that Ms. Batra and Mr. Batra were working for another company while at the same time working full time for RegenLab. Ms. Batra's and Mr. Batra's activities with that company included selling cosmetic products and attending tradeshows in the U.S.

40. RegenLab and the Batras terminated their relationship in March 2014.

41. RegenLab thereafter learned that both Ms. Batra and Mr. Batra were hired by Eclipse in March 2014 immediately following their termination by RegenLab. Their responsibilities for Eclipse included the commercialization of the Eclipse PRP product, which Mr. Batra had stated only a few months earlier was "a disaster."

42. Upon information and belief, Eclipse hired Ms. Batra and Mr. Batra because of their strategic positions within RegenLab, which gave them knowledge of RegenLab's confidential information, including customer lists, technical processes, product and marketing strategies, and business processes.

43. On information and belief, Estar and/or Eclipse and/or Healeon have and continue to exploit RegenLab's confidential information obtained from Ms. Batra and Mr. Batra to the detriment of RegenLab.

44. Termination of the distribution agreement between Regen Lab SA and Eclipse caused severe disruption to Regen Lab SA's sales activities in the U.S. As a consequence, RegenLab's sales in the U.S. suffered. RegenLab had and still has difficulties contacting customers who purchased its products through Eclipse. In addition, Eclipse now directly competes with RegenLab as it sells and promotes the infringing Eclipse PRP and/or Healeon PRP products.

The Infringing Eclipse PRP and Healeon PRP Products

45. In or about June 2013, Eclipse started selling the Eclipse PRP product in the U.S. This was less than two months after termination of the distribution agreement between Regen Lab SA and Eclipse.

46. Eclipse has sold and offered for sale, and continues to sell and offer for sale the Eclipse PRP product to RegenLab's past and potential customers.

47. The Eclipse PRP product is manufactured by Estar.

48. Upon information and belief, Eclipse is the sole distributor in the U.S. of the Eclipse PRP product.

49. Estar's Mycells product was approved by the FDA for use "to facilitate pre-mixing of allograft, autograft, or synthetic bone graft materials for application to an orthopedic surgical site" in a 510(k) titled "MyCells Autologous Platelet Preparation Kit" with number BK080057 (the "Mycells 510(k)").

50. Estar also developed a product called "Tropocells."

51. The Tropocells product was approved by the FDA for use to prepare platelet rich plasma that is "mixed with autograft and/or allograft bone prior to application to a bony defect" in a 510(k) titled "TropoCells Autologous Platelet Preparation Kit" and having number BK110035 (the "Tropocells 510(k)").

52. The Tropocells 510(k) states that the Tropocells product is substantially equivalent to the Mycells product, with the only material difference being that the Tropocells product "does not include a vial containing 10 CC of 10% calcium chloride solution."

53. The Tropocells product is substantially equivalent to the Mycells product.

54. According to FDA filings, Eclipse relabels the Tropocells product for distribution in the U.S. as the Eclipse PRP product.

55. Eclipse markets and distributes the Eclipse PRP product using the Tropocells 510(k).

56. The Eclipse PRP product is substantially equivalent to the Tropocells product.

57. The Eclipse PRP product is substantially equivalent to the Mycells product.

58. The Eclipse PRP product is only approved by the FDA for treating bony defects.

59. Eclipse has continued to unlawfully promote its products for "off label" uses despite assurances in 2013 that it was taking measures to prevent such actions.

60. In October 2015, the FDA issued another cease and desist letter to Eclipse for its "off label" promotion of the Eclipse PRP product, including for use in cosmetic dermatology and treatment of hair loss. The FDA letter states that Eclipse does not have "an approved application for premarket approval," its product is "misbranded," promotion has been "false and misleading," and that Eclipse should "immediately cease promoting Eclipse PRP™ for unapproved uses."

61. In March 2016, the FDA issued still another cease and desist letter to Eclipse, this time for its "MicroPen" that is used in combination with platelet rich plasma products. The FDA letter states that Eclipse does "not have an approved application for premarket approval," its product is "misbranded," there are "safety concerns," and that Eclipse should "immediately cease activities."

62. On information and belief, Healeon started selling its Healeon PRP product in the U.S. in 2014.

63. Healeon has sold and offered for sale, and continues to sell and offer for sale the Healeon PRP product to RegenLab's past and potential customers.

64. According to FDA filings, Eclipse relabels the Tropocells product as the Healeon PRP product.

65. Upon information and belief, Healeon is a distributor for Eclipse of the Healeon PRP product.

66. Upon information and belief, the Healeon PRP product is manufactured by Estar.

67. Healeon markets and distributes the Healeon PRP product using the Tropocells 510(k).

68. The Healeon PRP product is substantially equivalent to the Eclipse PRP product.

69. The Healeon PRP product is substantially equivalent to the Tropocells product.

70. The Healeon PRP product is substantially equivalent to the Mycells product.

The '957 Patent and RegenLab's Products

71. RegenLab is the exclusive licensee of U.S. Pat. No. 8,529,957 ("the '957 patent"), entitled "Cell preparations for extemporaneous use, useful for healing and rejuvenation in vivo," which was duly and legally issued by the United States Patent and Trademark Office on September

10, 2013. RegenLab's license includes all substantial rights under the '957 patent, including the right to sue in its own name and collect damages for any past, present, and future infringement.

72. The application that matured into the '957 patent published on December 24, 2009 as U.S. Pub. 2009/0317439.

73. The '957 patent claims priority to international application No. PCT/EP2007/058695, which was filed on August 21, 2007, which in turn claims priority to international application No. PCT/EP2006/065493, which was filed on August 21, 2006. Both applications published on February 28, 2008 as WO/2008/023026 and WO/2008/022651, respectively.

74. A number of continuation applications claim priority to the '957 patent. For example, U.S. App. No. 15/044498, entitled "Cell Preparations For Extemporaneous Use, Useful for Healing and Rejuvenation In Vivo," is currently pending before the U.S. Patent Office. U.S. App. No. 15/044498 published on June 9, 2016 as U.S. Pub. 2016/0158286.

75. RegenLab distributes products for preparing platelet rich plasma from a patient's own blood, including its RegenKit® products.

76. The RegenKit® products are marked with the '957 patent in accordance with 35 U.S.C. § 287.

77. Upon information and belief, Estar and/or Eclipse and/or Healeon copied the technology of the '957 patent when developing the Eclipse PRP and Healeon PRP products.

78. Upon information and belief, Estar and/or Eclipse and/or Healeon were aware of the '957 patent at the time of its issuance.

79. Upon information and belief, Estar and/or Eclipse and/or Healeon were aware of the U.S. application that matured into the '957 patent at the time of its publication in 2009.

80. Upon information and belief, Estar and/or Eclipse and/or Healeon were aware of the international applications to which the '957 patent claims priority at the time of their publication in 2008.

COUNT I
Infringement of the '957 Patent

81. RegenLab repeats and re-alleges each and every allegation in the foregoing paragraphs as if fully set forth herein.

82. Defendants are not authorized by RegenLab to use the technology of the '957 patent.

83. Upon information and belief, Defendants have been and still are directly infringing one or more claims of the '957 patent under 35 U.S.C. § 271(a) by making, using, selling, offering for sale, and/or importing infringing products without the authorization of RegenLab.

84. Upon information and belief, Defendants have been and still are actively inducing others to infringe one or more claims of the '957 patent under 35 U.S.C. § 271(b) through the sale, promotion, and/or instruction for use of infringing products. Upon information and belief, Defendants' sale, promotion, and/or instruction for use of infringing products have been and are made with the specific intent that those products be used to infringe the '957 patent.

85. Defendants are jointly and severally liable with each other as well as end-users who use Defendants' infringing products to infringe the '957 patent.

86. Upon information and belief, Defendants have not indemnified end-users for their infringement.

87. Upon information and belief, Defendants have purposefully and voluntarily placed infringing products in the stream of commerce with the expectation that those products will be purchased by end users in this District and elsewhere in the U.S.

88. Upon information and belief, Defendants have been and still are contributing to the infringement of one or more claims of the '957 patent by others under 35 U.S.C. § 271(c) through the sale, promotion, and/or instruction for use of infringing products. Upon information and belief, Defendants' infringing products are material to practicing the invention of the '957 patent, have no substantial non-infringing uses, and are known to Defendants to be especially made or especially adapted for use in infringing the '957 patent.

89. These allegations are based on RegenLab's current understanding of Defendants' products and RegenLab reserves to the right to amend them as more information becomes available.

90. Estar's and/or Eclipse's infringing products include the Eclipse PRP product. With regard to representative claim 20 of the '957 patent, on information and belief, the Eclipse PRP product is used to prepare a cell composition. On information and belief, the Eclipse PRP product is used to centrifuge whole blood in a separator tube selected from: a glass separator tube containing a polyester-based thixotropic gel and a buffered sodium citrate solution at 0.10 M; or a polyethylene terephthalate separator tube containing a thixotropic gel formed by a polymer mixture and an anhydrous sodium citrate at 3.5 mg/mL. On information and belief, the Eclipse PRP product is used to centrifuge at a force of about 1500 g up to about 2000 g for a sufficient length of time to form a barrier between full plasma containing platelets, lymphocytes and monocytes and a pellet containing the erythrocytes. On information and belief, the Eclipse PRP product is used to optionally separate enriched platelet rich plasma from full plasma by removing about half of the supernatant formed during the centrifuging step, said removed supernatant containing platelet poor

plasma, wherein the separation is made by collecting the supernatant from atop of said barrier; and wherein the enriched plasma is enriched in leucocytes, thrombocytes and adhesion proteins as compared to native whole blood. On information and belief, the Eclipse PRP product is used to re-suspend the enriched platelet rich plasma or the full plasma to form a platelet concentrate. On information and belief, the Eclipse PRP product is used to provide a cell extract comprising cells selected from the group consisting of adipocytes; adipose stem cells; fat cells; corneal cells; corneal limbal stem cells; cornea keratinocytes; dermal cells; fibroblasts; melanocytes; Langerhan's cells; bone marrow cells; muscle cells; satellite stem cells; myoblast progenitor stem cells; osteoblasts; chondrocytes; periosteal membrane cells; umbilical cord stem cells; stem cells; Schwann cells; cartilage cells; ligament cells; tendon cells; connective tissue cells, gingival cells and pancreas islet cells. On information and belief, the Eclipse PRP product is used to admix the platelet concentrate with the cell extract.

91. Estar's and/or Eclipse's and/or Healeon's infringing products include the Healeon PRP product. The Healeon PRP product is substantially similar to the Eclipse PRP product and infringes for the same reasons.

92. Defendants' infringement continues in willful disregard of RegenLab's rights, making this case exceptional under 35 U.S.C. § 285.

93. Estar and/or Eclipse and/or Healeon have had notice of the '957 patent since it issued on September 10, 2013.

94. Estar and/or Eclipse and/or Healeon have had notice of the patent applications underlying the '957 patent since before their infringement began. Under 35 U.S.C. §154(d), Defendants are liable for a reasonable royalty that adequately compensates RegenLab for infringements during the period between the dates of publication of the underlying patent

applications and the issuance of the '957 patent.

95. RegenLab has suffered and continues to suffer damage from loss of sales and customers by Defendants' infringement of the '957 patent, and claims all damages to which it is entitled, including but not limited to lost sales and profits and reasonable royalties.

96. The harm to RegenLab resulting from the infringing acts of Defendants is irreparable, continuing, not fully compensable by money damages, and will continue unless permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. That judgment be entered in favor of Plaintiff and against Defendants on each and every Claim in this Complaint;

B. That Defendants be adjudicated and decreed to have infringed, contributed to the infringement of, and/or induced the infringement of the '957 patent;

C. That a permanent injunction be entered against the Defendants, their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with the Defendants who receive actual notice of the injunction by personal service or otherwise, from any further infringement of the '957 patent pursuant to 35 U.S.C. § 283;

D. That Plaintiff be awarded its damages, suffered by reason of the infringements by Defendants, together with prejudgment interest;

E. That the damages awarded to Plaintiff be trebled pursuant to 35 U.S.C. § 284 due to the willful acts of infringement complained of herein;

F. That this be declared an exceptional case pursuant to 35 U.S.C. § 285;

G. That Plaintiff be awarded its attorneys' fees and costs; and

H. That Plaintiff be awarded any other and further relief that this Court may deem just and proper or otherwise permitted by law.

JURY DEMAND

Plaintiff demands a trial by jury on all claims and issues so triable.

Respectfully Submitted,

Date: November 11, 2016

/s/ Stephen Ball
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