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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

CV13-08567-ABC(JCGx)

LOS ANGELES BIOMEDICAL RESEARCH INSTITUTE AT HARBOR-UCLA MEDICAL CENTER,

Plaintiff,

v.

ELI LILLY AND COMPANY and LILLY USA, LLC,

Defendants.

Case No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

DEMAND FOR JURY TRIAL

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Plaintiff Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center ("LA BioMed") for its complaint against defendants Eli Lilly and Company and Lilly USA, LLC (collectively, "Lilly") alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 8,133,903 ("the '903 patent"). This action arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

PARTIES

2. Plaintiff LA BioMed is one of the country's leading non-profit biomedical research institutes. During its 61-year history, LA BioMed has been responsible for many pioneering medical breakthroughs, including creation of the first paramedic program and such life-saving inventions as the serum cholesterol test and surfactant treatment for premature babies. LA BioMed is a non-profit California corporation with a principal place of business at 1124 W Carson St., Torrance, California. LA BioMed owns, by valid assignment, all rights, title, and interest in the '903 patent.

3. Defendant Eli Lilly and Company is an Indiana company with its corporate office, principal place of business, and registered agent for service at Lilly Corporate Center, Indianapolis, Indiana. Defendant Eli Lilly and Company is also registered to do business and has designated an agent for the service of process in the State of California.

4. Defendant Lilly USA, LLC is an Indiana limited liability company operating as a wholly owned subsidiary of defendant Eli Lilly and Company, with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Lilly because Lilly, directly or through intermediaries (including distributors, retailers, and others), shipped, distributed, offered for sale, sells, and advertises its pharmaceutical products, including its Cialis® product, in the State of California and in the Central District of California. Lilly has purposefully and voluntarily advertised and marketed its Cialis product in California and has established distribution channels for putting its Cialis product into the stream of commerce with the expectation that such product would be prescribed and sold to patients for once-daily use in this District. Defendant Eli Lilly and Company has registered to do business and has designated an agent to accept service of process in the State of California.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b). A substantial part of the events giving rise to the claims herein occurred in this District, and Lilly does business in the State of California and has induced acts of infringement in this State and in this District.

FIRST CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 8,133,903)

8. Plaintiff LA BioMed incorporates by reference paragraphs 1 through 7 above as if fully set forth herein.

9. On March 13, 2012, United States Patent No. 8,133,903, titled "Methods of Use of Inhibitors of Phosphodiesterases and Modulators of Nitric Oxide-Reactive Oxygen Species, and Metalloproteinases in the Treatment of Peyronie's Disease, Arteriosclerosis and Other Fibrotic Diseases," was duly and legally issued. Assignment of the '903 patent to plaintiff LA BioMed was effective as of the issuance. A true and correct copy of the '903 patent is attached hereto as **Exhibit A**. Plaintiff LA BioMed owns all right, title, and interest to the patent, including the exclusive right to enforce the patent against infringers and to collect damages, including past damages, for infringement of the patent.

10. The '903 patent claims an invention by two of LA BioMed's award-winning senior scientists, Dr. Nestor Gonzalez-Cadavid and Dr. Jacob Rajfer, regarding the treatment of fibrosis. At least two such fibrotic conditions affect tissues of the penis. Specifically, corporal veno-occlusive dysfunction ("CVOD") is a fibrosis of the penile corpora cavernosa, and Peyronie's disease ("PD") is a fibrosis of the penile tunica albuginea. Peer-reviewed and publicly available clinical research studies show that a significant percentage of patients with erectile dysfunction ("ED") suffer from CVOD and/or PD. Drs. Gonzalez-Cadavid and

Rajfer demonstrated through their research that continuous long-term administration of enzyme phosphodiesterase-5 ("PDE-5") inhibitors for at least 45 days arrests or regresses fibrosis.

11. Drs. Gonzalez-Cadavid and Rajfer filed a provisional patent application, U.S. Provisional Application No. 60/420,281 ("the '281 provisional application"), describing their invention on October 22, 2002. Following the filing of the '281 provisional application, plaintiff LA BioMed extensively published its findings in peer-reviewed and publicly available journals that continuous long-term administration of PDE-5 inhibitors for 45 days or more is effective for treating CVOD and PD, including the following articles: (i) Valente et al., L-Arginine and phosphodiesterase (PDE) inhibitors counteract fibrosis in the Peyronie's fibrotic plaque and related fibroblast cultures, Nitric Oxide 2003, 9(4):229-244; (ii) Ferrini et al., Effects of long-term vardenafil treatment on the development of fibrotic plaques in a rat model of Peyronie's disease, BJU Int 2005, 97:625-633; (iii) Ferrini et al., Vardenafil prevents fibrosis and loss of corporal smooth muscle that occurs after bilateral cavernosal nerve resection in the rat, Urology 2006, 68:429-435; (iv) Ferrini et al., Long-term continuous treatment with sildenafil ameliorates aging-related erectile dysfunction and the underlying corporal fibrosis in the rat, Bio Reprod 2007, 76:915-923; (v) Kovanecz et al., Chronic daily tadalafil prevents the corporal fibrosis and veno-occlusive dysfunction that occurs after cavernosal nerve resection, BJU Int 2007, 101:203-210; (vi) Kovanecz et al., Long-

term continuous sildenafil treatment ameliorates corporal veno-occlusive dysfunction (CVOD) induced by cavernosal nerve resection in rats, Int J Impotence Res 2008, 20:202-212.

12. On October 21, 2003, plaintiff LA BioMed filed international patent application PCT/US03/33400 ("the '400 PCT application"), which claimed priority to the '281 provisional application. That international application published as WO 2004/037183 on May 6, 2004.

13. On February 13, 2004, plaintiff LA BioMed filed U.S. Patent Application No. 10/779,069 ("the '069 application"), which claimed priority to both the '281 provisional application and the '400 PCT application. The '069 application became publicly available on April 21, 2005 as U.S. Publication No. 2005/0085486. The '903 patent issued from the '069 application.

14. Lilly, directly or through intermediaries (including distributors, retailers, and others), ships, distributes, offers for sale, sells, and advertises the pharmaceutical drug tadalafil, a PDE-5 inhibitor, under the trade name Cialis. Lilly first obtained FDA approval in November 2003 for the use of Cialis on an as-needed basis to treat erectile dysfunction ("ED").

15. On information and belief, Lilly monitored patents, published applications, and other publications and attended conferences that discussed treatment of ED and the uses of PDE-5 inhibitors, and thereby learned of the relationship between ED and fibrosis. Specifically, on information and belief, Lilly

learned of LA BioMed's discovery of the utility of PDE-5 inhibitors in the treatment of penile fibrosis based on its attendance at conferences and its monitoring of patents, published applications and other publications relevant to treatment of ED and to uses of PDE-5 inhibitors.

16. Lilly obtained FDA approval in January 2008 to revise the prescription label for Cialis. As revised, the label instructs physicians to prescribe Cialis to ED patients for "once daily use" in a 2.5 mg dose, which may be increased to a 5 mg dose based upon efficacy and tolerability, for the treatment of ED.

17. On information and belief, Lilly expected, based upon LA BioMed's discovery, that "once daily" administration of Cialis would treat the penile fibrosis conditions underlying the symptoms suffered by many ED patients, resulting in an improvement of those patients' ED symptoms. On information and belief, Lilly knew that once-daily administration of Cialis was actually treating the penile fibrosis conditions underlying the ED symptoms in a significant number of the patients in these studies.

18. On information and belief, Lilly expected that it could obtain additional revenues from sales of Cialis by marketing and selling Cialis for once daily use. Once-daily Cialis sales were expected to generate 50% more revenue per patient than the as-needed version and were anticipated to generate $200–250 million in worldwide sales by 2010.

19. Lilly's actual sales of Cialis increased 27% in the United States in 2008

following its approval for "once daily use" by the FDA. According to Lilly's 2012 Annual Report, Cialis remains Lilly's fourth highest revenue producing drug. Lilly's 2012 revenues from U.S. sales of Cialis totaled $782 million dollars and its 2012 worldwide revenues from sales of Cialis totaled nearly $1.93 billion dollars.

20. On information and belief, the worldwide market for ED pharmaceuticals was estimated to be $4.3 billion dollars in 2013.

21. Plaintiff LA BioMed informed Lilly in February 2013 of the issuance of the '903 patent and that administration of tadalafil per Lilly's "once daily use" label for Cialis fell within the scope of the issued claims. LA BioMed again informed Lilly in May 2013 of the issuance of the '903 patent and explicitly listed the issued claims in its communication. Lilly accordingly had knowledge of the invention described in the '903 patent, of the issued claims of the '903 patent, and that "once daily" administration of tadalafil as explicitly instructed by Lilly's label constitutes direct infringement of the '903 patent at least as of February 2013, and certainly no later than May 2013.

22. On information and belief, Lilly had knowledge of the '903 patent prior to February 2013 based on its monitoring of patents, published applications, and other publications relevant to ED and to uses of PDE-5 inhibitors. In addition, Lilly has attended conferences at which information about LA BioMed's invention claimed in the '903 patent was presented.

23. Physicians prescribing treatment under the "once daily" instructions

provided in the prescription label for Lilly's Cialis product have been and are currently infringing at least one claim of the '903 patent by administering Cialis to ED patients within the United States in a manner which practices at least one of the claims of the '903 patent, including by administering Cialis at a dosage of less than 1.5 mg/kg/day according to a continuous long-term regimen of 45 days or more to patients suffering from penile tunical fibrosis or corporal tissue fibrosis, thus causing the arrest or regression of said penile fibrosis, in violation of 35 U.S.C. § 271(a), and unless enjoined, will continue to do so.

24. By instructing physicians in the "once daily" use of Cialis to treat ED, Lilly has been and is currently actively inducing and encouraging infringement of at least one claim of the '903 patent, and unless enjoined, will continue to do so. With actual knowledge of the '903 patent and that administration of tadalafil per Lilly's "once daily use" label for Cialis constitutes infringement of the issued claims of the '903 patent , Lilly actively induced and encouraged that infringement by instructing said physicians in the administration of the Cialis product in a manner that directly infringes the '903 patent, with specific intent to induce and encourage such infringement, or at a minimum with willful blindness to the known risk of such infringement, including, for example, by instructing said physicians to prescribe Cialis "for once daily use" in a 2.5 mg dose for the treatment of ED, which dose may be increased to 5 mg based upon efficacy and tolerability, in violation of 35 U.S.C. § 271(b).

25. Lilly's acts of indirect infringement of the '903 patent are willful. Lilly knew of the '903 patent and that instructing physicians to prescribe Cialis "for once daily use" for the treatment of ED would indirectly infringe the '903 patent, but acted despite an objectively high likelihood that such activities would infringe the '903 patent.

PRAYER FOR RELIEF

WHEREFORE, plaintiff LA BioMed demands the following relief against defendants Eli Lilly and Company and Lilly USA, LLC (collectively, "Lilly"):

a) entry of a judgment declaring that Lilly has induced infringement of one or more claims of the '903 patent in violation of 35 U.S.C. § 271*et seq.*;

b) an award of damages to compensate LA BioMed for Lilly's infringement of the '903 patent pursuant to 35 U.S.C. § 284, such damages to be trebled because of Lilly's willful infringement;

c) an accounting of all damages sustained by LA BioMed as the result of Lilly's infringement pursuant to 35 U.S.C. § 284;

d) a permanent injunction against the continuing infringement of the '903 patent, or in the alternative, if the Court finds that an injunction is not warranted, an award of post-judgment royalty to compensate for future infringement;

e) an award of pre-judgment and post-judgment interest and costs to plaintiff LA BioMed;

f) an award of reasonable attorneys' fees to plaintiff LA BioMed pursuant to 35 U.S.C. § 285 or as otherwise permitted by law;

g) an award of all costs of suit to plaintiff LA BioMed pursuant to 35 U.S.C. § 284, 28 U.S.C. § 1920, and any other applicable statute or rule; and

h) such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff LA BioMed hereby requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure as to all issues so triable.

Dated: November 20, 2013

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