UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. ADOCIA S.A., Defendant.	)))))))))	Civil Action No. 1:18-cv-3133

COMPLAINT

Plaintiff Eli Lilly and Company ("Lilly"), by its undersigned attorneys, brings this action against Adocia S.A. ("Adocia"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., in particular 35 U.S.C. § 256, and is brought pursuant to 28 U.S.C. §§ 2201 and 2202, for a declaratory judgment that the designations of inventorship currently appearing on United States Patent Nos. 9,901,623 (the "'623 Patent") and 9,993,555 (the "'555 Patent") (collectively, the "Patents-in-Suit") are complete and correct, as required by the patent laws of the United States, 35 U.S.C. §§ 101, 111, 116 and 256.

THE PARTIES

2. Plaintiff Lilly is a corporation organized and existing under the laws of the State of Indiana and has its headquarters and principal place of business at Lilly Corporate Center, Indianapolis, Indiana, 46285. Lilly is a research-based company dedicated to developing innovative drugs to improve the lives of patients. Lilly is the assignee and owner of the '623 and '555 Patents.

3. On information and belief, Defendant Adocia is a corporation organized and existing under the laws of the French Republic, with its headquarters and principal place of business at 115, avenue Lacassagne 69003, Lyon, France. On information and belief, Adocia is a clinical-stage biotechnology company.

JURISDICTION AND VENUE

4. This is a civil action arising under the patent laws of the United States of America, Title 35 of the U.S. Code, for a declaration of proper inventorship of the Patents-in-Suit.

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Adocia at least because (a) Adocia has purposefully directed its business activities at a resident of Indiana (*i.e.*, Lilly); (b) the current inventorship dispute arises out of or relates to the business activities directed at the resident of Indiana (*i.e.*, Lilly); and (c) the assertion of personal jurisdiction would comport with fair play and substantial justice. As described in more detail below, Adocia reached beyond France and into Indiana to create continuing business relationships and contractual obligations with a resident of Indiana (*i.e.*, Lilly).

7. Alternatively, this Court has personal jurisdiction over Adocia because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Lilly's claims arise under federal law; (b) Adocia is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Adocia has sufficient contacts in the United States as a whole, including, but not limited to, participating in continuing business relationships and contractual obligations with U.S. residents, and/or seeking patent protection from the United States Patent and Trademark Office (the "USPTO") by filing its own U.S. Patent Applications, such as U.S.

Pat. Appl. Nos. 12/219,679, 13/287,793 and 15/353,522, such that this Court's exercise of jurisdiction over Adocia satisfies due process.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391.

BACKGROUND

The Patents-in-Suit

9. The '623 Patent, entitled "Rapid-Acting Insulin Compositions," was duly and legally issued by the USPTO on February 27, 2018. Lilly owns all right, title, and interest in and to the '623 Patent. A true, correct, and complete copy of the '623 Patent is attached hereto as Exhibit A.

10. The '623 Patent relates to pharmaceutical compositions of insulin or an insulin analog that include certain concentrations of citrate, treprostinil, zinc and stabilizing agents. The '623 Patent explains that its claimed inventions are stable and have more rapid pharmacokinetic and/or pharmacodynamic action than commercial formulations of existing insulin analog products.

11. The '555 Patent, entitled "Rapid-Acting Insulin Compositions," was duly and legally issued by the USPTO on June 12, 2018. Lilly owns all right, title, and interest in and to the '555 Patent. A true, correct, and complete copy of the '555 Patent is attached hereto as Exhibit B.

12. The '555 Patent relates to pharmaceutical compositions of insulin or an insulin analog that include certain concentrations of citrate and zinc, along with a preservative, but do not include EDTA. The '555 Patent explains that its claimed inventions are stable and have more rapid pharmacokinetic and/or pharmacodynamic action than commercial formulations of existing insulin analog products.

13. Lilly scientists have worked since at least the 1990s to develop fast-acting insulin products. Unlike first-generation insulin products, which enter the bloodstream gradually and help regulate blood sugar throughout the day, fast-acting insulin products enter the bloodstream rapidly for acute treatment of short-term spikes in blood sugar caused by eating.

14. One approach Lilly pursued to develop fast-acting insulin was structural modification of insulin proteins to make insulin analogs that retain the activity of insulin but have improved pharmacokinetic properties, such as insulin lispro (sold by Lilly as Humalog®).

15. The Patents-in-Suit relate to formulations of insulin or an insulin analog containing certain concentrations of citrate, either alone or in the presence of the vasodilator treprostinil, that have a more rapid time action profile than existing insulin products. The named inventors also discovered that the chemical and physical stability of the new ultra-rapid insulin ("URI") formulations containing citrate can be maintained, without eliminating the improvements to the time action profile, by including zinc or other stabilizing agents, such as magnesium chloride, in the pharmaceutical composition.

16. Lilly's research leading to the Patents-in-Suit began at least as early as 2011. Lilly's successful development of the URI products claimed in the Patents-in-Suit was due to Lilly's robust internal development program, including Lilly's serendipitous discovery that a certain impurity can improve the time action profile of an insulin analog, as well as Lilly's analysis of published explanations about the time action profiles of other insulin products. Lilly's successful development of these URI products was not due to input from Adocia.

17. The individuals who contributed to the inventions claimed in the Patents-in-Suit were employees of Lilly at the times of their contributions. No other individual contributed to the inventions claimed in the Patents-in-Suit.

The Collaboration Between Lilly and Adocia

18. On information and belief, Adocia repeatedly reached out to Lilly in Indiana to propose a research collaboration to develop a URI product using Adocia's BioChaperone® technology.

19. No later than 2011, Lilly and Adocia began negotiating an agreement for the development of a URI product using Adocia's BioChaperone® technology.

20. On information and belief, Adocia's BioChaperone® technology uses polymers to form physical complexes with therapeutic proteins with the goal of improving the protein's time action profile. On information and belief, Adocia's business is built entirely on formulating existing therapeutic proteins with its BioChaperone® technology.

21. On December 13, 2011, Adocia and Lilly entered into a "Collaborative Research & License Agreement" to begin joint development of a URI product based on Lilly's Humalog® product formulated with a BioChaperone® molecule from Adocia.

22. On November 21, 2012, Adocia and Lilly signed a confidentiality agreement.

23. In July 2013, the 2011 agreement was terminated.

24. On December 16, 2013, Adocia and Lilly entered into a second confidentiality agreement.

25. On December 18, 2014, Adocia and Lilly entered into a second "Collaborative Research & License Agreement" for the joint development of a URI product based on Lilly's Humalog® product formulated with different BioChaperone® molecules from Adocia.

26. The research collaboration between Adocia and Lilly continued until January 2017.

27. Over the course of five years, Adocia purposefully directed its business activities into the state of Indiana.

28. For example, on November 27, 2012, Adocia representatives traveled to Lilly's headquarters in Indianapolis and participated in a formal meeting about the companies' joint development of a URI product. On information and belief, Adocia representatives traveled to Indianapolis for meetings about the research collaboration on other occasions.

29. As another example, on information and belief, Adocia and Lilly frequently met face-to-face and via teleconference to discuss issues related to the joint development of a URI product using Adocia's BioChaperone® technology.

30. As another example, under both agreements, the research collaboration was monitored and controlled by a Steering Committee made up of representatives from Lilly and Adocia who met regularly.

31. As another example, Adocia disclosed the structure of many of its proprietary BioChaperone® molecules to Lilly in Indiana, and supplied Lilly with BioChaperone® molecules, including shipping BioChaperone® molecules into Indiana.

32. As another example, Lilly's and Adocia's research teams met regularly to develop the manufacturing process for one of Adocia's BioChaperone® molecules.

33. As another example, Lilly and Adocia issued a joint press release from Indianapolis and Lyon, France on December 19, 2014, announcing the companies' "alliance to co-develop ultra-rapid insulin based on BioChaperone technology."

34. As another example, on information and belief, Lilly reimbursed Adocia over the course of the collaboration for certain research and development expenses.

35. As another example, on information and belief, Adocia and Lilly were in regular contact via telephone, mail and email.

36. The research collaborations between Adocia and Lilly, however, were separate from Lilly's internal program to develop a URI product using specific concentrations of citrate for a more rapid time action profile, along with other specific excipients added to maintain the stability required for an insulin-based pharmaceutical composition. Unlike Lilly's internal research and the claims of the Patents-in-Suit, the research collaboration between Lilly and Adocia focused only on URI products containing BioChaperone® molecules.

Adocia's Allegations of Inventorship of the Patents-in-Suit

37. Under the patent laws of the United States, the inventors of a duly and legally issued patent, including the Patents-in-Suit, are presumed to be correct.

38. Despite this, after the termination of the research collaboration between Lilly and Adocia for the joint development of a URI product using Adocia's BioChaperone® molecules, Adocia has repeatedly alleged to Lilly that Adocia employees should be listed as inventors on the Patents-in-Suit.

39. Adocia has alleged that its purported contributions to the pharmaceutical compositions of the Patents-in-Suit arose during Adocia's research with BioChaperone® molecules as part of the research collaborations between Lilly and Adocia.

40. On June 14, 2017, Adocia's CEO, Gérard Soula, wrote to the President of Lilly and Lilly's General Counsel demanding that "Lilly put in place a document hold prohibiting the destruction of any documents relating to the parties' collaborations and/or to any other internal or external development project relating to the development of an ultra-rapid insulin product," and that Lilly meet with Adocia to discuss, among other things, "[c]orrection of inventorship with

respect to" Lilly's U.S. Provisional Patent Application Nos. 62/092,407 and 62/210,469, from which the '555 Patent and the '623 Patent claim priority, respectively.

41. Two days later, on June 16, 2017, Adocia filed U.S. Patent Application No. 15/625,684 with claims directed to pharmaceutical compositions of insulin with specific concentrations of citrate, but without requiring a BioChaperone® molecule.

42. On July 24, 2017, Adocia's outside counsel, Tharan G. Lanier of the Jones Day law firm, wrote a letter to Lilly's in-house patent counsel, Jennifer Gregory, that identified U.S. Provisional Patent Application No. 62/092,407, from which the '555 Patent claims priority, and alleged, "What Lilly is attempting to patent now in multiple patent applications, without Adocia's consent, is Adocia's invention." The letter concluded, "Adocia's claims include both damages and control over the patent rights in all of the jurisdictions in which Lilly is seeking patent protection … ."

43. The parties met on July 27, 2017, in part to discuss Adocia's allegations about its purported inventorship of the Patents-in-Suit.

44. On September 5, 2017, Mr. Lanier wrote a letter to Ms. Gregory and Lilly's outside counsel, Konrad L. Cailteux of the law firm Weil, Gotshal & Manges LLP, that included a section entitled "Scope of Adocia's Claims, Damages and Other Relief." In this section, Adocia alleged that Lilly used Adocia's purportedly confidential information in Lilly's patent applications "giving rise to a variety of claims including those for correction of inventorship." Adocia went on to explain that "Adocia will see[k] correction of inventorship/ownership, a constructive trust over Lilly's patent applications and a declaration that Adocia is the true owner of the ideas, information and matter (expressed in various forms of intellectual property)

underlying Lilly's citrate-products. This nominally nonmonetary relief for Adocia has significant economic consequences that Lilly should consider in assessing this situation."

COUNT 1: DECLARATORY JUDGEMENT OF PROPER INVENTORSHIP OF THE '623 PATENT

45. Lilly incorporates by reference each of the preceding paragraphs as if fully set forth herein.

46. Adocia has repeatedly alleged, as described above, that its employees contributed to the inventions claimed in Lilly's intellectual property related to a URI product using specific concentrations of citrate and treprostinil for a more rapid time action profile and other specific excipients for increased stability, including the application that became the '623 Patent, and that Adocia's employees therefore should be named as co-inventors to that patent.

47. Adocia has threatened legal action to correct the inventorship of the '623 Patent.

48. Lilly owns all right, title and interest in the '623 Patent and has an interest in the '623 Patent recognized under the patent laws of the United States.

49. Lilly believes that the currently-named inventors on the '623 Patent are the true and correct inventors based on available information, and no employee or former employee of Adocia, or any other person, should be named as a co-inventor under the patent laws of the United States.

50. As a result of the foregoing facts, there is a real, immediate, substantial, and continuing justiciable controversy between Lilly and Adocia concerning the inventorship of the '623 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

51. The Court should enter a declaratory judgment in Lilly's favor that the currently-named inventors on the '623 Patent are the true and correct inventors, and that no other person should be named as a co-inventor.

52. This case is exceptional, and Lilly is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 2: DECLARATORY JUDGMENT OF PROPER INVENTORSHIP OF THE '555 PATENT

53. Lilly incorporates by reference each of the preceding paragraphs as if fully set forth herein.

54. Adocia has repeatedly alleged, as described above, that its employees contributed to the inventions claimed in Lilly's intellectual property related to a URI product using specific concentrations of citrate for a more rapid time action profile and other specific excipients for increased stability, including the application that became the '555 Patent, and that Adocia's employees therefore should be named as co-inventors to that patent.

55. Adocia has threatened legal action to correct the inventorship of the '555 Patent.

56. Lilly owns all right, title and interest in the '555 Patent and has an interest in the '555 Patent recognized under the patent laws of the United States.

57. Lilly believes that the currently-named inventors on the '555 Patent are the true and correct inventors based on available information, and no employee or former employee of Adocia, or any other person, should be named as a co-inventor under the patent laws of the United States.

58. As a result of the foregoing facts, there is a real, immediate, substantial, and continuing justiciable controversy between Lilly and Adocia concerning the inventorship of the

'555 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

59. The Court should enter a declaratory judgment in Lilly's favor that the currently-named inventors on the '555 Patent are the true and correct inventors, and that no other person should be named as a co-inventor.

60. This case is exceptional, and Lilly is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Lilly seeks the following relief:

A. A declaratory judgment that the '623 Patent correctly lists the proper inventors within the meaning of and as required by the patent laws of the United States, including 35 U.S.C. §§ 101, 111, 116 and 256;

B. A declaratory judgment that the '555 Patent correctly lists the proper inventors within the meaning of and as required by the patent laws of the United States, including 35 U.S.C. §§ 101, 111, 116 and 256;

C. The entry of judgment declaring that Adocia's acts render this an exceptional case, and awarding Lilly attorneys' fees pursuant to 35 U.S.C. § 285;

D. An award to Lilly of its costs and expenses in this action; and

E. Such further and other relief as this Court determines to be just and proper.

Dated: October 9, 2018

Respectfully submitted,

BINGHAM GREENEBAUM DOLL LLP

/s/ *D. Rusty Denton*

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