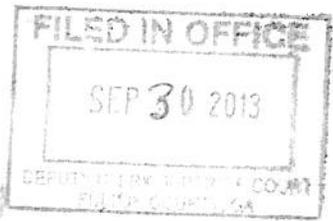


IN THE SUPERIOR COURT OF FULTON COUNTY
STATE OF GEORGIA



REGENICIN, INC.,)
)
Plaintiff,)
)
vs.)
)
LONZA WALKERSVILLE, INC.,)
LONZA GROUP LTD., LONZA)
AMERICA, INC.,)
)
Defendants.)
_____)

CIVIL ACTION NO.: _____

COMPLAINT FOR DAMAGES

In this matter, Plaintiff, Regenicin, Inc. ("Regenicin") seeks damages for breach of contract, breach of implied duty of good faith, tortious interference with business and contractual relations, unjust enrichment, quantum meruit, fraud, fraudulent inducement, negligent misrepresentation, violations of the Unfair Trade Practices Act, trademark infringement, patent infringement, conversion, state and federal civil RICO violations, and state and federal securities fraud against Lonza Walkersville, Inc. ("Lonza Walkersville"), Lonza America, Inc. ("Lonza America") and Lonza Group Ltd. ("Lonza Group") (collectively "Lonza") and complains as follows:

STATEMENT OF THE CASE

On July 21, 2010, Regenicin executed a Know-How License and Stock Purchase Agreement ("Regenicin/Lonza Know-How SPA") with Lonza Walkersville, an affiliate of Lonza Group. Pursuant to the Regenicin/Lonza Know-How SPA, upon consummation of a private offering and payment of Three Million Dollars (\$3,000,000.00) to Lonza Walkersville, Regenicin would receive an exclusive license to use certain proprietary know-how and

information necessary to develop and seek approval by the U.S. Food and Drug Administration (“FDA”) for commercial sale of a product called PermaDerm, a product derived from tissue-engineered skin prepared from autologous (patient’s own) skin cells. Further, under the Regenicin/Lonza Know-How SPA, Lonza Walkersville was to provide Regenicin with certain related assistance and support.

The Regenicin/Lonza Know-How SPA also provided that, once Regenicin secured FDA approval for commercial sale of PermaDerm, Regenicin would pay Lonza Walkersville an additional Two Million Dollars (\$2,000,000.00) to buy its subsidiary, Cutanogen Corporation, and that Lonza Walkersville would serve as Regenicin’s exclusive manufacturer and distributor for PermaDerm and would share in the product revenue.

Lonza determined early on that it would make more money on PermaDerm if PermaDerm was not approved by the FDA, which was contrary to the spirit and letter of the Regenicin/Lonza Know-How SPA. Unbeknownst to Regenicin, Lonza Walkersville never intended to fulfill its obligations under the Regenicin/Lonza Know-How SPA and even worse had given at least Thirteen (“13”) other companies the same “exclusive” license to use certain proprietary know-how and information necessary to develop and seek approval by the FDA that Lonza Walkersville gave Regenicin. Regenicin never had the exclusive license Lonza promised and never received the benefit of the Regenicin/Lonza Know-How SPA. Because of Lonza’s breaches and tortious conduct, Regenicin has lost millions of dollars in fees that it paid to Lonza Walkersville, which Lonza Walkersville did not earn, and hundreds of millions of dollars in consequential damages and lost opportunities.

PARTIES

1. Regenicin is a publicly-traded biotechnology company specializing in the

development of regenerative cell therapies to restore the health of damaged tissues and organs. Regenicin's principal office is located at 10 High Court, Little Falls, NJ, 07424. Regenicin is registered with the Georgia Secretary of State as a foreign corporation authorized to do business in Georgia and maintains a registered office in Fulton County, Georgia located at 3455 Peachtree Road, Suite 1500, Atlanta, Georgia 30326, where Paul M. Spizzirri serves as Regenicin's registered agent.

2. Regenicin Research of Georgia, LLC is a wholly owned subsidiary of Regenicin, Inc. ("Regenicin Research"). Regenicin Research is organized under the laws of Georgia as a domestic limited liability company organized. Regenicin Research maintains its principal office at 10 High Court Little Falls, New Jersey 07424 and has a registered agent in Georgia, Paul M. Spizzirri, at 3455 Peachtree Road, Suite 1500, Atlanta, GA 30326.

3. Upon information and belief, Lonza Group Ltd. ("Lonza Group") is a holding company organized under the laws of Switzerland with its principal office located at Muenchensteinerstrasse 38, CH-4002, Basel, Switzerland.

4. Lonza Group has several wholly-owned subsidiaries in North America. Three Lonza Group wholly-owned subsidiaries transact a significant amount of business in the State of Georgia, including in Fulton County -- Arch Treatment Technologies, Inc., Arch Chemicals, Inc. and Arch Wood Protection, Inc. These three Lonza Group wholly-owned subsidiaries own, use, or possess real and personal property situated in Georgia. Arch Treatment Technologies, Inc. is a foreign corporation authorized to do business in Georgia. Arch Treatment Technologies, Inc.'s principal office is located in Fulton County, Georgia at 5660 New Northside Drive, NW, Suite 1100, Atlanta, GA 30328. Arch Treatment Technologies, Inc.'s Georgia registered agent is Corporation Process Company located in Cobb County, Georgia at 328 Alexander Street, Suite

10, Marietta, GA 30060. Arch Chemicals, Inc. a foreign corporation authorized to do business in Georgia. Arch Chemicals, Inc. has three (3) offices in Fulton County, Georgia – 5660 New Northside Drive, Suite 1100, Atlanta, GA 30328; 1200 Bluegrass Lakes Parkway, Alpharetta, GA 30004; and 1400 Bluegrass Lakes Parkway, Alpharetta, GA 30004. Arch Chemicals, Inc.’s Georgia registered agent is Corporation Process Company located in Cobb County, Georgia at 328 Alexander Street, Suite 10, Marietta, GA 30060. Arch Wood Protection, Inc. is a foreign corporation authorized to do business in Georgia. Arch Wood Protection, Inc. maintains its principal office in Fulton County, Georgia at 5660 New Northside Drive NW, Suite 1100, Atlanta, GA 30328. Arch Wood Protection, Inc.’s Georgia registered agent is Candy Rainwater, located in Fulton County, Georgia at 5660 New Northside Drive, NW, Suite 1100, Atlanta, GA 30328.

5. Lonza America, Inc. (“Lonza America”) is a subsidiary of Lonza Group organized under the laws of Delaware as a corporation. Lonza America’s registered agent is National Corporate Research, Ltd. located at 615 S. DuPont Highway, Dover, DE 19901. Lonza America’s principal office is located in New Jersey at 90 Boroline Road, Allendale, NJ 07401. Lonza America transacts business in Georgia, including in Fulton County.

6. Lonza Walkersville, Inc. (“Lonza Walkersville”) is a wholly-owned subsidiary of Lonza Group. Lonza Walkersville is organized under the laws of Delaware as a corporation and maintains a principal office at 8830 Biggs Ford Rd, Walkersville Maryland. Lonza Walkersville is registered with the Georgia Secretary of State as a foreign corporation authorized to do business in Georgia. Lonza Walkersville’s registered agent in Georgia is National Corporate Research, LTD. located in Gwinnett County at 3675 Crestwood Parkway, Suite 350, Duluth Georgia 30096. Lonza Walkersville transacts business in Georgia, including, Fulton County.

Upon information and belief, Lonza Walkersville owns, uses, or possesses real or personal property situated in Georgia.

7. Upon information and belief, Lonza Group, Lonza Walkersville, Lonza America, Arch Treatment Technologies, Inc., Arch Wood Protection, Inc., Arch Chemicals, Inc. and other Lonza subsidiaries are operated by Lonza Group as a single business group headquartered in Basel, Switzerland known as “Lonza.” Lonza Group, Lonza America, Lonza Walkersville, Arch Treatment Technologies, Inc., Arch Wood Protection, Inc., Arch Chemicals, Inc. and other Lonza affiliates act in concert with one another under Lonza Group’s direction and control and present themselves to the marketplace as a unified entity, “Lonza,” that is a “global leader in the production and support of active pharmaceutical ingredients, both chemically and biotechnologically, as well as in microbial control,” according to www.lonza.com.

8. According to the “Lonza 2012 Annual Report,” the activities of Lonza, including those of its subsidiaries -- Lonza Walkersville, Lonza America, Arch Treatment Technologies, Inc., Arch Wood Protection, Inc., Arch Chemicals, Inc. and other Lonza subsidiaries, are organized into four operating divisions that are managed by a “Management Committee.” See a true and correct copy of the Lonza 2012 Annual Report filed herewith as **Exhibit “A”** and incorporated by this reference. The “Management Committee,” according to the “Lonza 2012 Annual Report,” is “responsible for leading Lonza and for developing and implementing the Lonza strategy after approval by the Board of Directors. It supports and coordinates the activities of the divisions and corporate functions.” Id.

9. In the “Lonza 2012 Annual Report,” Lonza Walkersville, Lonza America, Arch Treatment Technologies, Inc., Arch Wood Protection, Inc. and Arch Chemicals, Inc. are all identified as “subsidiaries,” defined as follows: “A subsidiary is an enterprise controlled by

Lonza Group Ltd. Control exists when the Company has the power, directly or indirectly, to govern the financial and operating policies of an enterprise so as to obtain benefits from its activities.” Id.

10. Financial statements of Lonza Group, Lonza America, Lonza Walkersville, Arch Treatment Technologies, Inc., Arch Wood Protection, Inc. and Arch Chemicals, Inc., along with other subsidiaries, are presented in the “Lonza 2012 Annual Report” on a consolidated basis. Id.

JURISDICTION AND VENUE

11. O.C.G.A. § 9-10-91(1) and (4) grant Georgia courts the unlimited authority to exercise personal jurisdiction over any nonresident who transacts any business in this state or “owns, uses, or possesses any real property situated within this state.”

12. Georgia law also allows the exercise of personal jurisdiction over a parent company that does business through one or more subsidiaries in Georgia.

13. The Fourteenth Amendment of the United States Constitution permits a state to exercise jurisdiction over an out-of-state defendant if that defendant has “minimal contacts” with the forum state “such that the maintenance of the suit does not offend traditional notions of fair plan and substantial justice.”

14. Lonza Group conducts business in Fulton County, Georgia through its wholly owned subsidiaries Arch Treatment Technologies, Inc., Arch Wood Protection, Inc. and Arch Chemicals, Inc. Lonza Group uses these subsidiaries for both production and sales. Accordingly, Lonza Group has a significant amount of agents and employees in Fulton County, Georgia – Arch Wood Protection, Inc. has One Hundred Five (105) employees in Atlanta, Georgia; Arch Chemicals, Inc. has Three Hundred Twenty-Nine (329) employees in Atlanta, Georgia; and Arch Treatment, Technologies, Inc. has more than Two Hundred (200) employees

in Atlanta, Georgia. Lonza Group's transactions through Arch Treatment Technologies, Inc., Arch Wood Protection, Inc. and Arch Chemicals, Inc. generate a significant amount of revenue for the Lonza Group.

15. Additionally, upon information and belief, Lonza Walkersville has transacted business in Georgia since at least 1991 and has had a registered agent in Georgia since that time.

16. This Court may exercise personal jurisdiction over Lonza Group consistent with the U.S. Constitution and O.C.G.A. § 9-10-91. Lonza Group, directly and/or through affiliates or subsidiaries under its direction and control that function in concert as ("Lonza") derives substantial revenue from Lonza services or products used or consumed in Georgia. Upon information and belief, Lonza has entered into and performed contracts with corporations domiciled in Georgia. Lonza has availed itself of the benefits of asserting and litigating a claim in Georgia. Lonza operates an interactive website at www.lonza.com which permits users, including Georgia residents, to order and to purchase products via the Internet from Lonza Group affiliates functioning as "Lonza" under Lonza Group's direction and control. In addition, upon information and belief, the Georgia activities of Lonza Walkersville, Lonza America, Arch Treatment Technologies, Inc., Arch Wood Protection, Inc., Arch Chemicals, Inc. and other Lonza affiliates, functioning in concert under Lonza Group's direction and control as a part of single business group known as "Lonza," may be attributed to Lonza Group for purposes of personal jurisdiction under principles of agency.

17. This Court may also exercise personal jurisdiction over Lonza Walkersville consistent with the U.S. Constitution and O.C.G.A. § 9-10-91. Upon information and belief, Lonza Walkersville has entered into and performed contracts with corporations domiciled in Georgia. Lonza Walkersville has availed itself of the benefits of asserting and litigating a claim

in Georgia. In addition, upon information and belief, Lonza Walkersville has had a consistent and continuous business presence in and has conducted transactions in the State of Georgia since at least 1991.

18. This Court may also exercise personal jurisdiction over Lonza America consistent with the U.S. Constitution and O.C.G.A. § 9-10-91. Lonza America, directly and/or through affiliates or subsidiaries under its direction and control that function in concert (“Lonza America”) derives substantial revenue from Lonza services or products used or consumed in Georgia. Upon information and belief, Lonza America has entered into and performed contracts with corporations domiciled in Georgia. Lonza America has availed itself of the benefits of asserting and litigating a claim in Georgia. Lonza America operates an interactive website at www.lonza.com which permits users, including Georgia residents, to order and to purchase products via the Internet from Lonza America affiliates. In addition, upon information and belief, the Georgia activities of Lonza Walkersville functioning in concert under Lonza America’s direction and control as a part of single business group may be attributed to Lonza America for purposes of personal jurisdiction under principles of agency.

19. Upon information and belief, Lonza Group, Lonza America, and Lonza Walkersville own, use, or possess real or personal property situated within the State of Georgia.

20. This Court has subject matter jurisdiction over this matter pursuant to GA. CONST., ART. 6, § 4, ¶ 1.

21. Venue is proper in this Court pursuant to O.C.G.A. § 14-2-510, O.C.G.A. § 9-10-93, GA. CONST., Art. 5, § 2, ¶6.

ALLEGATIONS COMMON TO ALL CLAIMS OF RELIEF

PermaDerm

22. PermaDerm is the only product derived from tissue-engineered skin prepared from autologous (patient's own) skin cells consisting of both epidermal and dermal layers. A proprietary collagen sponge is prepared and skin cells are added to produce a skin substitute that can be grafted surgically to wounds and result in permanent skin repair. A small harvested section of the patient's own skin can be grown to graft an area one hundred times its size in as little as thirty days.

23. These living, self-to-self skin graft tissues are intended to form permanent skin tissue that will not be rejected by the immune system of the patient, a critical possibility in porcine or cadaver skin grafts used today.

24. PermaDerm is a combination of cultured epithelium with a collagen-fibroblast implant that produces a skin substitute that contains both epidermal and dermal components. This model has been shown in preclinical studies to generate a functional skin barrier and in clinical studies to promote closure and healing of burns.

The 1998 Cutanogen License Agreement and the

2000 Cutanogen Shareholders' Agreement: Cutanogen Acquires PermaDerm

25. In or around 1998, PermaDerm product research and development was being led by Dr. Steven Boyce of the University of Cincinnati and Shriners Hospitals for Children.

26. The academic research and development of PermaDerm was licensed to and purchased by Cutanogen Corporation ("Cutanogen") by an agreement dated August 1998.

27. Dr. Boyce was a shareholder of Cutanogen and was its President. He has worked to develop PermaDerm and related technology at the University of Cincinnati and the Shriners

Hospitals over the past two (2) decades. Dr. Boyce obtained patent 7,741,116 Surgical device for skin therapy or testing on June 2, 2010.

28. On August 10, 2000, the Cutanogen shareholders entered into an agreement amongst themselves. See a true and correct copy of the Cutanogen Shareholders' Agreement filed herewith as **Exhibit "B"** and incorporated by this reference.

The Cutanogen SPA: CBSW Acquires Cutanogen

29. In a January 2006 Stock Purchase Agreement ("Cutanogen SPA"), Cutanogen shareholders sold their stock to a subsidiary of Cambrex Corporation known as Cambrex Bio Science Walkersville, Inc. ("CBSW"). See a true and correct copy of the January 2006 Stock Purchase Agreement ("Cutanogen SPA") filed herewith as **Exhibit "C"** and incorporated by this reference. Cambrex Corporation was a global, diversified life sciences company dedicated to providing products and services to accelerate and improve the discovery and commercialization of human therapeutics.

30. Cutanogen sold its stock in exchange for a specified dollar amount at closing, plus additional substantial amounts to be paid later upon the achievement of certain milestones with respect to the company's product.

31. Substantial additional payments, due to milestone achievement, were contractually contemplated within one (1) year.

32. Under Section 1.2 of the Cutanogen SPA, specified milestone payments ("Cutanogen Milestones") are required to be made based upon the achievement of certain events.

33. These milestone payments were apparently owed to Cutanogen shareholders but were not paid by Lonza until Cutanogen shareholders sued and settled with Lonza.

The October 2006 SPA: Lonza Acquires Cutanogen

34. On or about October 23, 2006, Cambrex Corporation, with its Bioproducts and Biopharma subsidiaries, including CBSW and Cutanogen, entered into a stock purchase agreement with Lonza America, Inc. (and with other companies related or affiliated with Lonza) for the sale of these businesses to Lonza.

35. Under the October 2006 SPA, Cambrex Corporation received cash consideration of Four Hundred Sixty Million Dollars (\$460,000,000.00), with a reported gain of Two Hundred Thirty-Two Million, One Hundred Sixteen Thousand Dollars (\$232,116,000.00) See a true and correct copy of the form 8-K for the October 2006 SPA filed herewith as **Exhibit “D”** and incorporated by this reference.

36. At the time of the transaction, the Bioproducts business manufactured and marketed research, therapeutic and analytical testing products based on cell biology and used in drug discovery and biotherapeutic manufacturing. The Biopharma business offered process development services and contract manufacturing under cGMP conditions for therapeutic proteins, vaccines, and other biologic drugs. When Lonza America acquired the Cambrex Corporation subsidiaries, Lonza decided that it did not want to be responsible for commercializing PermaDerm and did not want to be seen as a competitor to its clients. Lonza decided that it wanted to remain a manufacturer.

37. When Lonza America acquired the Cambrex Corporation subsidiaries, CBSW's name was changed to Lonza Walkersville.

Lonza Begins To Work With Randall McCoy And Ultimately Regenicin

38. In or around February 2006, CBSW entered into an agreement with McCoy Enterprises whereby McCoy Enterprises would provide FDA approval consultant services to

Lonza.

39. McCoy Enterprises and its principal, Randall McCoy, the eventual Chief Executive Officer of Regenicin, consulted with Lonza regarding PermaDerm FDA approval February through August, 2006. See a true and correct copy of McCoy Enterprises Invoices filed herewith as **Exhibit “E”** and incorporated by this reference.

40. During August, 2006 and 2007, 2008, 2009, Lonza had no plans to develop or commercialize PermaDerm. In 2007, it abandoned the PermaDerm trademark.

41. In or around 2007, McCoy Enterprises assisted CBSW to submit a pre-Investigational Device Exemption (“pre-IDE”) for PermaDerm to the FDA. CBSW and McCoy Enterprises then had a conference with the FDA to discuss the pre-IDE Package and at that meeting, FDA officials informed CBSW and McCoy Enterprises that the FDA would approve the IDE for PermaDerm if CBSW completed certain tasks, including but not limited to tech transfer studies on mice. McCoy and Lonza eventually completed a single mouse study to satisfy the FDA in Jan and Feb 2012 for the IND. However, neither CBSW nor Lonza Walkersville ever satisfactorily completed the tasks identified by the FDA at that 2007 meeting.

42. Lonza’s actions and inactions put the FDA approval and commercial development of PermaDerm in jeopardy. In so doing, Lonza also diminished Cutanogen’s value. Randall McCoy, however, still believed that he could get PermaDerm through the FDA-approval process and could develop and commercialize PermaDerm into a potentially life-saving and lucrative technology. He approached Lonza with an offer to purchase the know-how associated with PermaDerm and to then develop PermaDerm. In July 2007, Randall McCoy discussed with Lonza the possibility of McCoy Enterprises acquiring Cutanogen. While McCoy Enterprises and Lonza abandoned the idea of McCoy Enterprises purchasing Cutanogen, Lonza did eventually

enter into a Non-Binding Letter of Intent with another Randall McCoy company called PharmaDerm, LLC. See a true and correct copy of the April 23, 2008 Letter of Intent filed herewith as **Exhibit “F”** and incorporated by this reference.

43. Following the execution of Non-Binding Letter of Intent between PharmaDerm, LLC and Lonza, those two companies continued to conduct protracted acquisition negotiations. Those acquisition negotiations became more serious as Lonza Walkersville continued to suffer financially. In 2009, the Lonza Group announced tentative plans to shut down Lonza Walkersville due to poor performance and lack of profitability. In a last ditch effort to avoid closing Lonza Walkersville, Lonza pushed for Randall McCoy to close Vectoris’s acquisition of the PermaDerm know-how and Cutanogen by June 30, 2009.

44. Lonza Group was very involved with all facets of these acquisition discussions. Lonza Group had final approval over any agreements involving PermaDerm, including what would ultimately become the Regenicin/Lonza Know-How SPA.

The 2009 Vectoris/Lonza Know How SPA

45. To meet the June 30, 2009 deadline that Lonza imposed for the sale of the PermaDerm know-how and Cutanogen, Randall McCoy formed another company called Vectoris, Pharma, LLC (“Vectoris”) to close the deal in place of PharmaDerm. And Vectoris did enter into a Know-How Stock Purchase Agreement with Lonza Walkersville on or around June 30, 2009 (“Vectoris/Lonza Know-How SPA”).

46. Upon payment of Two Million Dollars (\$2,000,000.00) to Lonza Walkersville, Vectoris would receive an exclusive license to use certain proprietary know-how and information necessary to develop and seek approval by the U.S. Food and Drug Administration (“FDA”) for commercial sale of PermaDerm. The know how license also granted Vectoris

exclusive marketing and distribution rights world wide upon product approval. Further, under the Vectoris/Lonza Know-How SPA, Lonza was to provide Vectoris with certain related assistance and support.

47. In or around March 2009, on behalf of Lonza, Vectoris assisted Lonza to apply for and receive a grant from the Armed Forces Institute of Regenerative Medicine (“AFIRM”) for One Million, Five Hundred Thousand Dollars (\$1,500,000.00). See a true a correct copy of the AFIRM Grant Application filed herewith as **Exhibit “G”** and incorporated by this reference. The application noted that the projected advantages of PermaDerm had “been demonstrated in a clinical trial involving over fifty (50) pediatric patients” and explained that funding would support, among other things, the preparation and submission of an IDE application to the FDA to perform a limited study with PermaDerm in patients with full-thickness burns, involving greater than fifty percent (50%) of the Total Body Surface Area.

48. In or around August 2009, Vectoris entered into a manufacturing services agreement with Lonza (“Vectoris/Lonza Manufacturing Agreement”). See a true and correct copy of the Vectoris/Lonza Manufacturing Agreement filed herewith as **Exhibit “H”** and incorporated by this reference.

49. While Vectoris was raising the Two Million Dollars (\$2,000,000.00) required to complete the purchase of the PermaDerm know-how under the Vectoris/Lonza Know-How SPA, Randall McCoy of Vectoris, and Laurie Hahn, who at that time worked for Lonza but eventually would work for Regenicin, worked on the preparation of the FDA application.

50. Vectoris was raising the Two Million Dollars and Randall McCoy and Laurie Hahn were making progress on the FDA application, Lonza issued Vectoris a stop-work order in or around November 2009. Lonza explained that it would take control of the IDE application to

treat adults in a clinical trial and HDE packages to gain Orphan approval for children from the FDA for PermaDerm approval.

51. But Lonza did not tell Randall McCoy or Vectoris at that time that former Cutanogen shareholders had commenced a lawsuit against Lonza for Lonza's failure to make the milestone payments under the October 2006 SPA.

52. Around November 2009, Lonza applied for a grant from the Department of Defense.

53. Randall McCoy established Regenicin, Inc. as an alternate corporate entity designed to secure the funding demanded by Lonza to allow Randall McCoy to develop PermaDerm.

Cutanogen Shareholder Litigation Against Lonza

54. On October 22, 2009, former shareholders of Cutanogen filed a complaint against Lonza Walkersville alleging breach of the Cutanogen SPA.

55. The Cutanogen SPA provided that CBSW, which subsequently became Lonza Walkersville, would pay the shareholders a certain specified amount by closing, plus additional substantial amounts upon the achievement of certain "milestones" relating to the development and FDA approval of the company's product. The agreement further provided that CBSW would pay any and all unpaid milestone payments on an accelerated basis in the event of a merger, consolidation, or acquisition of Cutanogen by a third party.

56. In connection with the subsequent entry of the October 2006 SPA, Cambrex Corporation sold the stock of Cutanogen and other affiliated entities to Lonza America and received Four Hundred Sixty Million Dollars (\$460,000,000.00) in connection with the sale.

57. The former Cutanogen shareholders' lawsuit alleged that Lonza failed to make the

required milestone payments after the sale of the Cutanogen stock to Lonza America as required by the Cutanogen SPA and entry of the October 2006 SPA.

58. The former Cutanogen shareholders amended their complaint to include contract claims related to the entry of the Regencin/Lonza Know-How SPA, seeking accelerated milestone payments from Lonza.

**Termination Of Vectoris/Lonza Agreements And
Execution of Regencin/Lonza Know-How SPA**

59. In or around June 2010, Regencin entered into an agreement with Broadsmoore Group to raise money for Regencin's private offering. Regencin would use the money raised through the private offering, in part, to secure from Lonza an exclusive license to PermaDerm know-how and controlling interest in Cutanogen.

60. In connection with its private offering, Regencin prepared a Confidential Private Placement Memorandum ("Private Placement Memo"). The Private Placement Memo explained PermaDerm's role in Regencin's growth strategy and business plan, including the nature and purpose of the anticipated transaction with Lonza to secure Regencin's development of PermaDerm. Before Regencin shared that memorandum with any potential investors, Regencin emailed drafts of the Private Placement Memo to David Smith, Bradley Luria, and Scott Waldman (all with Lonza) for review, input and approval by Lonza. As an example, see a true and correct copy of an email dated July 19, 2010 which forwards an email dated July 18, 2010 including Messrs. Waldman and Luria, filed herewith as **Exhibit "I"** and incorporated by this reference. Before executing the Regencin/Lonza Know-How SPA, Lonza approved Regencin's release of the Private Placement Memo. See a true and correct copy of the Private Placement Memo dated July 21, 2010 filed herewith as **Exhibit "J"** and incorporated by this reference. Lonza also reviewed and edited presentation materials supporting the Private Placement Memo

and encouraged Regenicin's efforts to gain investors. See a true and correct copy of an email dated June 30, 2010 between Mr. McCoy and Mr. Smith filed herewith as **Exhibit "K"** and incorporated by this reference.

61. Randall McCoy became Chief Executive Officer of Regenicin on July 16, 2010.

62. On July 9, 2010, Regenicin filed to record the PermaDerm trademark. See a true and correct copy of the PermaDerm Trademark Printout filed herewith as **Exhibit "L"** and is incorporated by this reference. When McCoy informed Lonza that Regenicin had applied for the trademark to PermaDerm, Lonza expressed no objection.

63. As reflected in the Private Placement Memo, Regenicin intended "to develop and commercialize a potentially life-saving technology by the introduction of tissue-engineered skin substitutes intended to restore the qualities of healthy human skin. The success of our business plan is contingent, among other things, upon the successful implementation of the Lonza Transaction (including the payment of certain fees to Lonza and the later acquisition of its subsidiary, Cutanogen Corporation) and, the description of our business contained in this Memorandum assumes the closing thereof."

64. The Private Placement Memo described the "first stage" of the Lonza Transaction in which Regenicin would "receive, in exchange for the payment of \$3 million, an exclusive license to use certain proprietary 'Know-How' necessary to develop and seek the approval ('FDA Approval') by the FDA for the commercial sale of PermaDerm, including, without limitation, information relating to product specifications, manufacturing, testing, facilities, Master Batch Records and standard operating procedures, and Lonza will provide us with certain related assistance and support. The Regenicin/Lonza Know-How SPA also gave Regenicin exclusive rights for marketing and distribution world-wide. We believe we can create and

implement a successful strategy to conduct additional human clinical trials and to assemble and present other relevant information and data in order to obtain such approval for PermaDerm and possible related products in due course over the next few years.”

65. Upon receiving FDA Approval, the “second stage” of the Lonza Transaction contemplated that Regenicin “will execute a Stock Purchase Agreement pursuant to which the Company will purchase all of the outstanding stock of Cutanogen Corporation (‘Cutanogen’) from Lonza for an additional purchase price of \$2 million. Cutanogen holds certain exclusive licenses (the ‘Cutanogen Licenses’) to patent rights (‘Patent Rights’) owned by The Regents of the University of California and the University of Cincinnati and the Shriners Hospital for Children related to the commercialization of PermaDerm. Upon our acquisition of Cutanogen, we will obtain beneficial use of the Cutanogen Licenses.” The “second stage” also anticipated that Regenicin and Lonza would sign a Manufacturing Agreement and a Distribution Agreement, pursuant to which Regenicin would appoint Lonza as its exclusive manufacturer and distribution agent, respectively, for PermaDerm.

66. On or around July 21, 2010, Vectoris terminated both the Vectoris/Lonza Know-How SPA and the Vectoris/Lonza Manufacturing Agreement. See a true and correct copy of the Vectoris/Lonza Termination Letter filed herewith as **Exhibit “M”** and incorporated by this reference.

67. On July 21, 2010, Lonza Walkersville and Regenicin entered into a Know-How License and Stock Purchase Agreement with Regenicin (“Regenicin/Lonza Know-How SPA”). See a true and correct copy of the Regenicin/Lonza Know-How SPA filed herewith as **Exhibit “N”** and incorporated by this reference.

68. On August 13, 2010, Regenicin sold Four Million, Thirty-Two Thousand, Two

Hundred Fifty-Eight (4,032,258) shares of its common stock as a part of a Securities Purchase Agreement with certain accredited investors (the “Purchasers”) pursuant to an initial partial closing of a Private Placement Offering. See a true and correct copy of an August 13, 2010 SEC Form 8-K Report filed herewith as **Exhibit “O”** and incorporated by this reference.

69. As evidenced by the Regenicin/ Lonza Know-How SPA, both Regenicin and Lonza Walkersville intended for Regenicin to “assume responsibility for developing PermaDerm” and for Regenicin to “purchase the outstanding capital stock of Cutanogen Corporation.” (Regenicin/Lonza Know-How SPA, pg. 4). See also a true and correct copy of an April 11, 2011 Letter from Regenicin to the SEC filed herewith as **Exhibit “P”** and incorporated by this reference (including a summary of the parties’ obligations under the Regenicin/Lonza Know-How SPA).

70. In the Regenicin/Lonza Know-How SPA, Lonza Walkersville represented that it “owns all of the issued and outstanding capital stock of Cutanogen Corporation.” (Regenicin/Lonza Know-How SPA, pg. 4).

71. “Once the full FDA approval [was] achieved and [Regenicin] acquire[d] Cutanogen, Lonza [was to] serve as the [Regenicin’s] exclusive manufacturer and distributor and [would] be compensated for manufacturing.” See Exhibit “P”.

72. All parties to the Regenicin/Lonza Know-How and SPA negotiated it through the use of e-mail, telephone, facsimile, and mail communications. Bradley Luria, Scott Waldman, David Smith, Ralf Geier, Kelly Green, and possibly others, participated on behalf of Lonza. Lonza took the lead in drafting the agreement with input and proposed changes provided by the other parties. One point that Regenicin stressed during the negotiations as important and wanted to be clear was that “the know-how license granted under the agreement is exclusive and

worldwide.” Regenicin also wanted it to be clear that “the parties intend that the know-how license, when combined with the purchase of Cutanogen, should provide [Regenicin] with all rights related to the Contract Product, subject to Lonza’s retained rights under the agreement re manufacturing and distribution, etc., notwithstanding the caveat in paragraph 4.1 intending to avoid triggering milestone payments under the 2005 agreement between Lonza and former shareholders of Cutanogen.” Lonza accepted these changes. See a true and correct copy of an email dated July 20, 2010 filed herewith as **Exhibit “Q”** and incorporated by this reference. During these negotiations, Lonza did not disclose to Regenicin that former Cutanogen shareholders had filed a lawsuit against Lonza related to the previous Cutanogen SPA, nor did Lonza disclose to Regenicin that it had already sold the same “exclusive” licensing rights to numerous other companies, at least some of whom were obviously competitors of Regenicin.

Lonza’s Obligations And Breaches Under The Regenicin/Lonza Know-How SPA

73. Section 3.1 of the Regenicin/Lonza Know-How SPA, obligated Lonza Walkersville to provide Regenicin with “Current Know-How”.

74. Know-How means “information in support of a clinical trial for [PermaDerm], including, without limitation, information relating to product specifications, manufacturing, testing, facilities, etc. Know-How includes, but is not limited to, Master Batch Records and SOP’s.” (Regenicin/Lonza Know-How SPA, § 1.5).

75. Current Know-How is defined in the Regenicin/Lonza Know-How SPA as “Know-How that is in the possession of [Lonza Walkersville], and that exists on the effective date of this Agreement.” (Regenicin/Lonza Know How SPA, § 1.3).

76. Lonza Walkersville purported to provide Current Know-How to Regenicin via a disc. This disc included less than Two Hundred (200) pages of documents and only included

documents that were prepared or created before 2009. While Regenicin acknowledged receiving this disc in § 3.1 of the Regenicin/Lonza Know-How SPA, Regenicin never received and Lonza Walkersville never provided to Regenicin the Current Know-How required by the Regenicin/Lonza Know-How SPA.

77. Section 2.2(a) of the Regenicin/Lonza Know-How SPA obligated Lonza Walkersville to “produce and transfer Future Know-How to Regenicin”.

78. Future Know-How is defined in the Regenicin/Lonza Know-How SPA as “Know-How that is developed after the effective date of this Agreement by [Lonza Walkersville] at the reasonable request of Regenicin.” (Regenicin/Lonza Know-How SPA, § 1.4).

79. Regenicin made no less than Forty (40) requests to Lonza Walkersville for Future Know-How. See a true and correct copy of Regenicin’s Correspondence Requesting Future Know-How From Lonza filed herewith as **Exhibit “R”** and incorporated by this reference (including January 18, 2011 email and list of documents). But Lonza Walkersville never provided Future Know-How to Regenicin.

80. Section 2.2(b) of the Regenicin/Lonza Know How-SPA obligated Lonza Walkersville to “monitor prosecution and maintenance of Patent Rights.”

81. Section 1.6 of the Regenicin/Lonza Know-How SPA defines “Patent Rights” as “all patents and patent applications in any country or region of the world that cover [PermaDerm], and that are owned by or are licensed to [Lonza Walkersville] including, without limitation, the patents and patent applications that were licensed by [Lonza Walkersville] from the University of California, and from the University of Cincinnati and the Shriners Hospital for Children. A partial list of Patent Rights is set forth in Exhibit A.” See the partial list of Patent Rights filed herewith separately as **Exhibit “S”** and incorporated by this reference.

82. Even though Lonza invoiced Regenicin for “monitoring prosecution and maintenance of Patent Rights,” Lonza Walkersville never monitored prosecution of trademark and never maintained PermaDerm or TempaDerm trademarks in accordance with the Regenicin/Lonza Know-How SPA.

83. Section 2.2(c) of the Regenicin/Lonza Know-How SPA, obligated Lonza Walkersville to “maintain the Licenses.”

84. Even though Lonza invoiced Regenicin for “maintaining the Licenses,” Lonza Walkersville failed to maintain the Licenses in accordance with the Regenicin/Lonza Know-How SPA.

85. Additionally, Lonza Walkersville granted to Regenicin, and Regenicin accepted, an “exclusive license to use Know-How for the sole purposes of seeking FDA approval and, upon such approval, to use, market, offer for sale, sell and otherwise dispose of [PermaDerm] on a worldwide basis.”

86. As explained in more detail below, Lonza Walkersville failed to provide Regenicin with an “exclusive license” and, instead, granted the same “Know-How” to at least Thirteen (13) other companies around the world.

87. Section 4.3 of the Regenicin/Lonza Know-How SPA obligated Lonza Walkersville to transfer the results of the AFIRM Grant to Regenicin.

88. Lonza Walkersville never transferred the results of the AFIRM Grant to Regenicin.

89. Section 4.4 of the Regenicin/Lonza Know-How SPA obligated Lonza Walkersville to transfer the results of the Department of Defense Grant to Regenicin.

90. Despite billing Regenicin for the transfer of the DOD results, Lonza Walkersville

never transferred the DOD results to Regenicin.

91. In fact, between September 2010 and September 2011, Lonza Walkersville refused to provide Regenicin with any information relating to the DOD or AFIRM grants.

92. Section 2.2(d) of the Regenicin/Lonza Know-How SPA obligated Lonza Walkersville to execute the Stock Purchase Agreement.

93. Lonza never executed the Stock Purchase Agreement and made it impossible for the parties to achieve the conditions necessary for Regenicin and Lonza Walkersville to execute the Stock Purchase Agreement.

**Regenicin Satisfied Its Obligations under The Regenicin/Lonza Know-How SPA Or
Was Prohibited from Doing So by the Tortious and Other Conduct of Lonza in Breach of
That Agreement**

94. The Regenicin/Lonza Know-How SPA obligated Regenicin to pay Lonza Walkersville Three Million Dollars (\$3,000,000.00) before Lonza Walkersville's obligations under that agreement began. (Regenicin/Lonza Know-How SPA, Section 2.1).

95. Regenicin first paid Lonza Walkersville Seven Hundred Thousand Dollars (\$700,000.00) and, following the Initial Closing of its stock sale, dispersed to Lonza Walkersville the remaining Two Million, Three Hundred Thousand Dollars (\$2,300,000.00). See a true and correct copy of an August 13, 2010 SEC Form 8-K Report, attached hereto as Exhibit "O" and is incorporated by this reference.

96. Section 2.3(a) of the Regenicin/Lonza Know-How SPA obligated Regenicin to "reimburse [Lonza Walkersville] for transferring Current Know-How."

97. Regenicin met this obligation when it paid Lonza Walkersville Three Million Dollars (\$3,000,000.00). (Regenicin/Lonza Know-How SPA, § 6.1).

98. Section 2.3(b) of the Regenicin/Lonza Know-How SPA obligated Regenicin “to conduct pre-clinical and clinical trials” for PermaDerm.

99. Although Regenicin tried to meet this obligation under to § 2.3(b) of the Regenicin/Lonza Know-How SPA, Lonza Walkersville prohibited Regenicin from meeting this obligation and instructed Regenicin, in or around September 2010, after Lonza Walkersville received the DOD Grant, that Lonza Walkersville, not Regenicin, would “conduct pre-clinical and clinical trials”.

100. When Lonza Walkersville received the DOD Grant, Lonza Walkersville and Regenicin amended the Regenicin/Lonza Know-How SPA on or around September 15, 2010. See a true copy of the Amended Regenicin/Lonza Know-How SPA filed herewith as **Exhibit “T”** and incorporated by this reference. The only changes to the Regenicin/Lonza Know-How SPA related to the DOD Grant in that the DOD demanded to receive the most favorable price for PermaDerm. We will refer to the Amended Regenicin/Lonza Know-How SPA as Regenicin/Lonza Know-How SPA since the provisions of the two agreements are virtually the same.

101. Section 2.3(c) of the Regenicin/Lonza Know-How SPA obligated Regenicin “to apply for and obtain approval from the FDA for commercial sales of [PermaDerm].”

102. Regenicin tried to meet its obligation under to § 2.3(c) of the Regenicin/Lonza Know-How SPA. But Lonza Walkersville prohibited Regenicin from meeting this obligation and instructed Regenicin, in or around September 2010, after Lonza Walkersville received the DOD Grant, that Lonza Walkersville, not Regenicin, would “apply for and obtain approval from the FDA for commercial sales of [PermaDerm]”.

103. Section 2.3(d) of the Regenicin/Lonza Know-How SPA obligated Regenicin “to

reimburse [Lonza Walkersville] for providing Future Know-How.”

104. Since Lonza Walkersville never provided the Future Know-How to Regenicin, Regenicin never became obligated to reimburse Lonza Walkersville for the Future Know-How.

105. Section 2.3(e) of the Regenicin/Lonza Know-How SPA obligated Regenicin “to reimburse [Lonza Walkersville] for monitoring prosecution of Patent Rights.”

106. Lonza fraudulently invoiced Regenicin for “monitoring prosecution of Patent Rights” but Regenicin never received any proof that Lonza Walkersville actually completed this obligation. Regenicin paid Lonza approximately Sixty-Five Thousand Dollars (\$65,000.00) for monitoring services that Lonza Walkersville never substantiated were undertaken or completed. Regenicin met its obligation under § 2.3(e) of the Regenicin/Lonza Know-How SPA.

107. Section 2.3(f) of the Regenicin/Lonza Know-How SPA obligated Regenicin to “reimburse [Lonza Walkersville] for maintaining the Licenses.”

108. Lonza fraudulently charged Regenicin for “maintaining the Licenses” but Regenicin never received any proof that Lonza Walkersville actually completed this obligation. Regenicin paid Lonza approximately Sixty-Five Thousand Dollars (\$65,000.00) for Licensing services that Lonza Walkersville never provided. Regenicin met its obligation under § 2.3(f) of the Regenicin/Lonza Know-How SPA.

109. Section 2.3(g) of the Regenicin/Lonza Know-How SPA obligated Regenicin to “execute the Stock Purchase Agreement in accordance with Article 9.1.”

110. Regenicin could never execute the Stock Purchase Agreement portion of the Regenicin/Lonza Know-How SPA because Lonza prohibited all actions that would have caused the parties to reach this stage of the Regenicin/Lonza Know-How SPA.

111. Section 2.3(h) of the Regenicin/Lonza Know-How SPA obligated Regenicin to

“pay the purchase price for the outstanding capital stock of the Cutanogen Corporation.”

112. Regenicin could never purchase Cutanogen because Lonza prohibited all actions that would have caused the parties to reach this stage of the Regenicin/Lonza Know-How SPA.

113. Section 6.2 of the Regenicin/Lonza Know-How SPA obligated Regenicin to pay Two Million Dollars (\$2,000,000.00) to Lonza Walkersville upon the FDA’s approval of PermaDerm for commercial sale.

114. Regenicin could never fulfill its obligation under this portion of the Regenicin/Lonza Know-How SPA because Lonza prohibited all actions that would have caused the parties to reach this stage of the Regenicin/Lonza Know-How SPA.

115. Section 6.3 of the Regenicin/Lonza Know-How SPA obligated Regenicin to pay Lonza Walkersville Thirty-Three Percent (33%) of any money received by Lonza as a result of the AFIRM Grant in consideration for the development of PermaDerm and for the transfer of the results of the AFIRM Grant.

116. While Lonza did invoice Regenicin for the transfer of the AFIRM Grant results and Regenicin did pay Lonza for the AFIRM Grant results, Lonza never actually provided the complete AFIRM Grant results to Regenicin because Lonza never completed the required effort.

117. Section 6.4 of the Regenicin/Lonza Know-How SPA obligated Regenicin to pay Lonza Walkersville Thirty-Three Percent (33%) of any money received by Lonza as a result of the DOD Grant in consideration for the development of PermaDerm and for the transfer of the results of the DOD Grant.

118. While Lonza did invoice Regenicin for the transfer of the DOD Grant results and Regenicin did pay Lonza for the DOD Grant results, Lonza never actually provided the DOD Grant results to Regenicin.

119. Section 6.5 of the Regenicin/Lonza Know-How SPA obligated Regenicin to pay the milestone payments to the Cutanogen shareholders that Lonza was obligated to pay pursuant to the Cutanogen SPA and October 2006 SPA if Regenicin and Lonza Walkersville executed the Stock Purchase Agreement portion of the Regenicin/Lonza Know-How SPA.

120. Regenicin could never fulfill its obligation under this portion of the Regenicin/Lonza Know-How SPA because Lonza prohibited all actions that would have caused the parties to reach this stage of the Regenicin/Lonza Know-How SPA.

Lonza's Bad Faith and Misrepresentations

Lonza Gave Regenicin's Exclusive Licenses and Know-How Intellectual Property to No Fewer Than Thirteen (13) Other Companies

121. The Regenicin/Lonza Know-How SPA obligated Lonza to grant Regenicin an exclusive, worldwide license to use certain proprietary know-how and information necessary to develop and obtain approval from the FDA for the commercial sale of PermaDerm. Moreover, Lonza Walkersville agreed it would sell to Regenicin all outstanding stock of Cutanogen (which controlled certain exclusive patent licenses underlying PermaDerm) upon FDA approval of PermaDerm for the commercial sale of PermaDerm and payment of the additional Two Million Dollars (\$2,000,000.00) owed by Regenicin. However, before it entered into the Regenicin/Lonza Know-How SPA, Lonza executed agreements with the following companies to give these companies the same "exclusive licenses" and Know-How that it promised to Regenicin:

- (a) Advanced Biohealing;
- (b) Osiris Therapeutics, Inc.;
- (c) Bayer AG;
- (d) Intercytex Innovation;

- (e) Gamida Cell;
- (f) Athersys, Inc.;
- (g) Geron Corporation;
- (h) Keracure;
- (i) Mesoblast Limited Level
- (j) Smith and Nephew;
- (k) Pervasis;
- (l) Centocor, Inc.; and
- (m) Ethicon Inc (the “Thirteen Companies”).

122. Upon information and belief, each of the Thirteen Companies paid Lonza approximately Five Million Dollars (\$5,000,000.00) per year and a series of additional One Million Dollar (\$1,000,000.00) payments throughout the course of their respective PermaDerm license agreements with Lonza.

**The FDA Designation, PermaDerm Development and FDA-Approval Process, and
Clinical Trials**

123. Lonza made the following material misrepresentations to Regenicin relating to the FDA and PermaDerm development and FDA-Approval process and research:

- i. The Regenicin/Lonza Know-How SPA, the AFIRM grant application, the Private Placement Memo, and the Regenicin 8-K reports, which Lonza approved for dissemination to Regenicin investors, all provide a revealing snapshot and detailed summary of Lonza’s representations that formed the basis for the transactions included in the Regenicin/Lonza Know-How SPA. Lonza’s representations also formed the basis for Regenicin’s intended business plan for the development and commercialization of

PermaDerm. Lonza had the opportunity to review and make changes to these documents as necessary or appropriate. Moreover, Lonza, as the applicant on file with the FDA for PermaDerm, was the only entity able to communicate directly with the FDA.

ii. Lonza represented to Regenicin that prototypes of products had been used successfully to treat catastrophic burn injuries, chronic wounds, and congenital skin pathologies. Lonza also represented that preliminary data was being collected under a study monitored by the FDA, and that PermaDerm, a cultured skin substitute for burn treatment, had been designated by the FDA as a Humanitarian Use Device (HUD). Once a product receives a HUD designation, the developer of the product is guaranteed Seven (7) years market exclusivity for a specific indication following the product's approval by the FDA.

iii. Lonza represented to Regenicin and led Regenicin reasonably to believe that, like other skin substitutes of its kind, the FDA considered PermaDerm a medical device and that Lonza was seeking FDA approval for PermaDerm as a medical device, rather than as a biologic or drug designation, both of which have different requirements and take longer to approve. What Lonza did not tell Regenicin, and Regenicin did not know, was that, contrary to how Lonza was describing the status of PermaDerm's FDA approval and the strategy and timeline for developing and commercializing the use of PermaDerm, the FDA had warned Lonza that the FDA would not consider PermaDerm a medical device unless Lonza could demonstrate otherwise, which it had not.

iv. After obtaining Orphan Device designation, Lonza represented to Regenicin that it had already "commenced preparation of the HDE application" and expected to file it with the FDA "by the end of this year." The FDA has 6 months to

review HDE applications. After approval of HDE, sales of the HUD can begin. In March 2011, Regenicin was stunned to learn that, after approximately eight months of preparing PermaDerm for approval by the FDA as a medical device, that the FDA had sent a letter explaining that it had designated PermaDerm as a combination biologic/drug and that Lonza had known that the FDA had previously warned Lonza that it would not allow a medical designation unless Lonza showed why the FDA should do otherwise and it had failed to do so.

v. Lonza represented that Dr. Steven Boyce, one the creators of PermaDerm, would be a part of the team that would assist in getting PermaDerm approved and that this would be a favorable factor. However, Lonza knew that Dr. Boyce would not be helping Lonza and Regenicin due to the issues surrounding the lawsuit filed by former shareholders of Cutanogen.

vi. Lonza represented to Regenicin that it had access to reliable data from over One Hundred (100) completed PermaDerm clinical trials that Regenicin could use to support the FDA application for approval. On at least one (1) occasion in 2010 before executing the Regenicin/Lonza Know-How SPA, David Smith told McCoy that it would be easy to get approved by the FDA since they already had the data on One Hundred (100) PermaDerm patients and that he would get Regenicin access to that data. Even after March 2011 when Regenicin learned that the FDA had designated PermaDerm as a biologic/drug and had to completely re-work its application to meet the different requirements, Regenicin still believed that it could rely on the experience already gained from earlier trials of One Hundred (100) PermaDerm-treated patients. But in March 2012, when Regenicin questioned Lonza regarding the absence of the data, Lonza

explained that it had no access to the patient data; no intention to obtain the patient data; and no intention to use the patient data to assist with the FDA approval. Ellen Colket stated in an e-mail that “we are at this time unable to access any of the data from University of Cincinnati.” See email dated March 30, 2012 filed herewith as **Exhibit “U”** and incorporated by reference. Soon after, David Smith of Lonza admitted that the patient data would not be available for the application because he refused to pay the University of Cincinnati One Million Dollars (\$1,000,000.00) for access to the data, which had been improved based on previous feedback from the FDA. As a result, Regenycin had no prior human experience to include in the PermaDerm FDA application and had to approach the PermaDerm FDA application as a new and untested drug.

vii. Lonza misrepresented to Regenycin that the DOD had awarded Lonza Sixteen Million, Eight Hundred Thousand Dollars (\$16,800,000.00) for PermaDerm clinical trials and other activities related to PermaDerm when in fact the amount was much less. In November 2010, Lonza Group publicly repeated its claims regarding the amount of the DOD award at a conference attended by Regenycin. Lonza Group also made an announcement for the news wires that it had received more than Eighteen Million Dollars (\$18,000,000.00) in U.S. Defense funding to develop PermaDerm. See Biomedreports.com news report filed herewith as **Exhibit “V”** and incorporated by reference. Melanie Disa, a spokesperson for Lonza Group, said for the news wires on Thursday, November 11, 2010, that Lonza Walkersville’s unit received a One Million, Five Hundred Thousand Dollar (\$1,500,000.00) grant and a Sixteen Million, Eight Hundred Thousand Dollar (\$16,800,000.00) contract to develop and commercialize its PermaDerm product. Ms. Disa was also stated that “clinical trial should begin in early

2011.” Lonza not only misrepresented to Regenicin the amount of the grant when Lonza knew the grant was much less, but Lonza also reviewed and approved all press releases issues by Regenicin relating to their agreement and approved press releases sent out by Regenicin in November 2010 which reflected the wrong amount of Sixteen Million, Eight Hundred Thousand Dollar (\$16,800,000.00) for the award.

viii. Lonza misrepresented to Regenicin that Lonza was going to start clinical trials on adults, specifically Soldiers, in January 2011. To start clinical trials necessarily meant that Lonza had accomplished numerous expensive and time-consuming prerequisites, including but not limited to setting up clinical trial sites. In actuality, Lonza knew when it made that representation to Regenicin that additional clinical trials would never occur by January 2011. That is because Lonza knew that its preparation of an application to the FDA for approval of PermaDerm as a medical device would be rejected since the FDA had already notified Lonza that it considered PermaDerm a biologic or drug.

ix. Lonza misrepresented to Regenicin that Lonza had a viable supplier to manufacture and supply collagen substrates;

x. Lonza misrepresented to Regenicin that Lonza had been able to grow PermaDerm;

xi. Lonza misrepresented to Regenicin that PermaDerm was going to be available for patients in Twenty-Eight (28) days when the patient was admitted to the hospital for front side of the patient and Fourteen (14) additional days for back side of the patient;

xii. Lonza misrepresented to Regenicin that PermaDerm was applying for

FDA approval as a device with no reason to believe that the FDA would consider it as anything other than a drug or biologic. But see a true and correct copy of a March 14, 2011 SEC Form 8-K filed herewith as **Exhibit “W”** and incorporated by this reference.

xiii. Lonza misrepresented to Regenicin that Lonza had access to patient data from the University of Cincinnati that could be used to support the FDA application;

xiv. Lonza misrepresented to Regenicin that Lonza had transferred all Know-How to Regenicin;

xv. Lonza misrepresented to Regenicin that Lonza completed Patent Right monitoring services;

xvi. Lonza misrepresented to Regenicin that Lonza completed License maintenance services;

xvii. Lonza misrepresented to Regenicin that the DOD Grant information was confidential;

xviii. Lonza misrepresented to Regenicin that Lonza completed a Pre-Investigational Device Exemption (IDE) meeting and an IDE Application, which would allow Lonza to conduct tests on the device and use it on humans;

xix. Lonza misrepresented to Regenicin that Lonza completed two different successful and viable animal studies;

xx. Lonza misrepresented to Regenicin that Regenicin would be able to collect One Million Dollars (\$1,000,000.00) from DOD Grant to offset its costs. But see a true and correct copy of the June 19 and 22, 2012 emails from Dave Smith filed herewith as **Exhibit “X”** and incorporated by reference.

xxi. Lonza misrepresented to Regenicin that Lonza was not engaged or

involved in any law suits when in fact Lonza had been sued by former Cutanogen shareholders before entering the Regenicin/Lonza Know-How SPA. Regenicin learned about the lawsuit on December, 2011. In August, 2012, Lonza provided Regenicin with a copy of letter that Lonza had previously received from attorneys representing the former Cutanogen shareholders. That letter informed Regenicin that certain former Cutanogen shareholders had filed suit against Lonza in 2009 and had met with Lonza in June 2010 – the same time when Lonza and Regenicin conducted negotiations regarding the Regenicin/Lonza Know-How SPA. In January 2012, certain of the former Cutanogen shareholders filed a motion to amend their complaint to add claims involving Regenicin. Also in January 2012, Lonza sent Regenicin a formal notice demanding that Regenicin indemnify Lonza against the former Cutanogen shareholder claims.

xxii. Lonza misrepresented to Regenicin that Lonza was complying with DOD Grant requirements;

xxiii. Lonza misrepresented to Regenicin that Lonza would conduct Twenty (20) patient and Forty (40) patients trials before August 2012;

xxiv. Lonza misrepresented to Regenicin that Lonza had a viable registered collagen scaffold manufacturer;

xxv. Lonza misrepresented to Regenicin that PermaDerm would have a two (2) week shelf life; and

xxvi. Lonza misrepresented to Regenicin that Lonza would compensate Randall McCoy for consulting services.

xxvii. Lonza misrepresented to Vectoris and also Regenicin that Lonza would compensate Randall McCoy and Lauri Hahn for consulting services out of proceeds from

the AFIRM AND DOD.

Lonza's Bad Faith And Tortious Interference

124. In addition to the above-referenced material misrepresentations, the following Lonza actions illustrate Lonza's bad faith and interfering actions:

(a) Lonza abandoned the PermaDerm trademark and received notice that Regenicin applied for the PermaDerm trademark, yet Lonza aggressively attempted to stop Regenicin from recording the PermaDerm trademark;

(b) Lonza refused to cooperate with the FDA or comply with the FDA's explicit instructions and prevented Regenicin from bringing the PermaDerm approval process into compliance with the FDA's instructions;

(c) Lonza changed the PermaDerm manufacturing process without instructing or consulting with Regenicin or the proper experts;

(d) Lonza charged Regenicin for services that were never authorized or provided;

(e) Lonza refused to share important information with Regenicin;

(f) Lonza refused to approve almost all press releases and presentations that Regenicin prepared in order to satisfy Regenicin's obligations with Broadsmoore and Regenicin Shareholders; and

(g) Lonza sent correspondence to various contractors and businesses instructing them not to communicate with Regenicin about PermaDerm.

Lonza's Wrongful Termination of The Regenicin/Lonza Know-How SPA

125. On or around May 17, 2012, Lonza sent Regenicin a letter and Notice of Breach of Know-How License and Stock Purchase Agreement claiming that Regenicin had breached the

Regenicin/Lonza Know-How SPA by failing to pay outstanding invoices amounting to One Million, Eighteen Thousand, One Hundred Fifty-three and Sixty-Six Cents (\$1,018,153.66). See a true and correct copy of Lonza's May 17, 2012 Letter filed herewith as **Exhibit "Y"** and incorporated by this reference.

126. On or around July 20, 2012, Regenicin responded to Lonza's May 17, 2012 Letter and also provided Lonza with a Notice of Breach that detailed many, but not all, of Lonza's numerous breaches under the Regenicin/Lonza Know-How SPA. See a true and correct copy of Regenicin's July 20, 2012 letter filed herewith as **Exhibit "Z"** and incorporated by this reference.

127. Lonza refused to correct any of breaches, despite Regenicin's best efforts to mitigate the damage that Lonza caused. Accordingly, the Regenicin/Lonza Know-How SPA terminated as of July 2012.

128. By the end of 2011, Lonza was negotiating to sell one of its biotech facilities to a Chinese company for Seven Hundred Fifty Million Dollars (\$750,000,000.00). However, the Chinese company insisted that Lonza license to it the PermaDerm Know-How technology and the marketing and distribution rights held by Regenicin.

129. Approval of PermaDerm for commercial use in China would have occurred immediately upon or shortly after consummation of the Lonza biotech facility sale to the Chinese company.

130. Lonza never intended to and never did fulfill its obligations under the Regenicin/Lonza Know-How SPA and when it was presented with a business opportunity with the Chinese company, it fabricated breaches that it alleged Regenicin committed to terminate the Regenicin/Lonza Know-How SPA. However, it was Lonza, and not Regenicin that breached the

Regenicin/Lonza Know-How SPA.

Regenicin's Damages

131. Regenicin has been damaged by Lonza's breach of contract and tortious conduct in the amount of Four Million, Thirty-Eight Thousand, and Seven Hundred Forty-One Dollars (\$4,038,741.00) as follows:

(a) Three Million Dollars (\$3,000,000.00) for the licensing of PermaDerm intellectual property rights that were not provided to Regenicin;

(b) Two Hundred One Thousand, One Hundred Ninety-Seven Dollars (\$201,197.00) overpayment when Regenicin/Lonza Know-How SPA was initially executed;

(c) Two Hundred Sixteen Thousand, Nine Hundred Fifty Dollars (\$216,950.00) in overcharges under the AFIRM Grant;

(d) One Hundred Ten Thousand, Two Hundred Fifty Dollars (\$110,250.00) in unpaid fees owed to Regenicin;

(e) Five Hundred Ten Thousand, Three Hundred Forty-Four Dollars (\$510,344.00) in cash payments;

132. For Regenicin to obtain FDA approval of PermaDerm now will require Regenicin to undertake the following tasks and incur the following costs and delays: 1) Finish development of the original PermaDerm product; 2) Obtain the August 2010 PermaDerm patent, which will take approximately Twelve (12) months to secure the required technology transfer; 3) Re-commence the FDA-Application Process, which will involve approximately Six (6) months; 4) Complete the FDA-Application Review Process, which will involve approximately Four (4) months; 5) Conduct One (1) year of monitored clinical trials; 6) Obtain clinical data from

University of Cincinnati, which will involve approximately Six (6) months; and 7) Await FDA approval of application for commercialization of PermaDerm, which will involve Nine (9) months to One (1) year. Regenicin would not have to undertake any of these additional tasks nor incur the associated delays had Lonza honored its obligations under the Regenicin/Lonza Know-How SPA. To obtain the benefits of the bargain that it had with Lonza, Regenicin will now have to expend at least One Hundred Million Dollars (\$100,000,000.00). Just conducting clinical trials to collect the One Hundred (100) pediatric patients' clinical data that Lonza was to have delivered to Regenicin will cost in excess of Sixty Million Dollars (\$60,000,000.00) – One Hundred Seventy Thousand Dollars (\$170,000.00) to produce the required amount of PermaDerm for One Hundred (100) patients; Ten Million Dollars (\$10,000,000.00) to conduct surgery and treatment on One Hundred (100) patients at a cost of One Hundred Thousand Dollars (\$100,000.00) per patient; Fifty-Four Million Dollars (\$54,000,000.00) to provide Sixty (60) days of critical care to One Hundred (100) patients at a cost of Nine Thousand Dollars (\$9,000.00) per patient per day.

133. Lonza was supposed to provide a manufacturing facility for PermaDerm and Regenicin has suffered \$40,000,000 in damages relating to Lonza's failure to provide a manufacturing facility and services to Regenicin.

134. Regenicin lost a significant amount of opportunity in the market between 2010 and 2013. Had Lonza Walkersville honored its obligations under the Regenicin/Lonza Know-How SPA, Regenicin would have had FDA approval for the commercialization of PermaDerm in the United States by the Second Quarter of 2012. And by August 2012, Regenicin would have owned controlling ownership interest in Cutanogen. By depriving Regenicin of the know-how and technology to which it was entitled, Lonza Walkersville cost Regenicin the opportunity to

license PermaDerm internationally. Conservative estimates of the value of royalties from the licensing of PermaDerm in the non-U.S. market exceed Two Hundred Fifty Million Dollars (\$250,000,000.00) per year starting in 2010. Furthermore, by providing PermaDerm Know-How to the Thirteen Companies, Lonza wrongfully converted for its own gain Regenicin's opportunity to collect the license fees or royalties from the Thirteen Companies. Upon information and belief, those actions of Lonza damaged Regenicin in an amount in excess of Sixty-Five Million Dollars (\$65,000,000.00).

135. Additionally, in 2010 Vectoris/Regenicin was valued at One Billion, Eight Hundred Million Dollars (\$1,800,000,000.00). However, as of July 2012, Regenicin was valued at One Hundred Fifty-Seven Million Dollars (\$157,000,000.00). Accordingly, Regenicin has been damaged in the amount of One Billion, Six Hundred Forty-Three Million Dollars (\$1,643,000,000.00).

136. In 2010, Regenicin was authorized to issue Two Hundred Million (200,000,000) shares of stock at Two Dollars and Sixty Cents (\$2.60) per share, which totaled Five Hundred Twenty Million Dollars (\$520,000,000.00). As a proximate result of Lonza's conduct, Regenicin's stock currently sells at Three Cents (\$.03) per share, which totals Six Million Dollars (\$6,000,000.00) for a total loss of Five Hundred Fourteen Million Dollars (\$514,000,000.00).

137. From January 2009 through November 2009, Lonza enjoyed the benefits of approximately Four Thousand (4,000) hours of work from Regenicin personnel on the HDE application. And despite promises to compensate Regenicin for the value of that effort, Lonza has not made such compensation. Assigning a conservative hourly rate of \$250 to the time spent by Regenicin personnel yields an amount of One Million Dollars (\$1,000,000.00) worth of value

that Lonza has received but has not paid for.

CAUSES OF ACTION

COUNT 1 (BREACH OF CONTRACT)

138. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

139. As set forth above, Regenicin and Lonza Walkersville entered into the Regenicin/Lonza Know-How SPA whereby Lonza Walkersville agreed to produce and transfer Know-How to Regenicin; monitor prosecution and maintenance of the Patent Rights; maintain certain Licenses; execute a Stock Purchase Agreement in accordance with Article 9.1 of the Regenicin/Lonza Know-How SPA; and other obligations as more fully set forth in Exhibit “O” filed herewith.

140. Regenicin has performed all conditions, covenants, and promises required on its part to be performed in accordance with the terms and conditions of the Regenicin/Lonza Know-How SPA.

141. Lonza Walkersville breached the Regenicin/Lonza Know-How SPA when it:

- (a) Failed to provide Regenicin with the Current Know-How;
- (b) Failed to provide Regenicin with Future Know-How;
- (c) Failed to provide Regenicin with an exclusive license;
- (d) Failed to provide Regenicin with monitoring and prosecution of Patent Rights;
- (e) Failed to provide Regenicin with maintenance of certain Licenses;
- (f) Failed to provide Regenicin with AFIRM Grant results;
- (g) Failed to provide Regenicin with DOD Grant results;

- (h) Overcharged Regenicin for monitoring and prosecution of Patent Rights;
- (i) Overcharged Regenicin for maintenance of certain Licenses;
- (j) Overcharged Regenicin for transferring AFIRM Grant results; and
- (k) Overcharged Regenicin for transferring DOD Grant results.

142. As a result of Lonza Walkersville's breach of the Regenicin/Lonza Know-How SPA, Regenicin has been damaged in the amount of at least Two Billion, Two Hundred Sixty-Four Million, Thirty-Eight Thousand, Seven Hundred Forty-One Dollars (\$2,264,038,741.00), with additional damages in an amount to be proven at trial based on the facts alleged herein, including but not limited to interest and costs.

**COUNT 2
(BREACH OF THE DUTY OF GOOD FAITH AND FAIR DEALING)**

143. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

144. The Regenicin/Lonza Know-How SPA, like every agreement, carries an implied duty of good faith and fair dealing.

145. The implied duty of good faith and fair dealing prohibited Lonza Walkersville from taking action which could have the effect of destroying or injuring the rights of Regenicin to receive the fruits or benefits of the Regenicin/Lonza Know-How SPA.

146. Lonza Walkersville's duty to use best efforts to perform its obligations under the Regenicin/Lonza Know-How SPA requires more than the good faith, which is an implied covenant of the Regenicin/Lonza Know-How SPA.

147. Lonza Walkersville has failed to use its best efforts to perform its obligations under the Regenicin/Lonza Know-How SPA with greater care and diligence than the ordinary care and diligence to which it would ordinarily have been bound.

148. Lonza Walkersville also breached its duty of good faith and fair dealing by acting malevolently, for its own gain and as part of a purposeful scheme designed to deprive Regenicin of the benefits of the Regenicin/Lonza Know-How SPA.

149. Lonza Walkersville acted in bad faith and denied Regenicin the benefit of the Regenicin/Lonza Know-How SPA and destroyed the rights of Regenicin to receive the benefits of the Regenicin/Lonza Know-How SPA when it:

(a) intentionally interfered with Regenicin's effort to record the PermaDerm trademark;

(b) refused to cooperate with the FDA or comply with the FDA's explicit instructions and obstructed or prevented Regenicin from assisting with the FDA approval process;

(c) changed the PermaDerm manufacturing process without instructing or consulting with Regenicin or the proper experts;

(d) charged Regenicin for services that they never provided;

(e) refused to share important information with Regenicin;

(f) refused to approve any of press releases and presentations that Regenicin prepared in order to satisfy Regenicin's obligations with Broadsmoore and Regenicin's Shareholders; and

(g) instructed various contractors and businesses not to communicate with Regenicin about PermaDerm.

150. As a result of Lonza Walkersville's breach of the covenant of good faith and fair dealing, Regenicin has been damaged in the amount of at least Two Billion, Two Hundred Sixty-Four Million, Thirty-Eight Thousand, Seven Hundred Forty-One Dollars (\$2,264,038,741.00),

with additional damages in an amount to be proven at trial based on the facts alleged herein, including but not limited to interest and costs.

COUNT 3
(TORTIOUS INTERFERENCE WITH BUSINESS RELATIONS)

151. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

152. Regenicin had business relationships with Regenicin shareholders and the Broadsmoore Group.

153. Defendants knew that Regenicin had business relationships with Regenicin shareholders and the Broadsmoore Group.

154. Defendants, knowing of those relationships, intentionally interfered with them by:

(a) intentionally interfering with Regenicin's efforts to record the PermaDerm trademark;

(b) refusing to share important information with Regenicin;

(c) refusing to approve any of press releases and presentations that Regenicin prepared in order to satisfy Regenicin's obligations with Broadsmoore and Regenicin's Shareholders; and

(d) instructing various contractors and businesses not to communicate with Regenicin about PermaDerm.

155. Defendants acted with the sole purpose of harming Regenicin, or, failing that level of malice, used dishonest, unfair, or improper means to interfere with Regenicin's relationships with Regenicin Shareholders and the Broadsmoore Group.

156. Regenicin's relationships with Regenicin shareholders and the Broadsmoore Group were injured.

157. As a result of Defendants' tortious interference, Regenicin has been damaged in the amount of at least Five Hundred Fifteen Million, Thirty-Eight Thousand, Seven Hundred Forty-One Dollars (\$515,038,741.00), with additional damages in an amount to be proven at trial based on the facts alleged herein, including but not limited to interest and costs.

**COUNT 4
(TORTIOUS INTERFERENCE WITH PROSPECTIVE CONTRACTUAL
RELATIONS)**

158. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

159. Regenicin had prospective contracts with potential investors.

160. Regenicin had a reasonable expectation of economic advantage in its prospective contracts with potential investors.

161. However, Defendants maliciously interfered with those prospective contracts when they:

(a) refused to approve any of the press releases and presentations that Regenicin prepared; and

(b) instructed various contractors and businesses not to communicate with Regenicin about PermaDerm.

162. Regenicin was not able to enter into contracts with potential investors as a result of Defendants' malicious interference.

163. As a result of Defendants' tortious interference, Regenicin has been damaged in the amount of at least Five Hundred Fifteen Million, Thirty-Eight Thousand, Seven Hundred Forty-One Dollars (\$515,038,741.00), with additional damages in an amount to be proven at trial based on the facts alleged herein, including but not limited to interest and costs.

COUNT 5
(TORTIOUS INTERFERENCE WITH EXISTING CONTRACTUAL
RELATIONS- LONZA GROUP, LTD.)

164. Regencin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

165. Regencin and Lonza Walkersville entered into the Regencin/Lonza Know-How SPA.

166. Lonza Group knew about the Regencin/Lonza Know-How SPA.

167. Lonza Group intentionally procured Lonza Walkersville's breach of the Regencin/Lonza Know-How SPA when it:

- (a) entered into similar agreements with Thirteen (13) other companies; and
- (b) entered into other business arrangements that were contrary to the spirit and letter of the Regencin/Lonza Know-How SPA.

168. Lonza Walkersville breached the Regencin/Lonza Know-How SPA when it:

- (a) Failed to provide Regencin with the Current Know-How;
- (b) Failed to provide Regencin with Future Know-How;
- (c) Failed to provide Regencin with exclusive licenses;
- (d) Failed to provide Regencin with monitoring and prosecution of Patent Rights;
- (e) Failed to provide Regencin with maintenance of certain Licenses;
- (f) Failed to provide Regencin with AFIRM Grant results;
- (g) Failed to provide Regencin with DOD Grant results;
- (h) Overcharged Regencin for monitoring and prosecution of Patent Rights;
- (i) Overcharged Regencin for maintenance of certain Licenses;

- (j) Overcharged Regenicin for transferring AFIRM Grant results; and
- (k) Overcharged Regenicin for transferring DOD Grant results.

169. As a result of Lonza Group's tortious interference, Regenicin has been damaged in the amount of at least Five Hundred Fifteen Million, Thirty-Eight Thousand, Seven Hundred Forty-One Dollars (\$515,038,741.00), with additional damages in an amount to be proven at trial based on the facts alleged herein, including but not limited to interest and costs.

**COUNT 6
(NEGLIGENT MISREPRESENTATION)**

170. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

171. Defendants owed Regenicin a special duty of care as a result of Defendants' and Regenicin's (including Regenicin's predecessors and affiliates) longstanding relationship of trust, Defendants' superior knowledge with respect to PermaDerm and Regenicin's reliance on Defendants for their superior knowledge, expertise and manufacturing of PermaDerm.

172. Defendants promised to exclusively license certain intellectual property rights related to PermaDerm to Regenicin and made material misrepresentations and/or omissions of fact prior to and after entering the Regenicin/Lonza Know-How SPA and related agreements to grant an exclusive license to Regenicin to use certain intellectual property related to PermaDerm.

173. Specifically, Defendants made the following material misrepresentations and/or omissions of fact:

- i. Regenicin had an exclusive license to use Know-How;
- ii. Regenicin had an exclusive license to all of the patent rights, including patent applications, previously licensed to Lonza Walkersville pursuant to the Licenses;
- iii. Defendants would grant Regenicin an irrevocable license to "any and all . .

. LWI Intellectual Property” (including PermaDerm) used in the process of manufacturing PermaDerm;

iv. Dr. Steven Boyce, one the creators of PermaDerm, would assist in getting PermaDerm approved by the FDA;

v. A pre-IND/HDE meeting had taken place, although such meeting did not occur until May 31, 2011;

vi. Defendants had conducted over One Hundred (100 patient) clinical trials using PermaDerm, that Dr. Boyce was involved with these trials, and that such clinical trials would or could be used for FDA approval;

vii. In November 2010, Defendants told Regenicin and publicly announced that the DOD would provide Sixteen Million, Eight Hundred Thousand Dollars (\$16,800,000.00) for Lonza to conduct clinical trials for PermaDerm;

viii. Defendants would start clinical trials for PermaDerm on January 1, 2011;

ix. Regenicin would be compensated from the DOD grant for the time and effort Regenicin expended with respect to PermaDerm;

x. All of the Cutanogen stock would be transferred to Regenicin when the FDA approved PermaDerm for treatment for catastrophic burns;

xi. Regenicin would have significant time to sell PermaDerm to raise the additional Two Million Dollars (\$2,000,000.00) payment required under the Regenicin/Lonza Know-How SPA;

xii. Lonza had a viable supplier to manufacture and supply collagen substrates and for everything that was sold, Fifteen Percent (15%) of the manufacturing cost would be given to Defendants for sales and distribution and the remainder would be split with

Regenicin;

xiii. PermaDerm had minimal animal components;

xiv. Defendants had the ability to grow PermaDerm;

xv. PermaDerm would be available to a patient in Twenty-Eight (28) days for the first skin grafting with a Two (2) week shelf life, when in fact, Defendants had already changed the product to be available to a patient in Forty-Two (42) days with a Two (2) day shelf life;

xvi. Manufacturing costs for PermaDerm would be Thirty-Five Dollars (\$35.00) per square centimeter for first Two (2) years and at the end of two (2) years, manufacturing costs would be Twenty-Five Dollars(\$25.00) per square centimeter or less;

xvii. DOD Grant information would remain confidential, although Defendants arranged for a presentation which revealed how Defendants grow skin;

xviii. Defendants would execute a Stock Purchase Agreement in accordance with Article 9.1 of the Regenicin/Lonza Know-How SPA for the transfer of Cutanogen stock to Regenicin, although Defendants knew they could not enter into such an agreement because Defendants were in a lawsuit with former Cutanogen shareholders at that time and failed to inform Regenicin about the lawsuit;

xix. Defendants would monitor the prosecution of the Patent Rights and sent fraudulent invoices to Regenicin for such services, although Defendants did not perform these services;

xx. Defendants would maintain certain Licenses and sent fraudulent invoices to Regenicin for such services although Defendants did not perform these services;

xxi. Falsely represented the services Defendants provided to the DOD, sent fraudulent invoices regarding the amount of money paid by DOD to Defendants pursuant to the DOD grant and required Regenicin to pay Thirty-Three Percent (33%) of the false amount;

xxviii. FDA had not yet designated PermaDerm as a drug, or biologic and failed to inform Regenicin that PermaDerm was not designated for treatment by the FDA as a device but rather a drug/biologic, when they received such information from the FDA in early 2010 and did not inform Regenicin until 2011;

xxix. Defendants had access to patient data from the University of Cincinnati;

xxx. Defendants had transferred all Know-How to Regenicin;

xxxi. Defendants completed Pre-Humanitarian Device Exemption Application, meeting, which allows testing of device and use of PermaDerm on humans;

xxxii. Defendants completed two different animal studies;

xxxiii. Regenicin would be able to collect One Million Dollars (\$1,000,000.00) from DOD Grant to offset its costs;

xxxiv. Lonza Walkersville was not engaged or involved in any lawsuits;

xxxv. Lonza Walkersville was complying with DOD Grant requirements;

xxxvi. Lonza Walkersville would conduct Twenty (20) patient and Forty (40) patient trials before August 2012;

xxxvii. Lonza Walkersville had a viable registered collagen scaffold manufacturer;

xxxviii. Defendants would compensate Randall McCoy and Lauri Hahn for consulting services.

174. At the time Defendants made the aforementioned statements, Defendants knew the statements were false or negligently made such statements. In particular, Defendants had already transferred the “Know-How,” certain patent rights pursuant to the Licenses and other intellectual property related to PermaDerm to at least Thirteen (13) other corporate entities.

175. Defendants purposely or negligently made the aforementioned material misrepresentations with the specific intent that Regenicin would rely on their statements.

176. Regenicin did reasonably rely on Defendants’ misstatements to Regenicin’s detriment before and after executing the Regenicin/Lonza Know-How SPA, Manufacturing Agreement and other related agreements and paid Lonza Walkersville Three Million Dollars (\$3,000,000.00) in connection with such reliance.

177. As a proximate cause of Defendants’ material misrepresentations and/or omissions, Regenicin has suffered damages in an amount to be determined at trial in excess of Five Hundred Fourteen Million (\$514,000,000.00).

**COUNT 7
(COMMON LAW FRAUD)**

178. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

179. Defendants fraudulently deceived Regenicin when they promised to, amongst other things, exclusively license certain intellectual property rights related to PermaDerm to Regenicin and then failed to perform their obligations under the Regenicin/Lonza Know-How SPA and other related agreements (attached as exhibits to the Regenicin/Lonza Know-How SPA).

180. Defendants made the following material misrepresentations and/or omissions of fact to Regenicin prior to and after entering the Regenicin/Lonza Know-How SPA, which

include but are not limited to:

- i. Regenicin had an exclusive license to use Know-How;
- ii. Regenicin had an exclusive license to all of the patent rights, including patent applications, previously licensed to Lonza Walkersville pursuant to the Licenses;
- iii. Defendants would grant Regenicin an irrevocable license to “any and all . . . LWI Intellectual Property” (including PermaDerm) used in the process of manufacturing PermaDerm;
- iv. Dr. Steven Boyce, one the creators of PermaDerm, would assist in getting PermaDerm approved by the FDA;
- v. A pre-IDE/HDE meeting had taken place, although similar Pre-IND meeting did not occur until May 31, 2011;
- vi. Defendants had conducted over One Hundred (100 patient) clinical trials using PermaDerm, that Dr. Boyce was involved with these trials, and that such clinical trials would or could be used for FDA approval;
- vii. In November 2010, Defendants told Regenicin and publicly announced that the DOD would provide Sixteen Million, Eight Hundred Thousand Dollars (\$16,800,000.00) for Lonza to conduct clinical trials for PermaDerm;
- viii. Defendants would start clinical trials for PermaDerm on January 1, 2011;
- ix. Regenicin would be compensated from the DOD grant for the time and effort Regenicin expended with respect to PermaDerm;
- x. All of the Cutanogen stock would be transferred to Regenicin when the FDA approved PermaDerm for treatment for catastrophic burns;
- xi. Regenicin would have significant time to sell PermaDerm to raise the

additional Two Million Dollar (\$2,000,000.00) payment required under the Regenicin/Lonza Know-How SPA;

xxxix. Lonza had a viable supplier to manufacture and supply collagen substrates and for everything that was sold, Fifteen Percent (15%) of the manufacturing cost would be given to Defendants for sales and distribution and the remainder would be split with Regenicin;

xl. PermaDerm had minimal animal components;

xii. Defendants had the ability to grow PermaDerm;

xiii. PermaDerm would be available to a patient in Twenty-Eight (28) days for the first skin grafting with a Two (2) week shelf life, when in fact, Defendants had already changed the product to be available to a patient in Forty-Two (42) days with a Two (2) day shelf life;

xiv. Manufacturing costs for PermaDerm would be Thirty-Five Dollars (\$35.00) per square centimeter for first two (2) years and at the end of two (2) years, manufacturing costs would be Twenty-Five Dollars (\$25.00) per square centimeter or less;

xv. DOD Grant information would remain confidential, although Defendants arranged for a presentation which revealed how Defendants grow skin;

xvi. Defendants would execute a Stock Purchase Agreement in accordance with Article 9.1 of the Regenicin/Lonza Know-How SPA for the transfer of Cutanogen stock to Regenicin, although Defendants knew they could not enter into such an agreement because Defendants were in a lawsuit with Cutanogen at that time and failed to inform Regenicin about the lawsuit;

xvii. Defendants would monitor the prosecution of the Patent Rights and sent fraudulent invoices to Regenicin for such services, although Defendants did not perform these services;

xviii. Defendants would maintain certain Licenses and sent fraudulent invoices to Regenicin for such services although Defendants did not perform these services;

xix. Sent fraudulent invoices to Regenicin for the transfer of the AFIRM Grant results, which Regenicin paid, although Lonza never actually provided the AFIRM Grant results;

xx. Falsely represented the services Defendants provided to the DOD, sent fraudulent invoices regarding the amount of money paid by DOD to Defendants pursuant to the DOD grant and required Regenicin to pay Thirty-Three (33%) of the false amount;

xli. FDA had not yet designated PermaDerm as a device, drug, or biologic and failed to inform Regenicin that PermaDerm was not approved by the FDA as a device but rather a drug/biologic, when they received such information from the FDA in early 2010 and did not inform Regenicin until 2011;

xlii. Defendants had access to patient data from the University of Cincinnati;

xliii. Defendants had transferred all Know-How to Regenicin;

xliv. Defendants completed Pre-Investigational Device Exemption Application meeting which allows testing of device and use of PermaDerm on humans;

xlv. Defendants completed two different animal studies;

xlvi. Regenicin would be able to collect One Million Dollars (\$1,000,000.00) from DOD Grant to offset its costs;

xlvii. Lonza Walkersville was not engaged or involved in any lawsuits;

xlvi. Lonza Walkersville was complying with DOD Grant requirements;

xlix. Lonza Walkersville would conduct 20 patient and 40 patients trials before August 2012;

l. Lonza Walkersville had a viable registered collagen scaffold manufacturer;

li. Defendants would compensate Randall McCoy and Lauri Hahn for consulting services.

181. At the time Defendants made the aforementioned statements, Defendants knew the statements were false. In particular, Defendants had already transferred the “Know-How” pursuant to the Licenses and other intellectual property related to PermaDerm to at least thirteen other corporate entities.

182. Defendants made the aforementioned material misrepresentations with the specific intent that Regenicin would rely on their statements.

183. Regenicin did reasonably rely on Defendants’ misstatements to Regenicin’s detriment prior to and after executing the Regenicin/Lonza Know How SPA, Manufacturing Agreement and other related agreements and paid Lonza Walkersville \$3,000,000 in connection with such reliance.

184. As a proximate cause of Defendants’ deception and material misrepresentations and/or omissions, Walkersville has suffered damages in an amount to be determined at trial in excess of \$514,000,000.

**COUNT 8
(FRAUDULENT INDUCEMENT)**

185. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

186. On or about July 21, 2010, Regenicin and Lonza Walkersville entered into the Regenicin/Lonza Know-How SPA.

187. In order to induce Regenicin to enter into the Regenicin/Lonza Know-How SPA and related agreements, Defendants made the following material misrepresentations and/or omissions of fact, including but not limited to:

- i. Defendants would grant Regenicin an exclusive license to use Know-How;
- ii. Defendants would grant Regenicin an exclusive license to all of the patent rights, including patent applications, previously licensed to Lonza Walkersville pursuant to the Licenses;
- iii. Defendants would grant Plaintiff an irrevocable license to “any and all . . . LWI Intellectual Property” (including PermaDerm) used in the process of manufacturing PermaDerm;
- iv. Dr. Steven Boyce, one the creators of PermaDerm, would assist in getting PermaDerm approved by the FDA;
- v. Defendants had conducted over 100 patient clinical trials using PermaDerm, that Dr. Boyce was involved with these trials, and that such clinical trials would could be used for FDA approval;
- vi. The DOD would provide \$16.8 million for Lonza to do clinical trials for PermaDerm;
- vii. Defendants would start clinical trials for Permaderm on January 1, 2011, which meant that sites had already been set up;
- viii. Regenicin would be compensated from the DOD grant for the time and

effort Regenycin expended with respect to PermaDerm;

ix. All of the Cutanogen stock would be transferred to Regenycin when the FDA approved PermaDerm for treatment for catastrophic burns;

x. Regenycin would have significant time to sell PermaDerm to raise the additional \$2,000,000 payment required under the Regenycin/Lonza Know-How SPA;

lii. Lonza had a viable supplier to manufacture and supply collagen substrates and for everything that was sold, 15% of the manufacturing cost would be given to Defendants for sales and distribution and the remainder would be split with Regenycin;

liii. PermaDerm had minimal animal components;

xi. Defendants had the ability to grow PermaDerm;

xii. PermaDerm would be available to a patient in 28 days for the first skin grafting with a 2 week shelf life, when in fact, Defendants had already changed the product to be available to a patient in 42 days with a 2 day shelf life;

xiii. Manufacturing costs for PermaDerm would be \$35 per square centimeter for first two years and at the end of two years, manufacturing costs would be \$25 per square centimeter or less;

xiv. DOD Grant information would remain confidential;

xv. Defendants would execute a Stock Purchase Agreement in accordance with Article 9.1 of the Regenycin/Lonza Know-How SPA for the transfer of Cutanogen stock to Regenycin, although Defendants knew they could not enter into such an agreement because Defendants were in a lawsuit with former Cutanogen shareholders at that time and failed to inform Regenycin about the lawsuit;

xvi. Defendants would monitor the prosecution of the Patent Rights;

Defendants would maintain certain Licenses;

liv. FDA had not yet designated PermaDerm as a device, drug, or biologic;

lv. Defendants had access to patient data from the University of Cincinnati;

lvi. Defendants completed Pre-Humanitarian Device Exemption Application which allows testing of device and use of Permaderm on humans;

lvii. Defendants completed two different animal studies;

lviii. Regenicin would be able to collect \$1,000,000 from DOD Grant to offset its costs;

lix. Lonza Walkersville was not engaged or involved in any lawsuits;

lx. Lonza Walkersville would conduct 20 patient and 40 patients trials before August 2012;

lxi. Lonza Walkersville had a viable registered collagen scaffold manufacturer;

lxii. Defendants would compensate Randall McCoy for consulting services.

188. All the foregoing representations made by Defendants to Regenicin were false and Defendants knew that the statements were false at the time they made such representations. In particular, by mid-2009, Defendants had already transferred the “Know-How” pursuant to the Licenses and other intellectual property related to PermaDerm to at least thirteen other corporate entities.

189. Defendants made the aforementioned material misrepresentations with the specific intent that Regenicin would rely on their statements and to induce Regenicin to enter into the Regenicin/Lonza Know-How SPA and related agreements.

190. Regenicin did reasonably rely on Defendants’ misstatements to Regenicin’s detriment and executed the Regenicin/Lonza Know-How SPA and related agreements and paid

Lonza Walkersville \$3,000,000 in connection with such reliance.

191. As a direct and proximate result of Defendants' fraudulent inducement, Regenicin has suffered damages in an amount to be determined at trial in excess of \$514,000,000.

**COUNT 9
(VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT, N.J.S.A. § 56:8-2)**

192. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

193. Regenicin is a person and consumer under the New Jersey Consumer Fraud Act.

194. Defendants are persons under the New Jersey Consumer Fraud Act.

195. Defendants willfully and fraudulently deceived Regenicin when they promised to exclusively license certain intellectual property defined as "Know-How," "Current Know-How," and "Future Know-How"; exclusively license all of the patent rights, including patent applications, previously licensed to Lonza Walkersville pursuant to the Licenses; and grant an irrevocable license to "any and all . . . LWI Intellectual Property" (including PermaDerm) used in the process of manufacturing PermaDerm and then failed to perform their obligations under the Regenicin/Lonza Know-How SPA and other related agreements (attached as exhibits to the Regenicin/Lonza Know-How SPA).

196. As a direct and proximate result of Defendants' employment of deceptive practices and material misrepresentations and/or omissions, Regenicin sustained ascertainable losses pursuant to N.J.S.A. § 56:8-19, including the loss of \$3,000,000 provided to Defendants in exchange for certain intellectual property rights related to PermaDerm. The value and scope of the intellectual property rights Regenicin received from Defendants was less than, and different from, what it reasonably expected in view of Defendants' presentations.

197. Pursuant to N.J.S.A. § 56:8-19, in addition to any other legal or equitable relief

the court deems appropriate, Regenicin is entitled to an award threefold the damages sustained by any person and reasonable attorneys' fees, filing fees and costs of suit.

198. As a direct and proximate result of Defendants' employment of deceptive practices and material misrepresentations and/or omissions, Regenicin has suffered damages in an amount to be determined at trial and is entitled to an award of \$222,116,223 (treble damages for \$74,038,741 in damages), reasonable attorneys' fees, filing fees and costs of suit.

COUNT 10
(TRADEMARK INFRINGEMENT)

199. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

200. Regenicin paid Defendants \$3,000,000 for Defendants to exclusively license certain intellectual property defined as "Know-How," "Current Know-How," and "Future Know-How"; exclusively license all of the patent rights, including patent applications, previously licensed to Lonza Walkersville pursuant to the Licenses; and grant an irrevocable license to "any and all . . . LWI Intellectual Property" (including PermaDerm) used in the process of manufacturing PermaDerm.

201. Moreover, in 2007, Defendants abandoned the PermaDerm mark.

202. Regenicin subsequently obtained the rights to the PermaDerm mark.

203. Regenicin's mark, PermaDerm, is both distinctive and capable of being protected.

204. Defendants reproduced, copied, or made colorable imitation of the intellectual property contained in the PermaDerm trademark documents, which is Regenicin's mark.

205. This improper use of Regenicin's mark is likely to cause confusion or mistake or to deceive as to the source of origin of the PermaDerm mark or services related thereto.

206. In addition, Defendants reproduced, copied, or made colorable imitation of the

intellectual property information contained in the PermaDerm trademark documents and press releases. This application was intended has been used in connection with the sale, distribution, offering for sale, or advertising in New Jersey of any goods or services. These actions were taken without Plaintiff's consent.

207. Defendants committed these wrongful acts with the knowledge of its wrongdoing and in bad faith.

208. As a proximate result of Defendants' wrongful acts, Defendants are liable to Regenicin for Regenicin's actual damages, in the amount of \$30,000,000.

209. Furthermore, due to the egregious nature of Defendants' wrongful acts, coupled with the fact that Defendants had knowledge of the wrongful nature of its acts and acted in bad faith, Regenicin asks this court to enter judgment against Defendants for an amount not to exceed three times the ill-gotten profits made by Defendants or damages suffered by Regenicin, as well as an award of Regenicin's attorneys' fees.

210. Any reproduction, copies, or colorable imitations of Regenicin's marks should be disposed of or destroyed.

211. Regenicin also requests that this court grant temporary restraining orders and injunctions against Lonza in order to prevent the wrongful conduct described above.

**COUNT 11
(PATENT INFRINGEMENT)**

212. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

213. This court has jurisdiction over this federal patent infringement claim, as state courts may hear claims related to patent issues.

214. Regenicin paid Lonza Walkersville \$3,000,000 for Defendants to exclusively

license certain intellectual property defined as “Know-How,” “Current Know-How,” and “Future Know-How”; exclusively license all of the patent rights, including patent applications, previously licensed to Lonza Walkersville pursuant to the Licenses; and grant an irrevocable license to “any and all . . . LWI Intellectual Property” (including PermaDerm) used in the process of manufacturing PermaDerm.

215. Due to the parties’ execution of the Regenicin/Lonza Know-How SPA, and the transfer of some intellectual property related to PermaDerm and Patent Number 7452720, Regenicin has an irrevocable license, and therefore, title to the PermaDerm patent, which consists of Patent Number 7452720.

216. As a result of Defendants’ inequitable conduct, including, but not limited to: selling the license and intellectual property to Patent Number 7452720 to thirteen third-parties, subsequent to them selling the irrevocable license to Patent Number 7452720 to Regenicin, Regenicin’s rights to Patent Number 7452720 have been improperly infringed upon by Defendants.

217. Defendants had knowledge that they were infringing on Regenicin’s rights and license to Patent Number 7452720 and related intellectual property, and acted in bad faith when doing so.

218. Specifically, Defendants acted in bad faith because they knew Lonza Walkersville had contractual obligations requiring them to transfer to Regenicin the irrevocable license in Patent Number 7452720. Nonetheless, Defendants later decided that they would make more money by not fulfilling those obligations and instead selling the license and intellectual property to Patent Number 7452720 to thirteen third-party companies.

219. On June 1, 2011, Regenicin provided notice to Defendants of Defendants’

infringement of Regenicin's patent.

220. As a proximate result of Defendants' inequitable conduct, Regenicin has been damaged in the amount of \$30,000,000.

221. Regenicin is also entitled to all lost profits that occurred as a result of Defendants' infringement of Regenicin's patent.

COUNT 12
(UNJUST ENRICHMENT)

222. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

223. Regenicin paid Defendants \$3,000,000 for Defendants to exclusively license certain intellectual property defined as "Know-How," "Current Know-How," and "Future Know-How"; exclusively license all of the patent rights, including patent applications, previously licensed to Lonza Walkersville pursuant to the Licenses; and grant an irrevocable license to "any and all . . . LWI Intellectual Property" (including PermaDerm) used in the process of manufacturing PermaDerm. Regenicin also paid additional sums of money to Defendants that Defendants have wrongfully retained.

224. Regenicin conferred a benefit upon Defendants by paying Defendants \$3,000,000 for the transfer of agreed upon intellectual property rights related to PermaDerm. As Defendants did not transfer the agreed upon intellectual property rights, Defendants have retained money that rightly belongs to Regenicin.

225. Regenicin conferred a benefit upon Defendants by overpaying \$201,197 Regenicin/Lonza Know-How SPA was initially executed, paying \$216,950 in overcharges under the AFIRM Grant, not collecting \$110,250 in fees owed to Regenicin and providing \$510,344 in cash payments.

226. Defendants had knowledge of and accepted the benefit Regenicin conferred upon Defendants and have been enriched by their retention of Regenicin's funds at Regenicin's expense.

227. Defendants' retention of the benefit of funds which rightly belong to Regenicin under the circumstances by which it has come to possess that money would be unjust and inequitable.

228. As a direct and proximate result of Defendants' unjust enrichment, Regenicin has suffered damages in an amount to be determined at trial in excess of \$74,038,741.

**COUNT 13
(QUANTUM MERUIT)**

229. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

230. Regenicin and/or its affiliates, including but not limited to, McCoy Enterprises, Vectoris, Windstar and Randall McCoy, performed services for Defendants in connection with obtaining FDA approval of PermaDerm. Regenicin and/or its affiliates performed such services in good faith.

231. Defendants knowingly and willingly accepted the services rendered by Regenicin;

232. Regenicin reasonably expected to be compensated for the services rendered to Defendants;

233. The reasonable value of the services Regenicin rendered to Defendants is \$1,000,000.00 and Regenicin has suffered damages in an amount to be determined at trial in excess of \$1,000,000.00.

COUNT 14

(PRIMA FACIE TORT)

234. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

235. Defendants' intentional, willful and malicious actions including, but not limited to: the defrauding of Regenicin of substantial sums of money by falsely misrepresenting to Regenicin that it was transferring the PermaDerm portfolio to Regenicin, granting an exclusive license to Patent Number 7452720 that allowed Regenicin to sell PermaDerm, and selling all outstanding shares of Cutanogen to Regenicin in order to induce Regenicin to expend substantial sums of money in developing PermaDerm and obtaining FDA approval in order to have exclusive rights to sell and distribute PermaDerm. While making these representations, Defendants knew that they had already sold to at least thirteen third-party companies, separate licenses giving those companies the purported right to sell and distribute PermaDerm.

236. As a result of Defendants' intentional, willful and malicious actions, Regenicin is entitled to special damages.

237. There was no justification, legal or otherwise, for Defendants' intentional, willful and malicious actions.

238. Defendants' series of intentional, willful and malicious acts were unlawful.

239. In the event this court finds that none of Regenicin's tort causes of actions may stand, then Defendants are liable to Regenicin for prima facie tort in the amount of \$4,038,741.

COUNT 15

(VIOLATION OF NEW JERSEY STATE SECURITIES LAW)

240. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

241. This claim is asserted by Regenicin against Lonza Walkersville, Inc. and is based upon New Jersey state securities law, including N.J.S.A. § 49:3-52 and N.J.S.A. § 49:3-71.

242. Regenicin has standing to bring a securities fraud claim by virtue of its written agreement with Lonza Walkersville to purchase all outstanding Cutanogen securities. Regenicin and Lonza Walkersville signed and entered into the Regenicin/Lonza Know-How SPA on July 21, 2010. As part of that agreement, Regenicin agreed to purchase all outstanding capital stock of Cutanogen from Lonza Walkersville, who represented to Regenicin that it owned all issued and outstanding capital stock of Cutanogen.

243. Lonza Walkersville engaged and participated in a course of conduct and conspiracy to misrepresent and conceal adverse material information as described above, including the following:

i. Lonza Walkersville represented that it was granting Regenicin an exclusive license to use the Know-How while knowing that it had granted rights to at least 13 other companies as well;

ii. Lonza Walkersville represented that it was granting Regenicin an exclusive license to all of the patent rights, including patent applications, previously licensed to Lonza pursuant to the Licenses while knowing that it had granted licenses to at least 13 other companies as well ;

iii. Lonza Walkersville represented that it was granting Plaintiff an irrevocable license to “any and all . . . LWI Intellectual Property” (including PermaDerm) used in the process of manufacturing PermaDerm while knowing that that was not case;

iv. In 2010 prior to entering into the transaction, Lonza Walkersville represented to Regenicin that Dr. Steven Boyce, one the creators of PermaDerm, would

assist in getting PermaDerm approved by the FDA, knowing that former shareholders of Cutanogen were involved in litigation against Lonza;

v. In 2010 prior to entering into the transaction, Lonza represented to Regenicin that a pre-IND/HDE meeting had taken place, although such meeting did not occur until May 31, 2011;

vi. Defendants had conducted over 100 clinical trials using PermaDerm, that Dr. Boyce was involved with these trials, and that such clinical trials would or could be used for FDA approval;

vii. In November 2010, Lonza told Regenicin and publicly announced that the DOD would provide Sixteen Million, Eight Hundred Thousand Dollars (\$16,800,000.00) for Lonza to conduct clinical trials for PermaDerm when Lonza knew the amount awarded was much lower;

viii. In 2010 prior to executing the agreement, Lonza represented that the timeline would be ready for clinical trials for PermaDerm in January 2011, which meant that the FDA process must be well under way and sites already set up, which was not true.

ix. Regenicin would be compensated from the DOD grant for the time and effort Regenicin expended with respect to PermaDerm when this was not true;

x. All of the Cutanogen stock would be transferred to Regenicin when the FDA approved PermaDerm for treatment for catastrophic burns when Lonza never expected FDA approval to go through as planned;

xi. Regenicin would have significant time to sell PermaDerm to raise the additional \$2,000,000 payment required under the Regenicin/Lonza Know-How SPA;

xii. Lonza had a viable supplier to manufacture and supply collagen substrates and for everything that was sold, 15% of the manufacturing cost would be given to Defendants for sales and distribution and the remainder would be split with Regenicin;

xiii. PermaDerm had minimal animal components;

xiv. Defendants had the ability to grow PermaDerm;

xv. PermaDerm would be available to a patient in 28 days for the first skin grafting with a 2 week shelf life, when in fact, Defendants had already changed the product to be available to a patient in 42 days with a 2 day shelf life;

xvi. Manufacturing costs for PermaDerm would be \$35 per square centimeter for first two years and at the end of two years, manufacturing costs would be \$25 per square centimeter or less;

xvii. DOD Grant information would remain confidential, although Defendants arranged for a presentation which revealed how Defendants grow skin;

xviii. Defendants would execute a Stock Purchase Agreement in accordance with Article 9.1 of the Regenicin/Lonza Know-How SPA for the transfer of Cutanogen stock to Regenicin, although Defendants knew they could not enter into such an agreement because Defendants were in a lawsuit with former Cutanogen shareholders at that time and failed to inform Regenicin about the lawsuit;

xix. Defendants would monitor the prosecution of the Patent Rights and sent fraudulent invoices to Regenicin for such services, although Defendants did not perform these services;

xx. Defendants would maintain certain Licenses and sent fraudulent invoices to Regenicin for such services although Defendants did not perform these services;

xxi. Sent fraudulent invoices to Regenicin for the transfer of the AFIRM Grant results, which Regenicin paid, although Lonza never actually provided the AFIRM Grant results;

xxii. Falsely represented the services Defendants provided to the DOD, sent fraudulent invoices regarding the amount of money paid by DOD to Defendants pursuant to the DOD grant and required Regenicin to pay 33% of the false amount;

xxiii. FDA had not yet designated PermaDerm as a device, drug, or biologic and failed to inform Plaintiff that PermaDerm was not approved by the FDA as a device but rather a drug/biologic, when they received such information from the FDA in early 2010 and did not inform Regenicin until 2011;

xxiv. Defendants had access to patient data from the University of Cincinnati;

xxv. Defendants had transferred all Know-How to Regenicin;

xxvi. Defendants completed Pre-Humanitarian Device Exemption Application which allows testing of device and use of Permaderm on humans;

xxvii. Defendants completed two different animal studies;

xxviii. Regenicin would be able to collect \$1,000,000 from DOD Grant to offset its costs;

xxix. Lonza Walkersville was not engaged or involved in any lawsuits;

xxx. Lonza Walkersville was complying with DOD Grant requirements;

xxxi. Lonza Walkersville would conduct 20 patient and 40 patients trials before August 2012;

xxxii. Lonza Walkersville had a viable registered collagen scaffold manufacturer;

xxxiii. Defendants would compensate Randall McCoy for consulting services.

244. Lonza Walkersville recklessly employed devices, schemes, and artifices to defraud and recklessly engaged in acts, practices and a course of conduct as herein alleged in an effort to defraud Regenicin from substantial sums of money while at the same time profiting from government grants with no intent to follow through with its obligations or promises to Regenicin, including no intent to obtain FDA approval of PermaDerm as planned or to fulfill its obligation to sell Cutanogen stock to Regenicin. This included the formulation, making of and/or participating in the making of untrue statements of material facts and the omission to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, and subsequent efforts to conceal its fraud from Regenicin, including its efforts to shut Regenicin out of the FDA process and prevent Regenicin from engaging with anyone other than Lonza, who was the only party who could communicate directly with the FDA.

245. Lonza Walkersville's acts and practices operated as a fraud and deceit upon Regenicin in connection with the purchase of Cutanogen securities by Regenicin.

246. Lonza Walkersville made the statements identified above, which were materially false and misleading in violation of N.J.S.A. § 49:3-52 and N.J.S.A. § 49:3-71. These statements were materially false and misleading and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

247. Lonza Walkersville acted with knowledge of the falsity of the statements or with reckless regard to their truth.

248. Regenicin was in privity with Lonza Walkersville through the Regenicin/Lonza

Know-How SPA signed July 21, 2010. Regenicin relied on the statements set forth above and did not know the truth of the misrepresentations and omissions made by Lonza Walkersville. Had Regenicin known of the truth of the material misrepresentations or materially adverse information that was not disclosed by Lonza Walkersville at the time of entering into the Regenicin/Lonza Know-How SPA, Regenicin would not have agreed to enter the Regenicin/Lonza Know-How SPA, raise money from investors to fund the transactions with Lonza Walkersville, and would not have obligated itself to purchase shares of Cutanogen.

249. The acts and omissions by Lonza Walkersville were a substantial contributing cause of Regenicin's financial for which it seeks to recover damages.

250. Regenicin seeks an award compensating it for any injuries it has sustained that are substantially related to the purchase and impaired value of the Cutanogen securities as a result of Lonza Walkersville's unlawful conduct in an amount to be determined by the trier of fact exceeding \$5,000,000 (including any consideration paid by Regenicin in connection with the sale of the securities) and interest from the date of payment of any consideration paid for the securities and costs.

COUNT 16
(VIOLATION OF SECTION 10(B) OF THE EXCHANGE ACT AND RULE 10b-5)

251. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

252. This claim is asserted by Regenicin against Lonza Walkersville, Inc. and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder.

253. In connection with the transactions at issue, Lonza Walkersville used the means and instrumentalities of interstate commerce, including mail and wire communications.

254. Regenicin has standing to bring a securities fraud claim by virtue of its written agreement with Lonza Walkersville to purchase all outstanding Cutanogen securities. Regenicin and Lonza Walkersville signed and entered into the Regenicin/Lonza Know-How SPA on July 21, 2010. As part of that agreement, Regenicin agreed to purchase all outstanding capital stock of Cutanogen from Lonza Walkersville, who represented to Regenicin that it owned all issued and outstanding capital stock of Cutanogen.

255. Lonza Walkersville engaged and participated in a course of conduct and conspiracy to misrepresent and conceal adverse material information as specified herein, including the following:

i. Lonza Walkersville represented that it was granting Regenicin an exclusive license to use the Know-How while knowing that it had granted rights to at least 13 other companies as well;

ii. Lonza Walkersville represented that it was granting Regenicin an exclusive license to all of the patent rights, including patent applications, previously licensed to Lonza Walkersville pursuant to the Licenses while knowing that it had granted licenses to at least 13 other companies as well;

iii. Lonza Walkersville represented that it was granting Regenicin an irrevocable license to “any and all . . . LWI Intellectual Property” (including PermaDerm) used in the process of manufacturing PermaDerm while knowing that that was not case;

iv. In 2010 prior to entering into the transaction, Lonza Walkersville represented to Regenicin that Dr. Steven Boyce, one the creators of PermaDerm, would assist in getting PermaDerm approved by the FDA, knowing that former Cutanogen shareholders were involved in litigation against Lonza;

v. In 2010 prior to entering into the transaction, Lonza Walkersville represented to Regenicin that a pre-IND/HDE meeting had taken place, although such meeting did not occur until May 31, 2011;

vi. Defendants had conducted over 100 clinical trials using PermaDerm, that Dr. Boyce was involved with these trials, and that such clinical trials would could be used for FDA approval;

vii. In November 2010, Lonza Walkersville told Regenicin and publicly announced that the DOD would provide \$16.8 million for Lonza Walkersville to do clinical trials for PermaDerm when Lonza Walkersville knew the amount awarded was much lower;

viii. In 2010 prior to executing the agreement, Lonza Walkersville represented that the timeline would be ready for clinical trials for PermaDerm in January 2011, which meant that the FDA process must be well under way and sites already set up, which was not true.

ix. Regenicin would be compensated from the DOD grant for the time and effort Regenicin expended with respect to PermaDerm when this was not true;

x. All of the Cutanogen stock would be transferred to Regenicin when the FDA approved PermaDerm for treatment for catastrophic burns when Lonza Walkersville never expected FDA approval to go through as planned;

xi. Regenicin would have significant time to sell PermaDerm to raise the additional \$2,000,000 payment required under the Regenicin/Lonza Know-How SPA;

xii. Lonza Walkersville had a viable supplier to manufacture and supply collagen substrats and for everything that was sold, 15% of the manufacturing cost

would be given to Defendants for sales and distribution and the remainder would be split with Regenicin;

xiii. PermaDerm had minimal animal components

xiv. Defendants had the ability to grow PermaDerm;

xv. PermaDerm would be available to a patient in 28 days for the first skin grafting with a 2 week shelf life, when in fact, Defendants had already changed the product to be available to a patient in 42 days with a 2 day shelf life;

xvi. Manufacturing costs for PermaDerm would be \$35 per square centimeter for first two years and at the end of two years, manufacturing costs would be \$25 per square centimeter or less;

xvii. DOD Grant information would remain confidential, although Defendants arranged for a presentation which revealed how Defendants grow skin;

xviii. Lonza Walkersville would execute a Stock Purchase Agreement in accordance with Article 9.1 of the Regenicin/Lonza Know-How SPA for the transfer of Cutanogen stock to Regenicin, although Lonza Walkersville knew it could not enter into such an agreement because Lonza Walkersville was in a lawsuit with former Cutanogen shareholders at that time and failed to inform Regenicin about the lawsuit;

xix. Lonza Walkersville would monitor the prosecution of the Patent Rights and sent fraudulent invoices to Regenicin for such services, although Lonza Walkersville did not perform these services;

xx. Lonza Walkersville would maintain certain Licenses and sent fraudulent invoices to Regenicin for such services although Lonza Walkersville did not perform these services;

xxi. Sent fraudulent invoices to Regenicin for the transfer of the AFIRM Grant results, which Regenicin paid, although Lonza Walkersville never actually provided the AFIRM Grant results;

xxii. Falsely represented the services Lonza Walkersville provided to the DOD, sent fraudulent invoices regarding the amount of money paid by DOD to Lonza Walkersville pursuant to the DOD grant and required Regenicin to pay 33% of the false amount;

xxiii. FDA had not yet designated PermaDerm as a device, drug, or biologic and failed to inform Regenicin that PermaDerm was not approved by the FDA as a device but rather a drug/biologic, when they received such information from the FDA in early 2010 and did not inform Regenicin until 2011;

xxiv. Lonza Walkersville had access to patient data from the University of Cincinnati;

xxv. Lonza Walkersville had transferred all Know-How to Regenicin;

xxvi. Lonza Walkersville completed Pre-Humanitarian Device Exemption Application which allows testing of device and use of Permaderm on humans;

xxvii. Lonza Walkersville completed two different animal studies;

xxviii. Regenicin would be able to collect \$1,000,000 from DOD Grant to offset its costs;

xxix. Lonza Walkersville was not engaged or involved in any lawsuits;

xxx. Lonza Walkersville was complying with DOD Grant requirements;

xxxi. Lonza Walkersville would conduct 20 patient and 40 patients trials before August 2012;

xxxii. Lonza Walkersville had a viable registered collagen scaffold manufacturer;

xxxiii. Lonza Walkersville would compensate Randall McCoy for consulting services.

256. Lonza Walkersville recklessly employed devices, schemes, and artifices to defraud and recklessly engaged in acts, practices and a course of conduct as herein alleged in an effort to defraud Regenicin from substantial sums of money. This included the formulation, making of and/or participating in the making of untrue statements of material facts and the omission to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.

257. Lonza Walkersville's acts and practices operated as a fraud and deceit upon Regenicin in connection with the purchase of Cutanogen securities by Regenicin.

258. Lonza Walkersville made the statements identified above, which were materially false and misleading in violation of Section 10(b) of the Exchange Act and Rule 10b-5 thereunder. These statements were materially false and misleading and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

259. Lonza Walkersville acted with knowledge of the falsity of the statements or with reckless regard to their truth.

260. Regenicin reasonably relied on the statements set forth above in agreeing to enter the Regenicin/Lonza Know-How SPA and deciding to invest substantial sums of money into the development, FDA approval and sale of PermaDerm and to purchase all of the issued and outstanding shares of Cutanogen.

261. The misrepresented statements and omissions by Lonza Walkersville were a substantial contributing cause of Regenicin's investment loss. Had Regenicin known of the truth of the material misrepresentations or materially adverse information that was not disclosed by Lonza Walkersville, it would not have agreed to enter the Regenicin/Lonza Know-How SPA and purchase shares of Cutanogen. Nor would Regenicin have sustained damages given that the subsequent decline in value of Regenicin's investment in Cutanogen securities was attributable to the matter misrepresented or omitted by Lonza Walkersville.

262. Regenicin seeks an award compensating it for the damages it has sustained as a result of Lonza Walkersville's unlawful conduct in an amount to be determined by the trier of fact exceeding \$5,000,000. Regenicin further seeks an award for its attorneys' fees, expert fees, and other costs of litigation, as well as interest and such other relief that the trier of fact may deem just.

COUNT 17
(VIOLATION OF NEW JERSEY RICO STATUTE)

263. Regenicin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

264. This claim is asserted by Regenicin against Lonza Walkersville, Lonza Group, and Lonza America and based on the New Jersey Racketeering Act, N.J. Stat. Ann. §§ 2C:41-1 to -6.2.

265. The association in fact of one or more of Lonza Walkersville, Lonza Group, Lonza America, and others, is an enterprise within the meaning of the New Jersey RICO statute.

266. Lonza Walkersville, Lonza Group, and Lonza America conducted and participated in the conduct of the affairs of this enterprise through a pattern of racketeering

activity and for the unlawful purpose of intentionally defrauding Regenicin of substantial sums of money, frustrating Regenicin's business plan and efforts to obtain approval by the FDA for the commercialization of PermaDerm, and depriving Regenicin of its exclusive license to sell and distribute PermaDerm.

267. Lonza Walkersville, Lonza Group, and Lonza America devised and participated in a scheme whereby these entities would induce Regenicin to invest millions with Lonza Walkersville for the right to develop the PermaDerm product for approval by the FDA and commercialization when Lonza had determined that it would make more money on PermaDerm if it was not approved. Lonza never intended to fulfill its obligations to Regenicin. Lonza falsely misrepresented that it was selling Regenicin an exclusive license when it had already sold certain licenses to at least 13 other companies. Nor did Lonza intend to see the transaction through and sell all of the Cutanogen stock to Regenicin for a final payment of several million when it had realized it had an opportunity to make more profit by applying for and receiving government grants and potential overseas licenses which did not depend on the FDA approval. Lonza concealed its efforts, or lack thereof, regarding the FDA approval process from Regenicin and when Lonza could not get paid through a grant it would fraudulently invoice Regenicin. Eventually, Lonza's poor management and lack of oversight over the FDA approval process resulted in termination of the DOD grant and when questioned about its misrepresentations and fraud by Regenicin, Lonza terminated the relationship and blocked Regenicin from fulfilling its rights under the agreement.

268. In furtherance of the scheme, Defendants have committed indictable offenses of theft by deception under New Jersey state law. More specifically, Defendants committed theft by deception by purposely obtaining property of Regenicin by deception pursuant to N.J.S.A. §

2C:20-4. Defendants deceived Regenicin by purposely creating or reinforcing a false impression regarding the exclusive nature and value of the license rights it was granting to Regenicin for PermaDerm; preventing Regenicin from acquiring information which would affect its judgment of the transactions at issue; or failing to correct any false impression that Defendants previously created or reinforced, or which Defendants knew to be influencing Regenicin with whom they had a confidential relationship.

269. Defendants are persons under N.J.S.A. § 2C:20-4.

270. Defendants purposely obtained and/or exercised control over intellectual property rights rightfully belonging to Regenicin by deception.

271. Pursuant to the Regenicin/Lonza Know-How SPA, Lonza Walkersville was required to exclusively license certain intellectual property defined as “Know-How,” “Current Know-How,” and “Future Know-How”; exclusively license all of the patent rights, including patent applications, previously licensed to Lonza Walkersville pursuant to the Licenses; and grant an irrevocable license to “any and all . . . LWI Intellectual Property” (including PermaDerm) used in the process of manufacturing PermaDerm.

272. Regenicin paid Lonza Walkersville over \$3,000,000 for the licensing of such rights.

273. Defendants deceived Regenicin by purposely: (a) creating and reinforcing the false impression that it had transferred certain intellectual property rights related to Permaderm to Regenicin when Defendants knew that they had not transferred such rights; (b) preventing Regenicin from acquiring information about Defendants’ transfer of certain intellectual property rights to at least thirteen corporate entities prior to entering into the Regenicin/Lonza Know-How SPA and related agreements, which would affected Regenicin’s judgment of the transaction; and

(c) failing to correct the false impression that Defendants had transferred certain intellectual property rights related to Permaderm to Plaintiff which impression the Defendants previously created and reinforced.

274. Despite Defendants' failure to transfer the intellectual property rights rightfully belonging to Regenicin, Defendants retained \$3,000,000 paid by Regenicin for the transfer of those rights.

275. In furtherance of the scheme described above, Defendants have committed multiple indictable offenses including mail and wire fraud under 18 U.S.C. § 1341 and § 1342.

276. More specifically, Defendants have committed offenses under 18 U.S.C. § 1341 as follows:

(a) During the relevant period, Lonza Walkersville, Lonza Group, Lonza America, and the other members of the enterprise devised and/or participated in a scheme or artifice to defraud Regenicin of substantial sums of money, by means of false or fraudulent pretenses, representations or promises related to material fact and omissions inducing Regenicin to enter the Regenicin/Lonza Know-How SPA and agree to invest in the development, FDA approval, sale and distribution of PermaDerm and to purchase shares of Cutanogen at an inflated price, as described above.

(b) Lonza Walkersville, Lonza Group, and Lonza America acted willfully and with an intent to defraud or aided, abetted, counseled, commanded, induced or procured the commission of the scheme or artifice to defraud.

(c) Lonza Walkersville, Lonza Group, and Lonza America and other members of the enterprise caused numerous documents related to the negotiation, execution and closing of the Regenicin/Lonza Know-How License SPA, as well as subsequent invoices

related to the agreement, to be delivered or received by using the United States Postal Service or a private or commercial interstate carrier in furtherance of the scheme or artifice to defraud Regenicin.

(d) Lonza Walkersville, Lonza Group, and Lonza America and other members of the enterprise used or caused the use of the mails or knew the use of the mails was likely.

(e) The foregoing mailings constituted separate indictable acts of mail fraud which were undertaken as part of the pattern of racketeering performed by Defendants and other members of the enterprise having the purpose to defraud.

277. More specifically, Defendants have committed offenses under 18 U.S.C. § 1343 as follows:

(a) During the relevant period, Lonza Walkersville, Lonza Group, Lonza America and other members of the enterprise devised and/or participated in a scheme or artifice to defraud Regenicin of substantial sums of money, by means of false or fraudulent pretenses, representations or promises related to a material fact and omissions inducing Regenicin to enter the Regenicin/Lonza Know-How SPA and agree to invest in the development, FDA approval, sale and distribution of PermaDerm and to purchase shares of Cutanogen at an inflated price, as described above.

(b) Lonza Walkersville, Lonza Group, and Lonza America acted willfully and with an intent to defraud or aided, abetted, counseled, commanded, induced, or procured the commission of the scheme or artifice to defraud.

(c) Lonza Walkersville, Lonza Group, and Lonza America and other members of the enterprise used interstate wire transmissions, including telephone and e-mail

communications, to initiate, receive, or participate in numerous communications related to the scheme or artifice to defraud Plaintiff. For example, David Smith, Bradley Luria, Scott Waldman and Randall McCoy communicated through e-mails including approvals of the Private Placement Memo and supporting presentations shared with potential investors and subsequent press releases issued by Regenicin that contained misrepresentations from Defendants that Defendants knew were false.

(d) The foregoing wire communications constituted separate indictable acts of wire fraud which were undertaken as part of the pattern of racketeering performed by Lonza Walkersville, Lonza Group, and Lonza America and other members of the enterprise having the purpose to defraud.

278. In furtherance of the scheme, Defendants have committed indictable offenses of securities fraud under New Jersey state law pursuant to N.J.S.A. § 49:3-52 and N.J.S.A. § 49:3-71.

279. More specifically, Lonza Walkersville committed securities fraud under New Jersey law by engaging and participating in a course of conduct and conspiracy to misrepresent and conceal adverse material information as described above, including the following:

i. Lonza represented that it was granting Regenicin an exclusive license to use the Know How while knowing that it had granted rights to at least 13 other companies as well;

ii. Lonza represented that it was granting Regenicin an exclusive license to all of the patent rights, including patent applications, previously licensed to Lonza pursuant to the Licenses while knowing that it had granted licenses to at least 13 other companies as well ;

iii. Lonza represented that it was granting Regenicin an irrevocable license to “any and all . . . LWI Intellectual Property” (including PermaDerm) used in the process of manufacturing PermaDerm while knowing that that was not case;

iv. In 2010 prior to entering into the transaction, Lonza represented to Regenicin that Dr. Steven Boyce, one the creators of PermaDerm, would assist in getting PermaDerm approved by the FDA, knowing that he was involved with litigation against Lonza;

v. In 2010 prior to entering into the transaction, Lonza represented to Regenicin that a pre-IND/HDE meeting had taken place, although such meeting did not occur until May 31, 2011;

vi. Defendants had conducted over 100 clinical trials using PermaDerm, that Dr. Boyce was involved with these trials, and that such clinical trials would could be used for FDA approval;

vii. In November 2010, Lonza told Regenicin and publicly announced that the DOD would provide \$16.8 million for Lonza to do clinical trials for PermaDerm when Lonza knew the amount awarded was much lower;

viii. In 2010 prior to executing the agreement, Lonza represented that the timeline would be ready for clinical trials for PermaDerm in January 2011, which meant that the FDA process must be well under way and sites already set up, which was not true.

ix. Regenicin would be compensated from the DOD grant for the time and effort Regenicin expended with respect to PermaDerm when this was not true;

x. All of the Cutanogen stock would be transferred to Regenicin when the

FDA approved PermaDerm for treatment for catastrophic burns when Lonza never expected FDA approval to go through;

xi. Regenicin would have significant time to sell PermaDerm to raise the additional \$2,000,000 payment required under the Regenicin/Lonza Know-How SPA;

xii. Lonza had a viable supplier to manufacture and supply collagen substrates and for everything that was sold, 15% of the manufacturing cost would be given to Defendants for sales and distribution and the remainder would be split with Regenicin;

xiii. PermaDerm had minimal animal components;

xiv. Defendants had the ability to grow PermaDerm;

xv. PermaDerm would be available to a patient in 28 days for the first skin grafting with a 2 week shelf life, when in fact, Defendants had already changed the product to be available to a patient in 42 days with a 2 day shelf life;

xvi. Manufacturing costs for PermaDerm would be \$35 per square centimeter for first two years and at the end of two years, manufacturing costs would be \$25 per square centimeter or less;

xvii. DOD Grant information would remain confidential, although Defendants arranged for a presentation which revealed how Defendants grow skin;

xviii. Lonza Walkersville would execute a Stock Purchase Agreement in accordance with Article 9.1 of the Regenicin/Lonza Know-How SPA for the transfer of Cutanogen stock to Regenicin, although Lonza Walkersville knew it could not enter into such an agreement because Lonza Walkersville was in a lawsuit with former Cutanogen shareholders at that time and failed to inform Regenicin about the lawsuit;

xix. Lonza Walkersville would monitor the prosecution of the Patent Rights

and sent fraudulent invoices to Regenicin for such services, although Lonza Walkersville did not perform these services;

xx. Lonza Walkersville would maintain certain Licenses and sent fraudulent invoices to Regenicin for such services although Lonza Walkersville did not perform these services;

xxi. Sent fraudulent invoices to Regenicin for the transfer of the AFIRM Grant results, which Regenicin paid, although Lonza never actually provided the AFIRM Grant results;

xxii. Falsely represented the services Lonza Walkersville provided to the DOD, sent fraudulent invoices regarding the amount of money paid by DOD to Lonza Walkersville pursuant to the DOD grant and required Regenicin to pay 33% of the false amount;

xxiii. FDA had not yet designated PermaDerm as a device, drug, or biologic and failed to inform Regenicin that PermaDerm was not approved by the FDA as a device but rather a drug/biologic, when they received such information from the FDA in early 2010 and did not inform Regenicin until 2011;

xxiv. Lonza Walkersville had access to patient data from the University of Cincinnati;

xxv. Lonza Walkersville had transferred all Know-How to Regenicin;

xxvi. Lonza Walkersville completed Pre-Humanitarian Device Exemption Application which allows testing of device and use of Permaderm on humans;

xxvii. Lonza Walkersville completed two different animal studies;

xxviii. Regenicin would be able to collect \$1,000,000 from DOD Grant to offset

its costs;

xxix. Lonza Walkersville was not engaged or involved in any lawsuits;

xxx. Lonza Walkersville was complying with DOD Grant requirements;

xxxi. Lonza Walkersville would conduct 20 patient and 40 patients trials before August 2012;

xxxii. Lonza Walkersville had a viable registered collagen scaffold manufacturer;

xxxiii. Lonza Walkersville would compensate Randall McCoy for consulting services.

280. Lonza Walkersville recklessly employed devices, schemes, and artifices to defraud and recklessly engaged in acts, practices and a course of conduct as herein alleged in an effort to defraud Regenicin from substantial sums of money while at the same time profiting from government grants with no intent to fulfill Lonza Walkersville's obligations to obtain FDA approval of PermaDerm and sell the Cutanogen stock to Regenicin. This included the formulation, making of and/or participating in the making of untrue statements of material facts and the omission to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, and subsequent efforts to conceal its fraud by shutting Regenicin out of the FDA process.

281. Lonza Walkersville acts and practices operated as a fraud and deceit upon Plaintiff in connection with the purchase of Cutanogen securities by Plaintiff.

282. Lonza Walkersville made the statements identified above, which were materially false and misleading in violation of N.J.S.A. § 49:3-52 and N.J.S.A. § 49:3-71. These statements were materially false and misleading and omitted to state material facts necessary in order to

make the statements made, in light of the circumstances under which they were made, not misleading.

283. Lonza Walkersville acted with knowledge of the falsity of the statements or with reckless regard to their truth.

284. Regenicin was in privity with Lonza Walkersville through the Regenicin/Lonza Know-How SPA signed July 21, 2010. Regenicin relied on the statements set forth above and did not know the truth of the misrepresentations and omissions made by Lonza Walkersville. Had Regenicin known of the truth of the material misrepresentations or materially adverse information that was not disclosed by Lonza Walkersville at the time of entering into the Regenicin/Lonza Know-How SPA, Regenicin would not have agreed to enter the Regenicin/Lonza Know-How SPA, raise money from investors to fund the transactions with Lonza Walkersville, and would not have obligated itself to purchase shares of Cutanogen.

285. Commission of theft by deception, mail, wire and securities fraud constitute conduct within the meaning of “racketeering activity” as defined by the New Jersey Racketeering Act, N.J. Stat. Ann. §§ 2C:41-1 to -6.2.

286. Lonza Walkersville, Lonza Group, and Lonza America engaged in the conduct described above with the specific intent of obtaining unlawful monies and in furtherance of the scheme described above.

287. The acts set forth herein constitute a pattern of racketeering activity. Lonza Walkersville, Lonza Group, and Lonza America directly or indirectly conducted or participated in the conduct of the enterprise’s affairs through the described pattern of racketeering activity.

288. As a direct and proximate result of Defendants’ racketeering activities and violation of New Jersey’s RICO statute, Regenicin has incurred damages to its business and

property, in an amount to be proved by the trier of fact exceeding \$5,000,000.

289. Regencin is entitled to recover three times its actual damages sustained as well as reasonable attorneys' fees and costs of investigation and litigation, as provided in N.J.S.A. § 2C:41-4, and seeks prejudgment interest on the treble damages amount.

COUNT 18
(VIOLATION OF RICO 18 U.S.C. § 1962(C))

290. Regencin repeats and re-alleges all preceding allegations and subsequent Counts in this Complaint against Defendants as if set forth verbatim herein.

291. This claim is asserted by Regencin against Lonza Walkersville, Lonza Group, and Lonza America as a violation of 18 U.S.C. § 1962(c). Lonza Walkersville, Lonza Group, and Lonza America and others violated 18 U.S.C. § 1962(c) by conducting and participating in the conduct of the affairs of an enterprise through a pattern of racketeering as a means to defraud Regencin and make secret profits for themselves. Under Section 1962(c), it is "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c). Any person whose business or property has been injured by reason of this statute may recover damages from each person who caused the injury.

292. The term "enterprise" includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals or corporations associated in fact, although not a legal entity, engaged in interstate commerce, or whose activities affect interstate commerce. In this case, Lonza Walkersville, Lonza Group, Lonza America and other associated entities constitute an enterprise engaged in or whose activities affect interstate or foreign commerce. Lonza Walkersville, Lonza Group, and Lonza America

are employed by or associated with the enterprise and directed its affairs.

293. Defendants agreed to and did conduct and participate in the conduct of the enterprise's affairs through a pattern of racketeering activity and for the unlawful purpose of defrauding Plaintiff.

294. Section 1961(5) defines a "pattern of racketeering" as "at least two acts of racketeering activity . . . the last of which occurred within ten years after the commission of a prior act of racketeering activity." The acts must be related and continuous to form a "pattern of racketeering." "Related" is defined as "acts that have the same or similar purposes, results, participants, victims, methods of commission, or otherwise interrelated by distinguishing characteristics and are not isolated events." Continuity can be shown by alleging a closed-ended scheme, consisting of a series of related predicate acts extending over a substantial period of time, or an open-ended scheme. In order to properly allege an open-ended scheme, the plaintiff must establish the "threat of continuity." Two important factors in alleging and establishing "continuity" are (1) the duration of the alleged misconduct; and (2) a threat of continuing criminal conduct.

295. Defendants devised and participated in a scheme whereby whereby these entities would induce Regencin to invest millions with Lonza Walkersville for the right to develop the PermaDerm product for approval by the FDA and commercialization when Lonza had determined that it would make more money on PermaDerm if it was not approved. Lonza never intended to fulfill its obligations to Regencin. Lonza falsely misrepresented that it was selling Regencin an exclusive license when it had already sold certain licenses to at least 13 other companies. Nor did Lonza intend to see the transaction through and sell all of the Cutanogen stock to Regencin for a final payment of several million when it had realized it had an

opportunity to make more profit by applying for and receiving government grants and potential overseas licenses which did not depend on the FDA approval. Lonza concealed its efforts, or lack thereof, regarding the FDA approval process from Regenicin and when Lonza could not get paid through a grant it would fraudulently invoice Regenicin. Eventually, Lonza's poor management and lack of oversight over the FDA approval process resulted in termination of the DOD grant and when questioned about its misrepresentations and fraud by Regenicin, Lonza terminated the relationship and blocked Regenicin from fulfilling its rights under the agreement.

296. Pursuant to and in furtherance of their fraudulent scheme, Defendants committed multiple related acts of mail and wire fraud pursuant to 18 U.S.C. § 1341 and § 1342. Mail and wire fraud constitute conduct within the meaning of "racketeering activity," and the acts described herein constitute a pattern of racketeering activity pursuant to 18 U.S.C. § 1961(5).

297. More specifically, Defendants committed offenses under 18 U.S.C. § 1341 as follows:

(a) During the relevant period, Defendants and the other members of the enterprise devised and/or participated in a scheme or artifice to defraud Regenicin of substantial sums of money, by means of false or fraudulent pretenses, representations or promises related to material fact and omissions inducing Regenicin to enter the Regenicin/Lonza Know-How SPA and agree to invest in the development, FDA approval, sale and distribution of PermaDerm and to purchase shares of Cutanogen at an inflated price, as described above.

(b) Defendants acted willfully and with an intent to defraud or aided, abetted, counseled, commanded, induced or procured the commission of the scheme or artifice to defraud.

(c) As described above, Defendants and other members of the enterprise caused numerous documents related to the negotiation, execution and closing of the Regenicin/Lonza Know-How SP, as well as subsequent communication such as invoices, to be delivered or received by using the United States Postal Service or a private or commercial interstate carrier in furtherance of the scheme or artifice to defraud Regenicin. Defendants and other members of the enterprise used or caused the use of the mails or knew the use of the mails was likely.

(d) The foregoing mailings constituted separate indictable acts of mail fraud which were undertaken as part of the pattern of racketeering performed by LWI and other members of the enterprise having the purpose to defraud.

298. More specifically, Defendants have committed offenses under 18 U.S.C. § 1343 as follows:

(a) During the relevant period, Defendants and other members of the enterprise devised and/or participated in a scheme or artifice to defraud Regenicin of substantial sums of money, by means of false or fraudulent pretenses, representations or promises related to a material fact and omissions inducing Regenicin to enter the Regenicin/Lonza Know-How SPA and agree to invest in the development, FDA approval, sale and distribution of PermaDerm and to purchase shares of Cutanogen at an inflated price, as described above.

(b) Defendants acted willfully and with an intent to defraud or aided, abetted, counseled, commanded, induced, or procured the commission of the scheme or artifice to defraud.

(c) Defendants and other members of the enterprise used interstate wire transmissions, including telephone and e-mail communications, to initiate, receive, or participate in numerous communications related to the scheme or artifice to defraud Regenicin.

(d) The foregoing wire communications constituted separate indictable acts of wire fraud which were undertaken as part of the pattern of racketeering performed by Defendants and other members of the enterprise having the purpose to defraud.

299. Defendants also committed offenses of theft by deception constituting racketing activity.

300. Defendants are persons under N.J.S.A. §2C:20-4.

301. Defendants purposely obtained and/or exercised control over intellectual property rights rightfully belonging to Regenicin by deception.

302. Pursuant to the Regenicin/Lonza Know-How SPA, Lonza Walkersville was required to exclusively license certain intellectual property defined as “Know-How,” “Current Know-How,” and “Future Know-How”; exclusively license all of the patent rights, including patent applications, previously licensed to Lonza Walkersville pursuant to the Licenses; and grant an irrevocable license to “any and all . . . LWI Intellectual Property” (including PermaDerm) used in the process of manufacturing PermaDerm.

303. Regenicin paid Lonza Walkersville over \$3,000,000 for the licensing of such rights.

304. Defendants deceived Regenicin by purposely: (a) creating and reinforcing the false impression that Lonza Walkersville had transferred certain intellectual property rights related to Permaderm to Regenicin when Defendants knew that Lonza Walkersville had not

transferred such rights; (b) preventing Regenicin from acquiring information about Defendants' transfer of certain intellectual property rights to at least thirteen corporate entities prior to entering into the Regenicin/Lonza Know-How SPA and related agreements, which would affect Regenicin's judgment of the transaction; and (c) failing to correct the false impression that Lonza Walkersville had transferred certain intellectual property rights related to Permaderm to Regenicin which impression the Defendants previously created and reinforced.

305. Despite Lonza Walkersville's failure to transfer the intellectual property rights rightfully belonging to Regenicin, Defendants retained \$3,000,000 paid by Regenicin for the transfer of those rights.

306. Defendants have directly and indirectly conducted and participated in the conduct of the enterprise's affairs through the pattern of racketeering activity described above, in violation of 18 U.S.C. § 1962(c).

307. By reason of and as a direct and proximate result of Defendants' racketeering activities and violations of 18 U.S.C. § 1962(c), Regenicin has been injured in its business and property in an amount to be proven by the trier of fact exceeding \$5,000,000.

308. Regenicin requests that this Court enter judgment against Defendants for actual damages, treble damages, attorneys' fees, and prejudgment interest on the entire treble damages amount.

WHEREFORE, Regenicin respectfully prays for judgment against Defendants as follows:

- (a) All amounts demanded in each cause of action pled above;
- (b) Declaration that Regenicin owns the PermaDerm mark and that Lonza is enjoined from using the PermaDerm mark;
- (c) Lonza must turn over all PermaDerm Know-How in its possession;

- (d) Judgment in an amount to be determined at trial, including compensatory and punitive damages;
- (e) Pre- and post-judgment interest, to the fullest extent assessable at law or in equity, on all amount of damages;
- (f) Reasonable attorneys' fees, costs, and expenses;
- (g) Such other further relief as the Court may deem just and proper; and
- (h) Regenicin demands a trial by jury of twelve (12).

Submitted this 30th day of September, 2013.

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