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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

EKR THERAPEUTICS, INC., a Delaware Corporation,

Plaintiff,

v.

PHARMEDIUM HEALTHCARE CORPORATION, a Delaware Corporation, and PHARMEDIUM SERVICES LLC, a Delaware limited liability company,

Defendants.

Case No. 12CV0238 JAH BLM

Copyright/Trademark/Unfair Competition

COMPLAINT FOR:

1. **FALSE ADVERTISING AND UNFAIR COMPETITION UNDER 15 U.S.C. § 1125(a);**
2. **FALSE ADVERTISING UNDER CAL. BUS. & PROF. CODE § 17500; AND**
3. **UNFAIR COMPETITION UNDER CAL. BUS. & PROF. CODE § 17200**

DEMAND FOR JURY TRIAL

Plaintiff EKR Therapeutics, Inc. ("EKR" or "Plaintiff") as and for its complaint against Defendants PharMEDium Healthcare Corporation and PharMEDium Services LLC ("PharMEDium" or "Defendants"), states as follows:

Introduction

1. EKR manufactures and distributes CARDENE® RTU, the first and only shelf-stable and sterile pre-mixed, ready-to-use nicardipine injection product approved for marketing in the United States by the United States Food and Drug Administration ("FDA"). CARDENE® RTU is a life-saving drug that is administered to hospital patients suffering serious medical events who require a rapid reduction of blood pressure. EKR brings this action against PharMEDium, a manufacturer and marketer of unapproved pre-mixed nicardipine injection drug products that is unlawfully and unfairly marketing, promoting, distributing, and/or selling its unapproved pre-mixed nicardipine injection products in competition with EKR's CARDENE® RTU product.

2. Due to the proven public health concerns for drug safety and efficacy, it is against the law to market, distribute and/or sell any new drug product that is not FDA-approved (21 U.S.C. § 301 *et seq.*).

3. FDA approved CARDENE® RTU in 2008. Unlike diluted solution created using nicardipine ampoules, the CARDENE® RTU solution has a demonstrated stable room temperature shelf-life of up to two years.

4. Presently, EKR is the only lawful provider of an FDA-approved pre-mixed drug product containing nicardipine as the active ingredient.

5. Despite EKR's unique status as the only entity that can lawfully manufacture and market an FDA-approved pre-mixed nicardipine injection drug product in the United States, PharMEDium nevertheless markets its unapproved nicardipine injection products throughout the United States, including the State of California.

6. Moreover, through the means detailed herein, PharMEDium markets, promotes, distributes and sells its unapproved nicardipine products by relying on false and misleading statements, omissions and other tactics likely to (a) create false impressions and confusion regarding the safety, efficacy and FDA approval status of its nicardipine products and, concomitantly, EKR's CARDENE® RTU products; and (b) cause pharmacists, physicians, and hospital buyers mistakenly to conclude that PharMEDium's nicardipine products are interchangeable with EKR's FDA-approved CARDENE® RTU products or, even worse, that PharMEDium's products are safer than CARDENE® RTU products when they are not.

7. PharMEDium's unlawful marketing, advertising, promotion and distribution of its unapproved nicardipine injection products is not only misleading and deceptive, but irreparably harms EKR and poses grave health risks to California residents as well as to others.

8. EKR brings this action to enjoin PharMEDium's ongoing violations of the Lanham Act, 15 U.S.C. § 1125(a), California Business and Professions Code § 17500 and California Business and Professions Code § 17200. EKR seeks to prohibit PharMEDium from falsely and unfairly advertising, marketing, promoting and/or distributing its unapproved nicardipine injection products. EKR also seeks damages resulting from PharMEDium's unfair and unlawful conduct as set forth in the Prayer for Relief herein.

Parties

9. Plaintiff EKR Therapeutics, Inc. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 1545 U.S. Highway 206, Bedminster, New Jersey 07921.

10. EKR is a specialty pharmaceutical company focused on the acute-care hospital setting.

11. On information and belief, Defendant PharMEDium Healthcare Corporation is a corporation organized under the laws of the State of Delaware,

having its principal place of business at 150 North Field Drive, Suite 350, Lake Forest, Illinois 60045.

12. On information and belief, Defendant PharMEDium Services LLC is a Delaware limited liability company, having its principal place of business at 150 North Field Drive, Suite 350, Lake Forest, Illinois 60045.

13. On information and belief, PharMEDium's principal business is marketing and selling diluted or pre-mixed versions of injectable drug products for use in hospitals.

14. On information and belief, PharMEDium employs a sales force that promotes, markets and sells pre-mixed nicardipine injection drug products throughout the United States and in this judicial district.

15. On information and belief, PharMEDium has not obtained, nor ever sought to obtain, FDA approval for its pre-mixed nicardipine injection products.

Nature of the Action

16. This is a civil action for (1) false advertising and unfair competition under the Lanham Act (15 U.S.C. § 1125(a)), (2) false advertising under California Business and Professions Code § 17500, and (3) unfair competition under California Business and Professions Code § 17200.

Jurisdiction and Venue

17. This Court has subject matter jurisdiction over this action under Section 39 of the Lanham Act, 15 U.S.C. § 1121, and Title 28 of the United States Code § 1331 and 1338(a), and supplemental jurisdiction over state law claims under 28 U.S.C. § 1367(a).

18. This Court has personal jurisdiction over Defendants because Defendants have engaged in business activities in and directed to the State of California and this District, including the marketing, promotion, distribution, and/or sale of their unapproved pre-mixed nicardipine injection products, and have committed a tortious act within this District.

19. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and § 1391(c) because a substantial part of the events giving rise to the claims in this lawsuit occurred in this District and Defendants are subject to personal jurisdiction in this District.

Factual Background

A. FDA-Approved Nicardipine Injection Products

20. Nicardipine injection products are indicated for "the short-term treatment of hypertension when oral therapy is not feasible or not desirable." In practice, nicardipine injections are administered to hospitalized patients with elevated blood pressure due to serious medical events such as stroke, aortic dissections, elevated blood pressure due to kidney disease, or central nervous system injury, where rapid reduction of blood pressure as a life-saving intervention is warranted.

21. There are two forms of nicardipine injection approved by FDA pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"):

- nicardipine (2.5 mg/mL) in 10 mL glass ampoules, for dilution in 240 mL of intravenous fluid ("nicardipine ampoules"); and
- CARDENE® I.V. Pre-Mixed Injection 20 mg or 40 mg (0.1mg/mL or 0.2 mg/mL) ("CARDENE® RTU").

22. Nicardipine ampoules are currently available from EKR as CARDENE® I.V. (nicardipine for injection) and from various generic manufacturers. Nicardipine ampoules must be diluted in 240 mL of an appropriate diluent before being administered to a patient. This form of nicardipine was first approved for sale in the U.S. in 1992.

23. CARDENE® RTU is "ready to use" and does not require further dilution before it can be administered to a patient. For each strength of

CARDENE® RTU there are two diluent solution options: dextrose or sodium chloride. CARDENE® RTU is the only ready-to-use form of nicardipine approved by the FDA as being safe and effective for its intended use. It was approved for sale in the U.S. in 2008.

B. PharMEDium's Unapproved Nicardipine Injection Products

24. On information and belief, PharMEDium's nicardipine injection products consist of approved nicardipine ampoules mixed into an off-the-shelf commercially available plastic bag of diluent and approved nicardipine ampoules mixed into an off-the-shelf commercially available syringe of diluent.

25. On information and belief, PharMEDium's products are made available to hospitals and other customers in bulk, and not in response to a valid prescription for an identified patient.

26. The PharMEDium products are not FDA-approved, and as discussed below, these products are, on information and belief, misbranded, mislabeled and deceptive, and are being unlawfully manufactured and distributed in violation of the FDCA, as well as in violation of California Health and Safety Code §§ 111330, 111400, 111440, 111445 and 111550 and other state laws and regulations.

C. Safety Risks

1. FDA-Approved Labeling Warns That Nicardipine Injection Ampoules Have Very Short Stability After Being Filled Into I.V. Bags

27. Nicardipine ampoules require dilution with 240 mL of a suitable intravenous fluid before being administered to a patient by slow infusion at a final concentration of 0.1 mg/mL or 0.2 mg/mL.

28. The FDA-approved labeling for CARDENE® I.V. ampoules (and equivalent generic products) warns, "THE DILUTED SOLUTION IS STABLE FOR 24 HOURS AT ROOM TEMPERATURE" (capital letters in original).

29. Thus, for both safety and efficacy reasons, hospitals administering nicardipine therapy to patients using nicardipine ampoules must wait until they have an identified patient in need of the drug before diluting the drug and filling it into an I.V. bag for immediate administration.

30. On information and belief, PharMEDium's practice of simply pre-mixing nicardipine from approved nicardipine ampoule products into an off-the-shelf I.V. bag or syringe has not been demonstrated to FDA standards to result in a ready-to-use nicardipine injection product that will be safe, pure and stable beyond the 24-hour period specified in the FDA-approved labeling for the ampoule products.

2. Pre-Filled Nicardipine Injection Products Require a Highly Specialized Manufacturing Processes in Order to Overcome the Short-Stability Problem

31. The short-stability problem of diluted nicardipine ampoules, as well as difficulties in producing a sterile pre-filled nicardipine I.V. bag, posed technical barriers to the development of a pre-mixed, ready-to-use product.

32. Through extensive research and development efforts, EKR was able to develop CARDENE® RTU as the first and only FDA-approved shelf-stable and sterile pre-mixed ready-to-use nicardipine injection product. FDA approved CARDENE® RTU in 2008. Unlike diluted solution created using nicardipine ampoules, CARDENE® RTU has been demonstrated to have a stable room temperature shelf life of up to two years.

33. Reflecting the novelty of, and the innovation required to develop and produce such a product, the U.S. Patent and Trademark Office issued U.S. Patent No. 7,612,102 which covers pre-mixed ready-to-use nicardipine solution drug products.

34. The specification of the '102 patent describes the technical difficulties that had to be addressed in order to produce a safe and stable pre-mixed nicardipine product, as follows:

> The production of stable, ready-to-use, premixed pharmaceutical compositions comprising nicardipine and/or its pharmaceutically acceptable salts as the active ingredient presents different development hurdles than does the development of the concentrated ampoule product sold commercially as CARDENE® RTM I.V. As shown in FIG. 1, the percent of nicardipine remaining in solution decreases as function of pH over a twenty-four hour period. The percent decrease in nicardipine varies with the diluent and container chosen by the hospital staff.
>
> As described in the Examples, pH, the concentration of the active ingredient, and the composition of the container material affect the stability of the active ingredient and the formation of impurities. Thus, the development of a stable, ready-to-use premixed pharmaceutical composition requires simultaneous optimization of pH and nicardipine hydrochloride concentration, as well as selection of a pharmaceutically compatible container.

35. EKR solved the stability and sterility problems for pre-mixed nicardipine products through a combination of a modified pH range and the use of specially-designed I.V. bags filled using a proprietary aseptic manufacturing process developed by Baxter.

36. Because nicardipine is especially light-sensitive, the I.V. bag for the finished CARDENE® RTU product uses an opaque outer film to protect the product from light-induced degradation.

37. These processes and components for producing a shelf-stable and sterile pre-filled nicardipine product were extensively studied by EKR, and the data and results were reviewed by the FDA in connection with the approval of EKR's CARDENE® RTU product. On information and belief, no such FDA review has been conducted with respect to PharMEDium's manufacturing processes and product components.

38. Nicardipine ampoule products are sterile when manufactured, but that sterility is broken immediately upon opening the ampoule for dilution and filling into an I.V. bag or syringe. Where the diluted product is used immediately after

being mixed, no sterility-related safety concerns would be expected. However, a pre-filled nicardipine I.V. bag or syringe that is not intended for immediate use could pose safety problems unless the entire contents and components of the product are appropriately sterilized.

39. EKR is unaware of what, if any, sterilization processes PharMEDium uses for its pre-filled nicardipine products.

40. If PharMEDium is using sterilization techniques that have not been reviewed or approved by FDA, those techniques may exacerbate the products' stability and impurity levels.

3. Risk of Medication Error

41. On information and belief, PharMEDium is marketing, distributing and offering for sale six different unapproved versions of 250 mL pre-filled I.V. bags in the following strengths: 20 mg, 40 mg, 50 mg and 125 mg (in sodium chloride) and 25 mg and 125 mg (in dextrose).

42. Four of these products (20 mg, 40 mg and 50 mg in sodium chloride and 25 mg in dextrose) purport to contain the same amount of nicardipine per bag as EKR's CARDENE® RTU or an equivalent concentration. However, because PharMEDium's bags are 250 mL compared to CARDENE® RTU's 200 mL bags, the PharMEDium products do not deliver the same dosage strength at the same infusion rate as CARDENE® RTU and pose a significant risk of medication error if healthcare providers use the same flow rate settings on the I.V. pump as are used for CARDENE® RTU.

43. The two 125 mg strengths offered by PharMEDium have never been approved by the FDA, are unprecedented in the market and pose even greater risks of medication errors and the ability of healthcare providers to safely and effectively use these products in patients.

44. On information and belief, PharMEDium is also marketing, distributing and offering for sale four different unapproved nicardipine pre-filled syringe products in strengths of 1 mg/20 mL, 4 mg/20 mL, 10 mg/60 mL and 20 mg/60 mL.

45. There is no FDA-approved pre-filled syringe formulation of nicardipine injection at any strength. Moreover, because the only FDA-approved method of administration for nicardipine injection is by way of intravenous infusion, PharMEDium's pre-filled syringe presents a new, untested and unapproved method of administration.

D. The PharMEDium Products are Unlawful Under Federal and State Laws

46. PharMEDium's manufacturing and distribution of its pre-mixed nicardipine injection products violates the FDCA, as well as California law and pharmacy regulations, in several ways.

47. The PharMEDium products violate federal law because the products are a "new drug" and because they are not the subject of an approved New Drug Application ("NDA"). *See* 21 U.S.C. §§ 355(a) (requiring FDA approval of all "new drugs"), and 331(d) (prohibiting distribution of an unapproved new drug in violation of § 355).

48. FDA's regulations provide that "[a]ny parenteral drug product packaged in a plastic immediate container is not generally recognized as safe and effective" and is a "new drug" that "requires an approved new drug application as a condition for marketing." 21 C.F.R. § 310.509(a). Even when a pre-mixed parenteral drug product is not packaged in a plastic container, FDA has observed that the types of changes PharMEDium makes in converting nicardipine ampoules into pre-filled I.V. bags and syringes and reselling those bags and syringes to hospitals and other customers require an approved NDA unless those steps are performed in response to a valid prescription for an identified patient:

> Under these [NDA approval] provisions, each step in the manufacture and processing of a new drug or antibiotic,

> from handling of raw ingredients to final packaging, must be approved by FDA, whether carried out by the original manufacturer or by some subsequent handler or repacker of the product. Pharmacists are not exempt from these statutory requirements; however, the agency regards mixing, packaging, and other manipulations of approved drug by licensed pharmacists, consistent with the approved labeling of the product, as an approved use of the product if conducted within the practice of pharmacy, i.e., filling prescriptions for identified patients. Processing and repacking (including repackaging) of approved drugs by pharmacists for resale to hospitals, other pharmacies, etc., are beyond the practice of pharmacy and are thus subject to the requirements of premarket approval.

FDA, Compliance Policy Guidance Sec. 446.100, "Regulatory Action Regarding Approved New Drugs and Antibiotic Drug Products Subjected to Additional Processing or other Manipulations" ("Processing CPG"), ¶ 4 (emphasis added).[1]

49. The Processing CPG emphasizes that:

> FDA has even greater concern about the manipulation of approved sterile drug products, especially when the sterile container is opened or otherwise entered to conduct manipulations such as dissolving, diluting or aliquoting, refilling, resterilizing, or repackaging in new containers.

Id. ¶ 7 (emphasis added).

50. Because, on information and belief, PharMEDium's pre-mixed products utilize off-the-shelf commercially available diluent bags and syringes which are made out of plastic, PharMEDium's products are subject to prior FDA approval under 21 C.F.R. § 310.509(a).

51. The fact that PharMEDium modifies FDA-approved nicardipine ampoules violates additional FDA regulations which require prior FDA approval for

[1] The complete text of this Processing CPG is available at http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074385.htm.

the types of changes PharMEDium makes in converting nicardipine ampoules into pre-filled I.V. bags and syringes. *See* 21 C.F.R. § 314.70(b).

52. Under this regulation, prior FDA approval is required for any change in the drug substance, drug product, production process, quality controls, equipment, or facilities.

53. By modifying nicardipine ampoules into pre-mixed I.V. bags and syringes, and thus changing, among other things, the concentration of the nicardipine solution, without FDA approval, PharMEDium is, directly or indirectly, circumventing the very FDA regulations that EKR followed in order to obtain approval of its NDA, and any testing procedures used by PharMEDium have not undergone the rigorous NDA review process otherwise required for new drug products.

54. PharMEDium's products are essentially an attempted (and unapproved) copy of a commercially available product – CARDENE® RTU – that FDA has carefully reviewed and approved for safety and efficacy. This type of activity circumvents important public health requirements and undermines the drug approval process – the evidence-based system of drug review that consumers and health professionals rely on for safe and effective drugs.

55. The PharMEDium pre-filled nicardipine injection products are manufactured and distributed in violation of the FDCA because PharMEDium has not received prior FDA approval of its finished products or the changes that PharMEDium makes in converting nicardipine ampoules into pre-filled I.V. bags and syringes. Upon information and belief, PharMEDium's unapproved manufacturing procedures render its pre-filled nicardipine products adulterated in violation of the FDCA, 21 U.S.C. §§ 331 and 351.

56. Upon information and belief, the PharMEDium pre-filled nicardipine injection products are misbranded in violation of the FDCA because PharMEDium distributes its products with a label that represents that the product is stable for 90

days from the date of its manufacture in direct contradiction to the stability warning and instructions in the approved labeling for the nicardipine ampoule products that PharMEDium uses to create its pre-mixed products.

57. A drug product is misbranded under the Act "[i]f its labeling is false or misleading in any particular," or if "it is dangerous to health when used in the dosage or manner. . . suggested in the labeling thereof." 21 U.S.C. §§ 352(a), 352(j).

58. The PharMEDium products may also be misbranded under 21 U.S.C. § 352(f) if they are distributed without the FDA-approved labeling for nicardipine ampoule product that the company uses as its source for the nicardipine in the pre-mixed products.

59. PharMEDium cannot properly claim that its products are a "pharmacy compounded" product exempt from FDA regulation.

E. PharMEDium's False and Misleading Stability Claims

60. On information and belief, PharMEDium places a label on its pre-filled nicardipine injection products that states that the PharMEDium products will have a shelf life of 90 days.

61. Similarly, in the marketing and promotion of its pre-filled nicardipine injection products PharMEDium claims that its products will have a 90-day shelf life.

62. These claims are directly contrary to the stability warning and instructions in the approved labeling for nicardipine ampoule products that PharMEDium uses to create its pre-mixed products which expressly warn that "THE DILUTED SOLUTION IS STABLE FOR 24 HOURS AT ROOM TEMPERATURE" (capital letters in original).

63. On information and belief, PharMEDium's claim that its products will have a shelf life of 90 days is not supported by sound scientific evidence, let alone the rigorous scientific evidence necessary to obtain FDA approval.

64. The labels placed on PharMEDium's pre-filled nicardipine injection products and related shelf life claims are thus false and misleading, in that they are directly contrary to the stability warning and instructions in the approved labeling for nicardipine ampoule products that PharMEDium uses to create its pre-mixed products and contain the false and misleading statement that PharMEDium's products maintain stability for a period of 90 days when that has not been demonstrated to FDA standards to be the case.

65. The labels placed on PharMEDium's pre-filled nicardipine injection products and related shelf life claims are also false and misleading because they imply that its products are a safe and effective and/or FDA-approved alternative to or substitute for CARDENE® RTU when they are not.

F. PharMEDium's False and Misleading Safety Claims

66. PharMEDium's marketing and sale of its pre-mixed nicardipine injection products in interstate commerce is facilitated by PharMEDium's false and misleading representation that its products are "far easier" and "far safer" than other products.

67. On information and belief, PharMEDium has not undertaken the steps necessary to establish the safety and efficacy of its unapproved pre-mixed nicardipine injection products (through the filing of NDAs supported by clinical data) let alone that its products are safer than CARDENE® RTU.

68. On information and belief, the false and misleading marketing tactics employed by PharMEDium have misled their audience into believing that PharMEDium's unapproved pre-mixed nicardipine injection products are safe and effective and/or FDA-approved alternatives to or substitutes for CARDENE® RTU when they are not.

G. PharMEDium's Use of False NDC Numbers

69. PharMEDium's marketing and sales of its pre-mixed nicardipine injection products in interstate commerce is further facilitated by PharMEDium's

false and misleading representation that its products are listed in the National Drug Code Directory ("NDC") and have registered NDC numbers 61553-890-11, 61553-891-11, 61553-892-11, 61553-893-11, 61553-894-11, 61553-895-11, 61553-896-11, 61553-897-11, 61553-897-11, 61553-898-11 and 61553-899-11.

70. In fact, the NDC numbers associated with PharMEDium's nicardipine products are not registered with the FDA's National Drug Code Directory.

71. On information and belief, PharMEDium has no products registered with the FDA's National Drug Code Directory.

H. PharMEDium's False Claims Have Damaged EKR's Business

72. PhaMedium's false and misleading marketing of its pre-mixed nicardipine products as being a shelf-stable, ready-to-use nicardipine injection product that is comparable to and/or safer than CARDENE® RTU has positioned PharMEDium's products in the marketplace as a lower-cost alternative to or substitute for CARDENE® RTU.

73. On information and belief, as a result of these false and misleading practices, PharMEDium has wrongfully obtained business from a number of hospital buying groups that previously had obtained all of their requirements for nicardipine in pre-mixed and ready-to-use presentations from EKR alone.

74. On information and belief, other customers of EKR have indicated that they will also be switching to the PharMEDium product.

75. This misappropriation of EKR's business has damaged, among other things, EKR's profits, market share, reputation, and goodwill in the marketplace.

First Claim For Relief

False Advertising and Unfair Competition Under The Lanham Act (15 U.S.C. § 1125(a))

76. EKR restates and incorporates herein by reference Paragraphs 1-75 as though fully set forth herein.

77. PharMEDium makes, distributes, causes to be distributed, authorizes the distribution of, and/or otherwise disseminates false and/or misleading statements regarding its unapproved pre-mixed nicardipine injection products, including false and misleading statements that its products have a stable shelf life of 90 days, are registered with the FDA's National Drug Code Directory and are safer than CARDENE® RTU.

78. On information and belief, PharMEDium engages in such acts with the intent to deceive, mislead and/or confuse relevant consumers into believing that its unapproved pre-mixed nicardipine injection products are a safe and effective and/or FDA-approved alternative to or substitute for EKR's FDA-approved CARDENE® RTU product when they are not.

79. On information and belief, these false and/or misleading statements have been and are material to hospital pharmacists and buyers in selecting a pre-mixed nicardipine injection product for treatment of elevated blood pressure due to serious medical events such as stroke, aortic dissections, elevated blood pressure due to kidney disease, or central nervous system injury, where rapid reduction of blood pressure as a life-saving intervention is warranted.

80. On information and belief, PharMEDium knows, reasonably should know, or failed to investigate so as not to know, that these statements are false and/or misleading.

81. PharMEDium disseminated false and/or misleading statements and information to potential customers for the purpose of promoting the purchase and use of its unapproved pre-mixed nicardipine injection products as a safe and effective and/or FDA-approved alternative to or substitute for CARDENE® RTU when they are not.

82. On information and belief, the false and/or misleading statements and information disseminated by PharMEDium have actually deceived and/or have the tendency to deceive a substantial number of actual and potential purchasers.

83. As a result of PharMEDium's acts of false and misleading descriptions of fact, false and misleading and/or deceptive representations and unfair competition, EKR has suffered, currently suffers, and will continue to suffer damage and irreparable injury, including to its business, reputation and good will.

84. The false and/or misleading statements and information disseminated by PharMEDium constitute violations of Section 43(a) of the Lanham Act (15 U.S.C. § 1125(a)).

85. Pursuant to 15 U.S.C. § 1117, EKR is entitled to damages for PharMEDium's Lanham Act violations, an accounting of profits made by PharMEDium on sales of its pre-mixed nicardipine injection products, as well as recovery of costs of this action. Furthermore, EKR is informed and believes, and on that basis alleges, that PharMEDium's conduct was undertaken willfully and with the intention of causing confusion, mistake or deception, making this an exceptional case entitling EKR to recover additional damages and reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.

86. PharMEDium's conduct has caused, and will continue to cause, immediate and irreparable harm to EKR for which there is no adequate remedy at law. As such, EKR is entitled to injunctive relief as set forth in 15 U.S.C. § 1116.

Second Claim For Relief

Statutory False Advertising

(Cal. Bus. and Prof. Code § 17500)

87. EKR restates and incorporates herein by reference Paragraphs 1-86 as though fully set forth herein.

88. PharMEDium makes, distributes, causes to be distributed, authorizes the distribution of, and/or otherwise disseminates false and/or misleading statements in and directed to the State of California regarding its unapproved pre-mixed nicardipine injection products including false and misleading statements that

its products have a stable shelf life of 90 days, are registered with the FDA's National Drug Code Directory and are safer than CARDENE® RTU.

89. On information and belief, PharMEDium has made and continues to make the false and misleading statements alleged herein with the intent to deceive potential purchasers into believing that PharMEDium's unapproved pre-mixed nicardipine injection products are a safe and effective and/or FDA-approved alternative to or substitute for CARDENE® RTU when they are not.

90. On information and belief, PharMEDium's false and misleading statements as alleged herein have mislead actual and potential purchasers into believing that PharMEDium's unapproved pre-mixed nicardipine injection products are a safe and effective and/or FDA-approved alternative to or substitute for CARDENE® RTU when they are not.

91. On information and belief, PharMEDium knows, reasonably should know, or failed to investigate so as not to know, that these statements are false and/or misleading.

92. The acts of PharMEDium, as herein alleged, constitute false advertising in violation of California Business and Professions Code § 17500 *et seq.*

93. As a result of PharMEDium's willful and intentional acts alleged herein, EKR has suffered damages in an amount to be proven at trial and, unless PharMEDium's wrongful acts are enjoined, EKR will continue to suffer irreparable harm.

Third Claim for Relief

Unfair Competition

(Cal. Bus. and Prof. Code § 17200)

94. EKR restates and incorporates herein by reference Paragraphs 1-93 as though fully set forth herein.

95. The acts of PharMEDium, as herein alleged, constitute unlawful, unfair and deceptive business practices in violation of California Business and Professions Code §17200 *et seq.* Such acts include, without limitation, PharMEDium's unlawful distribution and sale of pre-mixed nicardipine drug products in violation of federal and state law, PharMEDium's unfair competition and false advertising in connection with the marketing and sale of its pre-mixed nicardipine injunction products in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a) and California Business and Professions Code § 17500 *et seq.* and PharMEDium's deceptive statements regarding its pre-mixed nicardipine drug products as alleged above.

96. As a result of PharMEDium's conduct, EKR has suffered and will continue to suffer damage to its business, reputation and goodwill.

97. PharMEDium's conduct has caused, and unless enjoined by this Court, will continue to cause immediate and irreparable harm to EKR for which there is no adequate remedy at law, and for which EKR is entitled to injunctive relief.

98. In addition to injunctive relief, the Court should award EKR such restitution, disgorgement and/or damages as are permitted by statute.

Prayer For Relief

WHEREFORE, EKR prays that this Court enter judgment against PharMEDium as follows:

A. That PharMEDium and all of their respective officers, agents, servants, representatives, employees, attorneys, and all other persons acting in concert with them be preliminarily and permanently enjoined from:

1. directly or indirectly engaging in false advertising, marketing and/or promotions of any kind relating to its unapproved nicardipine injection products and/or inducing others to substitute PharMEDium's unapproved nicardipine injection products for EKR's FDA-approved CARDENE® RTU product;

2. making or inducing others to make any false, misleading or deceptive statement of fact, or misrepresentation of fact in connection with the marketing, promotion, sale, offering for sale, manufacture, production, or distribution of PharMEDium's pre-mixed nicardipine injection products in such a fashion as to suggest that such products (a) have a stable shelf life beyond the 24 hours after dilution set forth in FDA-approved labeling for nicardipine ampoules, (b) are safer than EKR's FDA-approved CARDENE® RTU product, (c) is a generic or therapeutic equivalent to EKR's FDA-approved CARDENE® RTU product, or (d) can be interchanged with or substituted for EKR's FDA-approved CARDENE® RTU product;

B. That PharMEDium be ordered to correct any erroneous impression that persons may have derived concerning the nature, characteristics, or qualities of either PharMEDium's pre-mixed nicardipine injection products or EKR's FDA-approved CARDENE® RTU product, including without limitation:

1. the sending of a registered letter to (with a copy to EKR) all customers which PharMEDium knows or has reason to believe have received the false and/or misleading statements concerning PharMEDium's pre-mixed nicardipine injection products, notifying them of and correcting all such false and/or misleading statements;

2. the placement of corrective advertising to prevent the inducement of others from substituting PharMEDium's pre-mixed nicardipine injection products for EKR's FDA-approved CARDENE® RTU product;

C. That PharMEDium be adjudged to have violated the provisions of 15 U.S.C. § 1125(a) by unfairly competing against EKR by using false or misleading descriptions or representations of fact that misrepresent the nature, quality and characteristics of their unapproved pre-mixed nicardipine injection products and be enjoined from further such violations;

D. That PharMEDium be adjudged to have violated California Business and Professions Code § 17200 *et seq.* by unlawfully and unfairly competing against EKR and be enjoined from further such violations;

E. That PharMEDium be adjudged to have violated California Business and Professions Code § 17500 *et seq.* by engaging in false or misleading advertising and be enjoined from further such violations;

F. That EKR be awarded damages pursuant to 15 U.S.C. § 1117(a), sufficient to compensate it for the damage caused by PharMEDium's false and/or misleading statements and unfair competition;

G. That EKR be awarded PharMEDium's profits derived by reason of said acts, or as determined by an accounting;

H. That such damages and profits be trebled and awarded to EKR and that EKR be awarded its costs, attorneys' fees and expenses in this suit under 15 U.S.C. § 1117 as a result of PharMEDium's willful, intentional and deliberate acts in violation of the Lanham Act;

I. That EKR be awarded such restitution, disgorgement and/or damages as are permitted by California Business and Professions Code §§ 17200 *et seq.;*

J. That EKR be awarded damages for PharMEDium's false advertising under California Business and Professions Code § 17500;

K. That EKR be granted injunctive relief under 15 U.S.C. § 1116 *et seq.*, California Business and Professions Code § 17500 *et seq.* and California Business and Professions Code § 17200 *et seq.*;

L. That PharMEDium recall and remove from distribution supply chains all their unapproved pre-mixed nicardipine injection products bearing false or misleading labels, instructions or packaging;

M. That all of PharMEDium's false or misleading materials, including without limitation labels, instructions and packaging, be destroyed as allowed under 15 U.S.C. § 1118;

N. That PharMEDium file, within ten days from entry of an injunction, a declaration with this Court signed under penalty of perjury certifying the manner in which PharMEDium has complied with the terms of the injunction;

O. That EKR be awarded reasonable attorneys' fees and costs of suit herein;

P. That EKR be granted pre-judgment and post-judgment interest; and

Q. That EKR be granted such further relief as the Court deems just and proper.

DATED: January 30, 2012

QUINN EMANUEL URQUHART & SULLIVAN, LLP

By: _____
Scott B. Kidman
Attorneys for Plaintiff EKR Therapeutics, Inc.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure and Local Rule 38.1, Plaintiff EKR Therapeutics, Inc. demands a trial by jury on all issues triable of right by a jury.

DATED: January 30, 2012

QUINN EMANUEL URQUHART & SULLIVAN, LLP

By _____
Scott B. Kidman
Attorneys for Plaintiff EKR Therapeutics, Inc.

ORIGINAL

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

EKR THERAPEUTICS, INC., a Delaware Corporation

(b) County of Residence of First Listed Plaintiff Somerset Cty., NJ
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

QUINN EMANUEL URQUHART & SULLIVAN, LLP; 865 South Figueroa Street, 10th Floor; LA, California 90017;(213) 443 3000

DEFENDANTS

PHARMEDIUM HEALTHCARE CORP., a DE Corp., and PHARMEDIUM SERVICES LLC, a DE LLC,

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

12CV0238 JAH BLM

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☒ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☒ ~~890 Other Statutory Actions~~
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
15 U.S.C. § 1125(a)

Brief description of cause:
False Advertising Under Lanaham Act and under CA Sections 17200 and 17500

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND $**

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
01/30/2012

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # 34902 AMOUNT $350 APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

MB 01/30/12

DUPLICATE

Court Name: USDC California Southern
Division: 3
Receipt Number: CAS034902
Cashier ID: mbain
Transaction Date: 01/30/2012
Payer Name: LA DEPOSITIONS INC

CIVIL FILING FEE
For: EKR THERAPEUTICS V PHARMEDIUM
Case/Party: D-CAS-3-12-CV-000238-001
Amount: $350.00

CHECK
Check/Money Order Num: 117293
Amt Tendered: $350.00

Total Due: $350.00
Total Tendered: $350.00
Change Amt: $0.00

There will be a fee of $53.00
charged for any returned check.