

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 for injunctive relief and damages under 35 U.S.C. §§ 283 – 285, arising from Defendants’ unauthorized use of RegenLab’s patented technology in connection with Defendants’ using, actively inducing others to use, offering to sell, and/or selling accused 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 others, 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, Kanodia is a corporation organized and existing under the laws of the State of California and having a place of business at 521 Park Avenue, New York, NY 10065.

7. Upon information and belief, Kanodia is a purchaser, user, and promoter of medical and pharmaceutical products, including the accused products at issue in this litigation.

8. Upon information and belief, Garden City is a corporation organized and existing under the laws of the State of New York and having a place of business at 901 Stewart Avenue, Garden City, NY 11530.

9. Upon information and belief, Garden City is a purchaser, user, promoter, and distributor of medical and pharmaceutical products, including the accused products at issue in this litigation.

10. Upon information and belief, Goldenberg is a corporation organized and existing under the laws of the State of New York and having a place of business at 14 East 75th Street, New York, NY 10021.

11. Upon information and belief, Goldenberg is a purchaser, user, and promoter of medical and pharmaceutical products, including the accused products at issue in this litigation.

12. Upon information and belief, Primary Aesthetic is a business organized and existing under the laws of the State of New York and having a place of business at 460 Old Post Road, Suite 2G, Bedford, NY 10506.

13. Upon information and belief, Primary Aesthetic is a purchaser, user, and promoter of medical and pharmaceutical products, including the accused products at issue in this litigation.

14. Upon information and belief, NYMSS is a Limited Liability Company organized

and existing under the laws of the State of New York and having a place of business at 345 East 37 Street, Suite 301, New York, NY 10016.

15. Upon information and belief, NYMSS is a purchaser, user, and promoter of medical and pharmaceutical products, including the accused products at issue in this litigation.

16. Upon information and belief, Jacono is a Limited Liability Company organized and existing under the laws of the State of New York and having a place of business at 630 Park Ave., New York, NY 10065.

17. Upon information and belief, Jacono is a purchaser, user, and promoter of medical and pharmaceutical products, including the accused products at issue in this litigation.

18. Upon information and belief, Koru is a Limited Liability Company organized and existing under the laws of the State of New York and having a place of business at 341 East 78th Street, New York, NY 10075.

19. Upon information and belief, Koru is a purchaser, user, and promoter of medical and pharmaceutical products, including the accused products at issue in this litigation.

20. Upon information and belief, Jane or John Doe are additional purchasers, users, promoters, and distributors of medical and pharmaceutical products, including the accused products at issue in this litigation. RegenLab may seek to add them to this Complaint as they are identified.

JURISDICTION AND VENUE

21. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

22. Defendants have been doing business in this District, and have and are advertising, distributing, offering to sell, and/or selling products that infringe RegenLab's patent rights to persons located within this District, and are using the same in this District.

23. Kanodia resides in this district, has committed acts of infringement, and has a regular and established place of business in this district. Kanodia markets accused products through physical sales at its place of business in New York. Kanodia also markets accused products through operation of an interactive website, available at www.drkanodia.com, which is publicly accessible to consumers in New York and throughout the U.S.

24. Garden City resides in this district, has committed acts of infringement, and has a regular and established place of business in this district. Garden City markets accused products through physical sales at its place of business in New York. Garden City also markets accused products through operation of an interactive website, available at www.gardencityderm.com, which is publicly accessible to consumers in New York and throughout the U.S.

25. Goldenberg resides in this district, has committed acts of infringement, and has a regular and established place of business in this district. Goldenberg markets accused products through physical sales at its place of business in New York. Goldenberg also markets accused products through operation of an interactive website, available at <http://goldenbergdermatology.com/>, which is publicly accessible to consumers in New York and throughout the U.S.

26. Primary Aesthetic resides in this district, has committed acts of infringement, and has a regular and established place of business in this district. Primary Aesthetic markets accused products through physical sales at its place of business in New York. Primary Aesthetic also markets accused products through operation of an interactive website, available at www.primaryaestheticskincare.net, which is publicly accessible to consumers in New York and throughout the U.S.

27. NYMSS resides in this district, has committed acts of infringement, and has a

regular and established place of business in this district. NYMSS markets accused products through physical sales at its place of business in New York. NYMSS also markets accused products through operation of an interactive website, available at www.skincare NYC.com, which is publicly accessible to consumers in New York and throughout the U.S.

28. Jacono resides in this district, has committed acts of infringement, and has a regular and established place of business in this district. Jacono markets accused products through physical sales at its place of business in New York. Jacono also markets accused products through operation of an interactive website, available at www.newyorkfacialplasticsurgery.com, which is publicly accessible to consumers in New York and throughout the U.S.

29. Koru resides in this district, has committed acts of infringement, and has a regular and established place of business in this district. Koru markets accused products through physical sales at its place of business in New York. Koru also markets accused products through operation of an interactive website, available at www.korunyc.com, which is publicly accessible to consumers in New York and throughout the U.S.

30. Jane or John Doe reside in this district, have committed acts of infringement, and have regular and established places of business in this district. Jane or John Doe market accused products through physical sales at their places of business in New York. Jane or John Doe also market accused products through operation of interactive websites that are publicly accessible to consumers in New York and throughout the U.S.

31. 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.

32. 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 And Inducement By Estar/Eclipse

33. RegenLab alleges that a product sold under the brand “Eclipse PRP” is promoted for use, sold, offered to be sold, and used to infringe RegenLab’s patent rights. Estar Technologies Ltd. (“Estar”) is the manufacturer of this product, which Estar and its distributors market under various other brand names, including Healeon PRP, Tropocells, Mycells, and Cellenis (collectively, “accused products”).

34. Upon information and belief, Estar began developing accused products in 2006 to compete with RegenLab’s own products.

35. On or about June 2009, Regen Lab SA met with Estar and informed Estar that its products infringe its patent rights. Despite this, Estar has continued to promote and sell accused products, including those at issue in this litigation.

36. The Eclipse PRP product is distributed by Eclipse Aesthetics LLC (“Eclipse”).

Upon information and belief, Eclipse sells the Eclipse PRP product to Defendants, who then use, promote, offer to sell, and/or resell the Eclipse PRP product, with the knowledge and intent that the products be used to infringe RegenLab's patents rights.

37. Before Eclipse was a distributor for Estar, it was RegenLab's U.S. distributor. The January 2011 distribution agreement between RegenLab and Eclipse acknowledges RegenLab's patent rights. In fact, when Eclipse was RegenLab's distributor it marketed RegenLab's products as "patented." Despite this, Eclipse has continued to promote and sell accused products, including those at issue in this litigation, with the knowledge and intent that the products be used to infringe RegenLab's patents rights.

38. In April 2013, the U.S. Food and Drug Administration ("FDA") issued a cease and desist letter to Eclipse for "off label" promotion which could significantly affect safety and/or effectiveness. Shortly thereafter, Regen Lab SA terminated the distribution agreement with Eclipse due to Eclipse's serious breaches of U.S. regulations.

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

40. 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.

41. Upon information and belief, Estar and/or Eclipse copied RegenLab's products that incorporate RegenLab's patented technology to develop the Eclipse PRP product. RegenLab has filed suit against Estar and Eclipse for patent infringement, Case No. 16-cv-08771 (ALC) (S.D.N.Y.) ("Estar/Eclipse Case"), but Estar and Eclipse have argued they are not liable in New

York, leaving their New York customers to litigate on their behalf.

42. 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 accused products.

43. In March 2014, Eclipse hired former employees of RegenLab. Upon information and belief, Eclipse hired these employees 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. On information and belief, Estar and/or Eclipse have exploited and continue to exploit RegenLab's confidential information obtained from these employees to the detriment of RegenLab.

44. In October 2015, the FDA issued another a cease and desist letter to Eclipse for its "off label" promotion of the Eclipse PRP product. 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." 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."

45. With full knowledge of RegenLab's patent rights, Estar and Eclipse have actively induced their customers, including the Defendants in this litigation, to infringe RegenLab's

patent rights.

The Patents and RegenLab's Products

46. 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.

47. RegenLab is the exclusive licensee of U.S. Pat. No. 9,833,478 (“the ‘478 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 December 5, 2017. The ‘478 patent is a continuation of the ‘957 patent. RegenLab’s license includes all substantial rights under the ‘478 patent, including the right to sue in its own name and collect damages for any past, present, and future infringement.

48. The ‘957 and ‘478 patents claim 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.

49. A number of continuation applications claim priority to the ‘957 and ‘478 patents. For example, U.S. App. No. 15/044,498 is currently pending before the United States Patent and Trademark Office. This published on June 9, 2016 as U.S. Pub. 2016/0158286. U.S. App. No. 15/605,696 is also currently pending before the U.S. Patent Office, and published on September 14, 2017 as U.S. Pub. 2017/0258839.

50. RegenLab distributes products for preparing platelet rich plasma from a patient’s own blood, including its RegenKit® products. The RegenKit® products are marked with the

‘957 and ‘478 patents in accordance with 35 U.S.C. § 287.

The Filing of the Complaint in the Present Action

51. RegenLab filed the Complaint in the present action on May 22, 2017, (Dkt. 1), alleging patent infringement against Kanodia, Trifecta Health Medical P.C. (“Trifecta”), and Garden City (collectively “Original Defendants”). Soon afterward, in the Estar/Eclipse Case, Eclipse filed a motion to stay RegenLab’s case against the Original Defendants. In conjunction with Eclipse’s motion, Eclipse filed affidavits from the Original Defendants describing their use of the Eclipse PRP product. The affidavits were conclusory and incomplete, and did not address RegenLab’s claims of infringement. For example, Garden City’s declaration only addressed commercial promotion of “Eclipse PRP kits,” but said nothing of promotion of infringing methods of use of such kits. In any event, the Original Defendants’ affidavits evidence their direct infringement of the ‘478 patent. No defendant has argued that any structural limitation of the ‘957 or ‘478 patents is missing in the accused products.

52. In its motion, Eclipse also raised the so-called medical immunity provision of 35 U.S.C. § 287(c) in defense of RegenLab’s claims against the Original Defendants. Section 287(c) does not apply to the Original Defendants’ (or any defendants’) activities, or RegenLab’s claims of infringement, because (1) their activities are not a “medical activity” as defined by the statute; (2) Defendants’ activities are directly related to the commercial development, promotion, offer for sale, sale, and/or distribution of accused products, which activities fall outside Section 287(c); and (3) even if Section 287(c) were applicable, the statute only provides relief from liability, not a finding or judgment as to infringement.

53. Ultimately, the Court in the Estar/Eclipse Case denied Eclipse’s motion to stay and determined that RegenLab should not be enjoined from suing additional customers for their

commercial promotion and use of the Eclipse PRP product.

54. Upon information and belief, following the Court's denial of Eclipse's motion to stay, Estar and Eclipse have interceded in this litigation to frustrate resolution at the expense of Defendants. For example, Estar and Eclipse's press releases attest to their "defending" customers in New York. In a press release dated September 12, 2017, Estar and Eclipse state that "Eclipse and its manufacturer, Estar Technologies, Ltd. are currently defending the [Original Defendants] that Eclipse alleges RegenLab wrongly sued." In another press release dated December 18, 2017, Estar and Eclipse state "Eclipse and manufacturer Estar Medical pledge to step-in and defend Eclipse PRP customers sued or threatened to be sued by RegenLab"

55. Through their involvement, Estar and Eclipse have thwarted settlement discussions between RegenLab and Kanodia, and RegenLab and Garden City. By way of example, RegenLab sought settlement with Kanodia, Trifecta, and Garden City in the same manner. Kanodia and Garden City share the same counsel as Estar and Eclipse, while Trifecta is represented by independent counsel. Trifecta listened and gave credence to RegenLab's reasonable concerns of infringement and resolution was reached with respect to the '957 patent after Trifecta provided RegenLab more information. In contrast, RegenLab has not been able to resolve its claims against Kanodia and Garden City.

56. From the outset of the Estar/Eclipse Case, RegenLab has only sought to stop infringement of its patent rights in New York. Despite RegenLab's efforts, Estar and Eclipse continue to profit off RegenLab's proprietary technology in New York without consequence while inducing their customers to also infringe, creating liability for their customers that is independent of the liability accruing to them.

COUNTS I & II
Infringement of the '957 and '478 Patents

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

58. With regard to representative claim 20 of the '957 patent, on information and belief, the Eclipse PRP product is used by Defendants and/or their customers and/or others they induce 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.

59. With regard to representative claim 1 of the '478 patent, on information and belief, the Eclipse PRP product is a medical separator system for preparation of a platelet rich plasma. On information and belief, the Eclipse PRP product includes a tube containing only two additives, wherein said two additives are: a thixotropic gel disposed in the tube, said thixotropic gel being adapted for separating platelet rich plasma and including a polymer mixture; and an anticoagulant disposed in the tube, said anticoagulant including a buffered sodium citrate solution at 0.1 M. On information and belief, the Eclipse PRP product's tube is adapted to be centrifuged for a length of time wherein said thixotropic gel is adapted to separate blood cells in whole blood to provide a platelet concentrate containing less than 1% hematocrit.

60. Defendants are not authorized by RegenLab to use the technology of the '957 and '478 patents.

61. Defendants have not alleged that any claimed structural limitations of the '957 and '478 patents are missing in the Eclipse PRP product. Indeed, the only non-infringement argument that the Original Defendants have raised—that they do not perform the mixing step of the '957 patent—is irrelevant to RegenLab's new system claims in the '478 patent.

62. Upon information and belief, Defendants have been and still are actively inducing others to infringe one or more claims of the '957 and '478 patents under 35 U.S.C. § 271(b) through the offer for sale, sale, promotion, and/or instructions for use of accused products. Upon

information and belief, Defendants' offer for sale, sale, promotion, and/or instructions for use of accused products have been and are made with the specific intent and knowledge (or should have had knowledge) that those products be used to infringe the '957 and '478 patents. Defendants thereby induce and encourage others to infringe the '957 and '478 patents.

63. Upon information and belief, Defendants induce their customers to infringe the '957 and '478 patents when they promote, sell, and offer to sell the Eclipse PRP product. Upon information and belief, Defendants instruct their customers to use the Eclipse PRP product in an infringing way. This includes instructing customers to use the Eclipse PRP product in accordance with its packaged instructions, which address centrifuging blood and mixing platelet-rich plasma with cell extracts.

64. The Eclipse PRP product is regulated by the FDA. The Eclipse PRP product is packaged with instructions for use providing the FDA-approved intended use, which is directed toward mixing platelet rich plasma with a cell extract. Therefore, upon information and belief, promotion and use of the Eclipse PRP product infringes the '957 and '478 patents.

65. Many users of the Eclipse PRP product perform all of the steps of the '957 patent. (*See Estar/Eclipse Case, Dkt. 93.*) Eclipse stated during a hearing with the Court in the Estar/Eclipse Case that users of the Eclipse PRP product perform all the steps of the '957 patent. Upon information and belief, Defendants have knowledge of others' use of the Eclipse PRP product in an infringing way, and specifically seek to induce them to infringe the '957 patent through sale and promotion of the Eclipse PRP product. This includes use of the Eclipse PRP product according to packaged instructions.

66. In addition, upon information and belief, many users of the Eclipse PRP product perform all of the steps of the '957 patent through combination of use of the Eclipse PRP product

and a microneedling device, such as the Eclipse MicroPen or Eclipse MicroPen Elite (collectively, “Eclipse MicroPen”). Eclipse MicroPen is a device that punctures a patient’s skin with an array of needles. In the practice of combining use of the Eclipse PRP product and microneedling, plasma obtained with the Eclipse PRP product is administered on a patient’s skin, followed by a practitioner’s using the microneedling device on the skin, effectively admixing platelet rich plasma with a cell extract (e.g., from skin). In addition, practitioners can mix other cell extracts with platelet rich plasma to infringe RegenLab’s patents, such as stem cells, fat cells, or collagen.

67. Upon information and belief, Defendants’ promotion of the Eclipse PRP product with any microneedling device also induces infringement of the ‘957 patent. Likewise, Defendants’ promotion of use of the Eclipse MicroPen with any accused infringing product induces infringement of the ‘957 patent.

68. Upon information and belief, Defendants have been and still are directly infringing at least claim 20 of the ‘957 patent and at least claims 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, 13, 14, 17, 18, 19, and 20 of the ‘478 patent under 35 U.S.C. § 271(a) by using, selling, offering to sell, and/or promoting accused products in an infringing way without the authorization of RegenLab. RegenLab’s investigation is ongoing, and RegenLab reserves the right to assert additional claims at a later date.

69. Upon information and belief, Defendants’ infringement occurs in New York. This includes Defendants’ promotion, use, offer to sell, and selling of the Eclipse PRP product at their respective physical locations in New York.

70. Kanodia advertises the Eclipse PRP product on its website, www.drkanodia.com. Kanodia also has a video posted on its website showing its use of the Eclipse PRP product. These

activities induce customers to infringe by instructing them to use the Eclipse PRP product in an infringing way, as well as shows Kanodia's own use of the Eclipse PRP product.

71. Upon information and belief, Kanodia directly infringes the '957 and '478 patents at its location in New York by using the Eclipse PRP product in an infringing way. Upon information and belief, Kanodia offers a number of cosmetic treatments, some advertised on its website, which include using the Eclipse PRP product in an infringing way. For example, Kanodia's website shows the Eclipse PRP product multiple times:



www.drkanodia.com/cosmetic-plastic-surgery-beverly-hills/hair-growth/. Kanodia's website shows the Eclipse PRP product while referencing the FDA intended use: "The PRP is mixed with autograph or allograft bone prior to application to an orthopedic surgical site." Kanodia's website also has a link for purchasing its products:



www.drkanodia.com/cosmetic-plastic-surgery-beverly-hills/hair-growth/. These promotions and activities demonstrate direct infringement and induce customers to infringe by instructing them to use the Eclipse PRP product in an infringing way.

72. In addition, Raj Kanodia submitted a sworn declaration in the Estar/Eclipse Case attesting to use of the Eclipse PRP product at Kanodia’s office. This evidences direct infringement of the ‘478 patent.

73. Garden City advertises the Eclipse PRP product on its website, www.gardencityderm.com. For example, the website has a section titled “New Products at Garden City Dermatology” that lists the Eclipse PRP product next to other products that Garden City sells, including vitamins:

New Products at Garden City Dermatology



www.gardencityderm.com/index.html. The website also has a section titled “Our Products” that lists the Eclipse PRP product for sale at an “UNBEATABLE PRICE!” next to other products that Garden City sells, including vitamins:

Our Products

All Products



www.gardencityderm.com/new_products.html. These activities induce customers to infringe by instructing them to use the Eclipse PRP product in an infringing way. Upon information and

belief, Garden City directly infringes the '478 patent at its location in New York by distributing and using the Eclipse PRP product. Upon information and belief, Garden City offers a number of cosmetic treatments, some advertised on its website, which include using the Eclipse PRP product. For example, in the Estar/Eclipse Case, Dr. Theodore J. Daly submitted a sworn declaration on behalf of Garden City attesting to his purchase and use of the Eclipse PRP product at Garden City. These admissions evidence direct infringement of the '478 patent.

74. Goldenberg advertises the Eclipse PRP product on its website, www.goldenbergdermatology.com/. For example, the website has a section titled, "MICRONEEDLING TREATMENTS IN NEW YORK CITY" that states: "PRP or Platelet-Rich Plasma treatments are performed using the Eclipse PRP HC system." This promotion induces customers to infringe by instructing them to use the Eclipse PRP product in an infringing way.

75. Upon information and belief, Goldenberg directly infringes the '957 and '478 patents at its location in New York by using the Eclipse PRP product in an infringing way. Goldenberg offers a number of cosmetic treatments, some advertised on its website, which include using the Eclipse PRP product in an infringing way. For example, in the website section titled "MICRONEEDLING TREATMENTS IN NEW YORK CITY," Goldenberg provides a subsection called "Microneedling with Eclipse MicroPen," which states: "Micro-needling is performed using the Eclipse MicroPen, a cordless device with a microneedle tip and a high-speed motor. . . . For enhanced results, microneedling can be combined with **platelet rich plasma (PRP)**. . . . PRP enhances the treatment and helps stimulate collagen growth and skin recovery. . . . The best results are seen when patients combine microneedling with **PRP treatments.**" (emphases in original).

76. Goldenberg also advertises mixing platelet rich plasma with other cell extracts, including stem cells, which use results in infringement of the '957 patent. For example, Goldenberg's website has a section called "Stem Cell Aesthetics" that states: "Stem cell injections can be used alone or in combination with **platelet rich plasma** to promote hair follicle growth and support existing hair follicles." (emphasis in original). These promotions and activities induce customers to infringe by instructing them to use the Eclipse PRP product in an infringing way, as well as shows Goldenberg's own use of the Eclipse PRP product.

77. Primary Aesthetic advertises the Eclipse PRP product on its website, www.primaryaestheticskincare.net. For example, the website has a section titled, "What is Skin Micro-Needling" that displays a promotion of the Eclipse PRP product.

Advances In Platelet-Rich Plasma

PRP is a viable and intact concentration of human platelets in a small volume of plasma.



Features & Benefits

- Convenient Procedure: Takes less than 30 minutes
- Small Volume of Blood Required: Better patient tolerance
- Best Value – highest volume PRP Yield: ~6 mL's of PRP per 10 mL tube
- Optimum Platelet Recovery: 87% ± 10%
- Consistent platelet concentration – allowing for predictable performance
- Pure PRP: High-tech gel removes ~97.8% contaminating red blood cells
- No foreign components – Virtually eliminates the rise of adverse reactions
- Pyrogen Free
- FDA Clearance: 501(k) number: BK110035



Process

1. During a short office visit a small amount of a patient's own blood is drawn (similar to what is required for basic lab test) into a 10 mL vacuum collection tube containing a proprietary separator gel.
2. The tube is placed into a centrifuge and spun to isolate the platelet- rich plasma.
3. The contaminating red and white blood cells are displaced and located below the separator gel.
4. The PRP is ready for use according to the clinical use requirements; yielding ~6 mL's of autologous platelet-rich plasma (A-PRP).

<http://primaryaestheticskincare.net/micro-needling-bedford/>. This promotion induces customers to infringe by instructing them to use the Eclipse PRP product in an infringing way.

78. Upon information and belief, Primary Aesthetic directly infringes the ‘957 and ‘478 patent at its location in New York by using the Eclipse PRP product in an infringing way. Primary Aesthetic offers a number of cosmetic treatments, some advertised on its website, which include using the Eclipse PRP product in an infringing way. For example, in the website section titled, “What is Skin Micro-Needling,” Primary Aesthetic includes a subsection called, “The Eclipse MicroPen,” which provides a video clip from the television show, “The Doctors,” showing use of the Eclipse MicroPen. The subsection further includes an image of the Eclipse MicroPen and a statement that “Skin needling procedures are performed . . . with the use of the sterile Micropen needle head.”



<http://primaryaestheticskincare.net/micro-needling-bedford/>. These promotions and activities induce customers to infringe by instructing them to use the Eclipse PRP product in an infringing way, as well as shows Primary Aesthetic’s own use of the Eclipse PRP product.

79. NYMSS advertises the Eclipse PRP product on its website, www.skincarenyc.com. For example, the website has a section titled, “Micro-Needling with PRP (Platelet Rich Plasma) For Hairloss” that displays a promotion for the Eclipse PRP product:

Micro-Needling With PRP (Platelet Rich Plasma) For Hairloss



<http://skincarenyc.com/micro-needling-with-prp-platelet-rich-plasma-for-hairloss/>. NYMSS’s website shows the Eclipse PRP product while referencing the FDA intended use: “The PRP is mixed with autograph or allograft bone prior to application to an orthopedic surgical site.” This promotion induces customers to infringe by instructing them to use the Eclipse PRP product in an infringing way.

80. Upon information and belief, NYMSS directly infringes the ‘957 and ‘478 patents at its location in New York by using the Eclipse PRP product in an infringing way. NYMSS offers a number of cosmetic treatments, some advertised on its website, which include using the Eclipse PRP product in an infringing way. For example, NYMSS’s website has a section called “Micro-Needling with PRP For Acne Scars & Rejuvenation” with a subsection called “Eclipse PRP – Platelet Rich Plasma,” which provides “Eclipse PRP treatment is actually a combination of microneedling and the use of Platelet Rich Plasma. Our practice uses the Eclipse MicroPen® Elite microneedling with Platelet Rich Plasma or PRP from your blood.” The section called “Micro-Needling with PRP For Acne Scars & Rejuvenation” further includes an image of the Eclipse MicroPen:

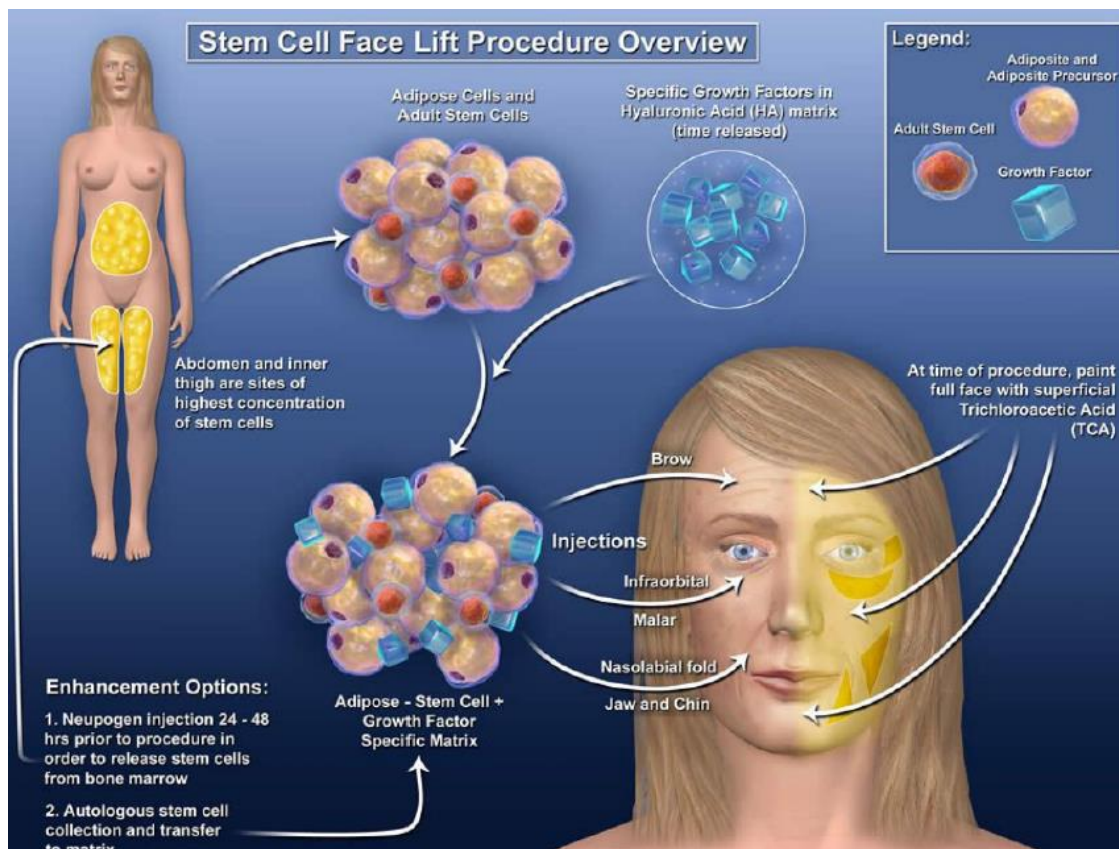


<http://skincare NYC.com/micro-needling-with-prp-platelet-rich-plasma-for-acne-scars-and-rejuvenation/>. These promotions and activities induce customers to infringe by instructing them to use the Eclipse PRP product in an infringing way, as well as shows NYMSS's own use of the Eclipse PRP product.

81. Jacono advertises the Eclipse PRP product on its website, www.newyorkfacialplasticsurgery.com/. For example, the website has a section titled, "DERMAPEN MICRO NEEDLING WITH PRP" that provides: "Dr. Jacono is proud to be one of a small group of top facial plastic surgeons offering the combination of two new innovations, using Dermapen Micro Needling of the skin with growth factor enriched Platelet Rich Plasma (PRP from Eclipse)." This promotion induces customers to infringe by instructing them to use the Eclipse PRP product in an infringing way.

82. Upon information and belief, Jacono directly infringes the '957 and '478 patents at its location in New York by using the Eclipse PRP product in an infringing way. Jacono offers a number of cosmetic treatments, some advertised on its website, which include using the Eclipse PRP product in an infringing way. For example, as described above, Jacono's website offers services utilizing the combination of microneedling and the Eclipse PRP product.

83. Jacono also advertises mixing platelet rich plasma with other cell extracts, including stem cells, which results in infringement of the '957 patent. For example, Jacono's website has a section called "STEM CELL FACELIFT," with a subsection called "How is a Stem Cell Facelift performed," which provides: "During this stem cell facelift procedure fat is suctioned from abdomen, thighs or flanks, and then is purified to maximize the number of Adult Derived Stem Cells that exist in the fat. Blood is then drawn from the patient and is processed to create platelet rich plasma (PRP) which is rich in growth hormones that is added to the fat already rich in stem cells. Adding this helps maximize the efficacy of the procedure. This mixture of stem cells, fat, and hormones is transferred back into deflated areas of the face, such as drooping cheeks and jawline." A graphic of the process is also included in the subsection:



<http://www.newyorkfacialplasticsurgery.com/stem-cell-facelift.html>. These promotions and activities induce customers to infringe by instructing them to use the Eclipse PRP product in an infringing way, as well as shows Jacono's own use of the Eclipse PRP product.

84. Koru advertises the Eclipse Micropen on its website, korunyc.com. For example, the website has a section titled, "COLLAGEN INDUCTION THERAPY/MEDICAL MICRONEEDLING," which includes a graphic showing the Eclipse Micropen:



<http://korunyc.com/collagen-induction-therapymedical-microneedling/>. This promotion induces customers to infringe by instructing them to use the Eclipse PRP product in an infringing way.

85. Upon information and belief, Koru directly infringes the '957 and '478 patents at its location in New York by using the Eclipse PRP product in an infringing way. Koru offers a number of cosmetic treatments, some advertised on its website, which include using the Eclipse PRP product in an infringing way. For example, in the website section called "COLLAGEN INDUCTION THERAPY/MEDICAL MICRONEEDLING," Koru includes a subsection called "ECLIPSE PRP – PLATELET RICH PLASMA," which provides, "Eclipse PRP treatment is actually a combination of microneedling and the use of Platelet Rich Plasma. Our practice uses the Eclipse Micropen® Elite microneedling with Platelet Rich Plasma or PRP from your blood." These promotions and activities induce customers to infringe by instructing them to use the

Eclipse PRP product in an infringing way, as well as shows Koru's own use of the Eclipse PRP product.

86. Estar and/or Eclipse have had notice of the '957 patent since it issued on September 10, 2013, and have had notice of the '478 patent since it issued on December 5, 2017.

87. Defendants have had notice of the '957 patent since it issued on September 10, 2013, and have had notice of the '478 patent since it issued on December 5, 2017.

88. Defendants are jointly and severally liable with Estar and/or Eclipse for infringement of the '957 and '478 patents.

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

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

91. RegenLab has suffered and continues to suffer damage from loss of sales and customers in New York and throughout the U.S. by Defendants' infringement of the '957 and '478 patents, and claims all damages to which it is entitled, including but not limited to lost sales and profits and reasonable royalties.

92. 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 and/or induced the infringement of the '957 and '478 patents;

C. That a permanent injunction be entered against Defendants, their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with Defendants who receive actual notice of the injunction by personal service or otherwise, from any further infringement of the '957 and '478 patents 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: March 1, 2018

/s/ Stephen Ball

Stephen Ball (SB0202)
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REGENLAB USA LLC

CERTIFICATE OF SERVICE

This is to certify that on this March 1, 2018, a true and correct copy of the foregoing **SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT** was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may access this filing through the court's CM/ECF System.

March 1, 2018
Date

/s/ Joan M. Burnett
Joan M. Burnett