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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MALLINCKRODT LLC, MALLINCKRODT INC. and NUVO RESEARCH INC. Plaintiffs, v. METRICS, INC., D/B/A COASTAL PHARMACEUTICALS, Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs Mallinckrodt LLC, Mallinckrodt Inc. and Nuvo Research Inc. (collectively "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Metrics, Inc., d/b/a Coastal Pharmaceuticals ("Coastal"), herein allege:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Coastal filing Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of Plaintiffs' pharmaceutical product PENNSAID® prior to the expiration of United States Patent Nos. 8,217,078 ("the '078 patent"); 8,546,450 ("the '450 patent"); and 8,618,164 ("the '164 patent") (collectively, "the patents-in-suit") which cover the use of PENNSAID®.

PARTIES

2. Plaintiff Mallinckrodt LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

3. Plaintiff Mallinckrodt Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

4. Plaintiff Nuvo Research Inc. ("Nuvo") is a corporation organized and existing under the laws of Ontario, having a place of business at 7560 Airport Road, Unit 10, Mississauga, Ontario L4T 4H4, Canada.

5. On information and belief, Defendant Metrics, Inc., is a corporation organized and existing under the laws of the state of North Carolina with a principal place of business at 1240 Sugg Parkway, Greenville, NC 27834. On information and belief, Metrics is in the business of selling generic pharmaceutical products, which it distributes in the State of New

Jersey and throughout the United States. Metrics' registered agent for service of process in the State of New Jersey is the Corporation Trust Company, 820 Bear Tavern Road, West Trenton, New Jersey 08628.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Coastal by virtue of, inter alia, its presence in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law, and having engaged in systemic and continuous contacts with the State of New Jersey.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

PENNSAID®

9. PENNSAID® was first developed in Canada by Nuvo as a treatment for the signs and symptoms of osteoarthritis, particularly of the knee.

10. PENNSAID® contains the active ingredient diclofenac, a non-steroidal anti-inflammatory drug ("NSAID") that is formulated with dimethyl sulfoxide ("DMSO"), a powerful solvent. PENNSAID® is applied multiple times per day by spreading the solution onto the skin surrounding the knee. On information and belief, the DMSO in PENNSAID® is a penetration enhancer that allows the diclofenac to penetrate the skin and migrate to the source of inflammation. Because PENNSAID® contains what is understood to be a penetration enhancer, there were early concerns that other topical products applied to the same area during treatment with PENNSAID® – other NSAIDs, corticosteroids, insect repellant, sunscreen, etc. – might also penetrate the skin and present a danger of toxicity.

11. For this reason, the March 13, 2003 PENNSAID® Canadian Foreign Product Monograph advised physicians at the time to inform patients not to apply any other topical medication to the treated area during the course of treatment.

12. This limitation presented problems during treatment with PENNSAID® because the most frequently noted adverse drug reaction in patients treated with PENNSAID® was application site skin irritation and dermatitis. Application site skin irritation and dermatitis are regularly treated with topical medications, particularly topical medications called corticosteroids, to relieve those conditions. Because the monograph instructed that topical medications were contraindicated during the course of treatment with PENNSAID®, patients that experienced these adverse reactions either had to discontinue application of PENNSAID® or leave the application site skin irritation and dermatitis untreated.

13. During drug development, the Nuvo researchers who became the inventors of the patents-in-suit surprisingly discovered that a second topical product can be safely applied to the application site during treatment with PENNSAID® if the treated area is first allowed to dry. For instance, the inventors discovered that patients experiencing application site skin irritation and dermatitis can be safely treated with a second topical product, for example a corticosteroid, provided that the area treated with PENNSAID® is allowed to dry before the second topical product is applied.

14. In 2009, Mallinckrodt LLC licensed Nuvo's pending patent applications and know-how concerning PENNSAID® patents and sought approval from the FDA to market PENNSAID® in the United States. The FDA approved Mallinckrodt's New Drug Application No. 020947 ("the PENNSAID® NDA") for diclofenac sodium topical solution 1.5%, under the trade name PENNSAID®, on November 4, 2009.

15. As a part of the regulatory process for obtaining approval of the PENNSAID® NDA, Mallinckrodt Inc. was required by the FDA to submit a proposed label for the drug. *See* 21 C.F.R. § 201.56(b). The label for PENNSAID® instructs physicians and patients, inter alia, about the proper prescribing, dosage and administration, warnings and precautions, and side effect information of PENNSAID®.

16. The label for PENNSAID® indicates, inter alia, that the most common adverse events associated with using diclofenac sodium topical solution are application site skin reactions. Because of the discovery that a second topical product can be safely applied during treatment with PENNSAID® if the area treated with PENNSAID® is allowed to dry, the label for PENNSAID® instructs physicians and patients to apply PENNSAID® to the knee and then allow the area to dry before applying another topical product.

17. A physician familiar with the application of topical medications such as PENNSAID® would therefore understand that topical products used to treat application site reactions would be subject to the label's instruction to allow the treated area to dry before applying another topical product.

18. Plaintiffs have educated prescribing physicians regarding the use of PENNSAID®. Physicians are informed that a common side effect of the use of such a diclofenac sodium topical solution 1.5% is application site skin irritation and dermatitis. Physicians are told that an appropriate method for treating the resulting skin irritation is to wait until the application site is dry after application of PENNSAID® and then apply a topical product including, but not limited to, a corticosteroid. Further, on information and belief, it is the standard of care for physicians to treat application site skin irritation and dermatitis by using topical corticosteroid drug products. One or more claims of the patents-in-suit cover the method

of applying diclofenac sodium topical solution 1.5%, waiting for the treated area to dry, and then applying a second topical product, such as a topical corticosteroid.

19. The label for PENNSAID® indicates, inter alia, that a patient should avoid exposure of treated knees with PENNSAID® to natural or artificial sunlight.

20. Because of the discovery that a second topical product can be safely applied during treatment with PENNSAID® if the area treated with PENNSAID® is allowed to dry, the label for PENNSAID® instructs physicians and patients to apply PENNSAID® to the knee and then allow the area to dry before applying another topical product. A physician familiar with the application of topical medications such as PENNSAID® would therefore understand that sunscreens should be used and would be subject to the label's instruction to allow the treated area to dry before applying another topical product, such as a sunscreen.

21. Plaintiffs have educated prescribing physicians regarding the use of PENNSAID® with sunscreens. Physicians are informed that an appropriate method for applying sunscreens is to wait until the application site is dry after application of PENNSAID® and then apply a topical product. One or more claims of the patents-in-suit cover the method of applying diclofenac sodium topical solution 1.5%, waiting for the treated area to dry, and then applying a second topical product, such as a sunscreen.

22. The label for PENNSAID® indicates, inter alia, that it is appropriate for a physician to treat a patient with a combination of PENNSAID® and an oral NSAID provided the benefit outweighs the risk. The label further recommends conducting periodic laboratory evaluations.

23. Osteoarthritis patients frequently suffer from severe or breakthrough pain. A physician understands a patient using PENNSAID® to treat signs and symptoms of

osteoarthritis, such as osteoarthritis of the knee, may experience severe or breakthrough pain that requires the use of an oral NSAID in combination with PENNSAID® provided that the benefit outweighs the risk as taught by the label's instructions.

24. Plaintiffs have educated prescribing physicians regarding the use of PENNSAID® with oral NSAIDS. One or more claims of the patents-in-suit cover the method of treating a patient with an oral NSAID and PENNSAID®.

THE PATENTS-IN-SUIT

25. The Nuvo researchers who discovered that a second medication can be safely applied during treatment with PENNSAID® filed patent applications beginning in March 2009 to protect their inventions.

26. On July 10, 2012 the United States Patent and Trademark Office issued the '078 patent, entitled "Treatment of Pain with Topical Diclofenac." The '078 patent was assigned to Nuvo, by inventors Jagat Singh, Joseph Zev Shainhouse, Bradley S. Galer, Robert Dominic King-Smith, Lisa Marie Grierson, Maria Burian, Jonathan Wilkin, Edward T. Kisak, and John M. Newsam. Nuvo granted Mallinckrodt LLC an exclusive license under the '078 patent with respect to, inter alia, topical diclofenac products known as PENNSAID®. A copy of the '078 patent is attached hereto as Exhibit A.

27. On October 1, 2013 the United States Patent and Trademark Office issued the '450 patent, entitled "Treatment of pain with topical diclofenac compounds." The '450 patent was assigned to Nuvo, by inventors Jagat Singh, Joseph Zev Shainhouse, Bradley S. Galer, Robert Dominic King-Smith, Lisa Marie Grierson, Maria Burian, Jonathan Wilkin, Edward T. Kisak, and John M. Newsam. Nuvo granted Mallinckrodt LLC an exclusive license under the

'078 patent with respect to, inter alia, topical diclofenac products known as PENNSAID®. A copy of the '450 patent is attached hereto as Exhibit B.

28. On December 31, 2013 the United States Patent and Trademark Office issued the '164 patent, entitled "Treatment of pain with topical diclofenac compounds." The '164 patent was assigned to Nuvo, by inventors Jagat Singh, Joseph Zev Shainhouse, Bradley S. Galer, Robert Dominic King-Smith, Lisa Marie Grierson, Maria Burian, Jonathan Wilkin, Edward T. Kisak, and John M. Newsam. Nuvo granted Mallinckrodt LLC an exclusive license under the '164 patent with respect to, inter alia, topical diclofenac products known as PENNSAID®. A copy of the '164 patent is attached hereto as Exhibit C.

29. The patents-in-suit are listed for PENNSAID® in the Patent and Exclusivity Information Addendum of the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"). The Patent Use Codes listed in the Orange Book for the PENNSAID® product are "Use of topical diclofenac on the knee and a second topical medication on the same knee" for the '078 patent; "Use of topical diclofenac on the knee and a second topical prescription medication on the same knee" for the '164 patent; and "Use of topical diclofenac on the knee and a second topical agent selected from sunscreen and insect repellant" and "Combination use of topical diclofenac on the knee and administration of an oral NSAID" for the '450 patent.

COASTAL'S ANDA

30. On information and belief, Coastal submitted ANDA No. 205178 ("the Coastal ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market diclofenac sodium topical solution 1.5% before the expiration of the patents-in-suit expire. The diclofenac

sodium topical solution described in the Coastal ANDA is herein referred to as the "Coastal Product."

31. The Coastal ANDA refers to and relies upon the PENNSAID® NDA and contains data that, according to Coastal, demonstrate the bioequivalence of the Coastal Product and PENNSAID®.

32. On or about February 21, 2014, Coastal sent to Plaintiffs a letter (the "Coastal Notification") stating that Coastal had included a certification in the Coastal ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the patents-in-suit are invalid or will not be infringed by the commercial manufacture, use, or sale of the Coastal Product (the "Coastal Paragraph IV Certification").

COUNT I
COASTAL'S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,217,078 UNDER 35 U.S.C. § 271(e)(2)(A)

33. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-32 of this Complaint.

34. Coastal has infringed the '078 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Coastal ANDA, by which Coastal seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Coastal Product prior to the expiration of the '078 patent.

35. Plaintiffs will be substantially and irreparably harmed if Coastal is not enjoined from infringing the '078 patent.

36. Plaintiffs have no adequate remedy at law.

COUNT II
COASTAL'S INDUCEMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,217,078 UNDER 35 U.S.C. § 271(b)

37. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-36 of this Complaint.

38. On information and belief, approval of the Coastal ANDA is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of a drug product that is marketed and sold for use in a method claimed in one or more claims of the '078 patent, immediately or imminently upon approval of the Coastal ANDA.

39. The FDA requires Coastal's proposed label for the Coastal Product to contain the same prescribing, dosage and administration, and side effect information as found on the PENNSAID® label. *See* 21 C.F.R. § 314.94(8)(iv).

40. On information and belief, Coastal's proposed label for the Coastal Product will instruct patients and physicians to apply the Coastal Product to the knee and then allow the area to dry before applying another topical medication. On information and belief, Coastal's proposed label for the Coastal Product will inform patients and physicians that the most common side effect of using a diclofenac sodium topical solution 1.5%, including the Coastal Product, is application site skin irritation. On information and belief, Coastal is aware that patients and physicians using this product will use another topical medication to treat application site skin irritation and that the application of a second topical medication would be subject to the label's instruction to allow the treated area to dry before application. On information and belief, Coastal will be marketing the Coastal Product with specific intent, and/or with desire, to actively induce, aid and abet infringement of the '078 patent. Coastal knows or reasonably should know that its proposed conduct will induce infringement of the '078 patent.

41. On information and belief, Coastal's generic marketing practices include listing generic products on its website and referring physicians and patients to a corresponding brand name product. On information and belief, Coastal intends to do the same for the Coastal Product, namely Coastal intends to list its generic product and refer patients to Plaintiffs' product, PENNSAID®. On information and belief, such marketing practices are likely to lead physicians prescribing, and patients using, a generic diclofenac sodium topical solution product to infer that recommendations regarding the use of PENNSAID®, including recommendations relating to the treatment of side effects stemming from the use of PENNSAID®, also apply to the Coastal Product.

42. On information and belief, the acts of infringement alleged above are and have been deliberate and willful.

43. Plaintiffs will be substantially and irreparably harmed if Coastal is not enjoined from inducing infringement of the '078 patent.

44. Plaintiffs have no adequate remedy at law.

COUNT III
COASTAL'S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,546,450 UNDER 35 U.S.C. § 271(e)(2)(A)

45. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-45 of this Complaint.

46. Coastal has infringed the '450 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Coastal ANDA, by which Coastal seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Coastal Product prior to the expiration of the '450 patent.

47. Plaintiffs will be substantially and irreparably harmed if Coastal is not enjoined from infringing the '450 patent.

48. Plaintiffs have no adequate remedy at law.

COUNT IV
COASTAL'S INDUCEMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,546,450 UNDER 35 U.S.C. § 271(b)

49. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-48 of this Complaint.

50. On information and belief, approval of the Coastal ANDA is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of a drug product that is marketed and sold for use in a method claimed in one or more claims of the '450 patent, immediately or imminently upon approval of the Coastal ANDA.

51. The FDA requires Coastal's proposed label for the Coastal Product to contain the same prescribing, dosage and administration, warnings and precautions, and side effect information as found on the PENNSAID® label. *See* 21 C.F.R. § 314.94(8)(iv).

52. On information and belief, Coastal's proposed label for the Coastal Product will instruct patients and physicians to apply the Coastal Product to the knee and then allow the area to dry before applying a sunscreen or an insect repellant. On information and belief, Coastal's proposed label for the Coastal Product will inform patients and physicians to avoid exposure of the treated knee to natural or artificial sunlight when using a diclofenac sodium topical solution 1.5%, including the Coastal Product. On information and belief, Coastal is aware that patients and physicians using this product will use sunscreen on the application site and that the application of a sunscreen would be subject to the label's instruction to allow the treated area to dry before application.

53. On information and belief, Coastal's proposed label for the Coastal Product will instruct patients and physicians that it is appropriate to treat a patient with a combination of PENNSAID® and an oral NSAID provided the benefit outweighs the risk. Further, the proposed label will recommend conducting periodic laboratory evaluations.

54. On information and belief, Coastal will be marketing the Coastal Product with specific intent, and/or with desire, to actively induce, aid and abet infringement of the '450 patent. Coastal knows or reasonably should know that its proposed conduct will induce infringement of the '450 patent.

55. On information and belief, Coastal's generic marketing practices include listing generic products on its website and referring physicians and patients to a corresponding brand name product. On information and belief, Coastal intends to do the same for the Coastal Product, namely Coastal intends to list its generic product and refer patients to Plaintiffs' product, PENNSAID®. On information and belief, such marketing practices are likely to lead physicians prescribing, and patients using, a generic diclofenac sodium topical solution product to infer that recommendations regarding the use of PENNSAID®, including recommendations relating to the treatment of side effects stemming from the use of PENNSAID®, also apply to the Coastal Product.

56. On information and belief, the acts of infringement alleged above are and have been deliberate and willful.

57. Plaintiffs will be substantially and irreparably harmed if Coastal is not enjoined from inducing infringement of the '450 patent.

58. Plaintiffs have no adequate remedy at law.

COUNT V
COASTAL'S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,618,164 UNDER 35 U.S.C. § 271(e)(2)(A)

59. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-58 of this Complaint.

60. Coastal has infringed the '164 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Coastal ANDA, by which Coastal seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Coastal Product prior to the expiration of the '164 patent.

61. Plaintiffs will be substantially and irreparably harmed if Coastal is not enjoined from infringing the '164 patent.

62. Plaintiffs have no adequate remedy at law.

COUNT VI
COASTAL'S INDUCEMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,618,164 UNDER 35 U.S.C. § 271(b)

63. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-62 of this Complaint.

64. On information and belief, approval of the Coastal ANDA is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of a drug product that is marketed and sold for use in a method claimed in one or more claims of the '164 patent, immediately or imminently upon approval of the Coastal ANDA.

65. The FDA requires Coastal's proposed label for the Coastal Product to contain the same prescribing, dosage and administration, and side effect information as found on the PENNSAID® label. *See* 21 C.F.R. § 314.94(8)(iv).

66. On information and belief, Coastal's proposed label for the Coastal Product will instruct patients and physicians to apply the Coastal Product to the knee and then allow the area to dry before applying a second topical prescription medication. On information and belief, Coastal's proposed label for the Coastal Product will inform patients and physicians that the most common side effect of using a diclofenac sodium topical solution 1.5%, including the Coastal Product, is application site skin irritation. On information and belief, Coastal is aware that patients and physicians using this product will use a second topical prescription medication to treat application site skin irritation and that the application of a second topical prescription medication would be subject to the label's instruction to allow the treated area to dry before application. On information and belief, Coastal will be marketing the Coastal Product with specific intent, and/or with desire, to actively induce, aid and abet infringement of the '164 patent. Coastal knows or reasonably should know that its proposed conduct will induce infringement of the '164 patent.

67. On information and belief, Coastal's generic marketing practices include listing generic products on its website and referring physicians and patients to a corresponding brand name product. On information and belief, Coastal intends to do the same for the Coastal Product, namely Coastal intends to list its generic product and refer patients to Plaintiffs' product, PENNSAID®. On information and belief, such marketing practices are likely to lead physicians prescribing, and patients using, a generic diclofenac sodium topical solution product to infer that recommendations regarding the use of PENNSAID®, including recommendations relating to the treatment of side effects stemming from the use of PENNSAID®, also apply to the Coastal Product.

68. On information and belief, the acts of infringement alleged above are and have

been deliberate and willful.

69. Plaintiffs will be substantially and irreparably harmed if Coastal is not enjoined from inducing infringement of the ’164 patent.

70. Plaintiffs have no adequate remedy at law.

COUNT VII
EXCEPTIONAL CASE WITH RESPECT TO COASTAL UNDER 35 U.S.C. § 285

71. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-70 of this Complaint.

72. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285 in light of Coastal’s conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Coastal and respectfully request the following relief:

A. A judgment declaring that Coastal has directly infringed and will induce infringement of U.S. Patent No. 8,217,078;

B. A judgment declaring that Coastal has directly infringed and will induce infringement of U.S. Patent No. 8,546,450;

C. A judgment declaring that Coastal has directly infringed and will induce infringement of U.S. Patent No. 8,618,164;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Coastal, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling the Coastal Product within the United States, or importing the Coastal Product into the United States, prior to the expiration date of the patents-in-suit;

E. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 205178 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the patents-in-suit, including any exclusivities and extensions;

F. If Coastal commercially manufactures, uses, offers to sell, or sells the Coastal Product within the United States, or imports the Coastal Product into the United States, prior to the expiration of the patents-in-suit, including any exclusivities and extensions, a judgment awarding Plaintiffs monetary relief together with interest;

G. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285.

H. Costs and expenses in this action; and

I. Such other relief as the Court deems just and proper.

LITE DEPALMA GREENBERG, LLC

Dated: April 7, 2014

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

I, Michael E. Patunas, hereby certify that the matter in controversy in this action is not related to any actions presently pending before the United States District Court for the District of New Jersey. The matter in controversy in this action is, however, related to the following actions which are or were before the United States District Court for the District of Delaware: *Mallinckrodt LLC et al v. Amneal Pharmaceuticals LLC*, C.A. 1:14-cv-00389-RGA; *IGI Laboratories, Inc., v. Mallinckrodt LLC et al*., C.A. No. 13-cv-02044-RGA; *Mallinckrodt LLC et al v. Lupin Ltd et al*., C.A. No. 12-cv-01087-RGA (closed); and *Mallinckrodt LLC et al v. Taro Pharmaceutical Industries Ltd. et al*, C.A. 13-cv-00494-RGA (closed).

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

LITE DEPALMA GREENBERG, LLC

Dated: April 7, 2014

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