IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

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Plaintiff,

Civil No. 2:15-cv-01202

V.

ELI LILLY AND COMPANY, and BROOKSHIRE BROTHERS, INC.,

Defendants.

JURY TRIAL DEMANDED

ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Erfindergemeinschaft UroPep GbR ("UroPep") files this Original Complaint for patent infringement against Defendants Eli Lilly and Company and Brookshire Brothers, Inc.,¹ and to the best of its knowledge, information and belief, alleges as follows:

NATURE OF THE ACTION

1. This is a claim for infringement of United States Patent No. 8,791,124 (hereinafter, "the '124 Patent") arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*. This Court has exclusive jurisdiction over the subject matter of this Original Complaint pursuant to 28 U.S.C §§ 1331 and 1338(a).

PARTIES

2. Plaintiff UroPep is a Gesellschaft buegerlichen Rechts organized and existing under the laws of Germany, having its offices and principal place of business at Erfindergemeinschaft UroPep GbR, Feodor-Lynen-Str. 31, 30625 Hannover, Germany.

¹ Brookshire Brothers, Inc. shall be referred to as "Brookshire Brothers," Eli Lilly and Company shall be referred to as "Eli Lilly," and collectively Eli Lilly and Brookshire Brothers shall be referred to as "Defendants."

- 3. Defendant Eli Lilly is a corporation organized and existing under the laws of the State of Indiana, having its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly is authorized to do business in the State of Texas and has appointed National Registered Agents, Inc. at 1999 Bryan Street, Suite 900, Dallas, TX 75201 as its registered agent to accept service of process in Texas. Eli Lilly is in the business of advertising, marketing, making, distributing, using, offering to sell, selling, and importing into the United States pharmaceuticals, including Cialis®, which is also known by its generic name tadalafil, and which "is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of . . . benign prostatic hyperplasia (BPH)." *Prescribing Information*, CIALIS.COM, http://pi.lilly.com/us/cialis-pi.pdf at 1 (last visited June 11, 2015). Eli Lilly makes, uses, offers to sell, and sells Cialis® for treatment of BPH in the United States, including within this District.
- 4. Defendant Brookshire Brothers is a corporation organized and existing under the laws of the State of Texas, having corporate offices and a principal place of business at 1201 Ellen Trout Dr., Lufkin, TX 75904. Brookshire Brothers is licensed by the State of Texas to operate numerous pharmacies such that Brookshire Brothers is in the business of advertising, marketing, distributing, offering to sell, and selling pharmaceuticals, including Cialis® for treatment of BPH.

JURISDICTION AND VENUE

- 5. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code, including 35 U.S.C. §§ 271 and 281-285.
- 6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1367.

- 7. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b). On information and belief, each Defendant is deemed to reside in this judicial district, has committed acts of infringement in this judicial district, has purposely transacted business in this judicial district, and/or has regular and established places of business in this judicial district.
- 8. On information and belief, each Defendant is subject to this Court's specific and/or general jurisdiction pursuant to due process and/or the Texas Long Arm Statute, due at least to their substantial business in this State and this District, including: (a) at least part of their infringing activities alleged herein; and (b) regularly doing or soliciting business, engaging in other persistent conduct, and/or deriving substantial revenue from goods sold and services provided to Texas residents.
- 9. Defendants have substantial continuous and systematic business contacts with the State of Texas. Defendants directly, or through subsidiaries or intermediaries (including distributors, sales representatives, pharmacies, insurers, and physicians), conduct business extensively throughout Texas, by shipping, distributing, offering for sale, advertising, marketing, and selling products in the State of Texas and the Eastern District of Texas. Defendants have directly and through their subsidiaries or intermediaries (including distributors, sales representatives, pharmacies, insurers, and physicians) purposefully and voluntarily placed Cialis® for treatment of BPH into the stream of commerce with the intention and expectation that Cialis® for treatment of BPH will be purchased and used in the Eastern District of Texas. Cialis® for treatment of BPH has been and continues to be purchased and used in the State of Texas and, more particularly, within the Eastern District of Texas, achieving substantial sales for Defendants.

- 10. This Court previously has found pharmaceutical manufacturers subject to specific personal jurisdiction where the pharmaceutical manufacturers held state-issued licenses and had well established contacts with Texas distributors, pharmacies, insurers, and state agencies as the ways and means to further sales. *E.g., Allergan, Inc. v. Actavis, Inc.*, No: 2:14-cv-00638, Dkt. No. 97 at 13 (E.D. Tex. Dec. 23, 2014). On information and belief, Eli Lilly is a licensed drug distributor in Texas and has established contacts via its own sales representatives, and with distributors, pharmacies, insurers, physicians, and consumers in this District, as well as with Texas state agencies, to further sales of its products, including at least Cialis® for treatment of BPH.
- 11. Courts have previously found pharmaceutical manufacturers subject to general jurisdiction based on appointment of a registered agent in a jurisdiction for the purpose of accepting service of process. *See, e.g., Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, 1:14-cv-935, Dkt. No. 30 at 21 (D. Del. Jan. 14, 2015), *Otsuka Pharm. Co., Ltd., v. Mylan Inc.*, 1:14-cv-4508, Dkt. No. 67 at 23-32 (D.N.J. Mar. 23, 2015). Eli Lilly has submitted itself to the jurisdiction of the Court voluntarily by registering with the Texas Secretary of State's Office to do business in the State of Texas and by appointing National Registered Agents, Inc. at 1999 Bryan Street, Suite 900, Dallas, TX 75201 as its registered agent to accept service of process in Texas.
- 12. Eli Lilly previously has availed itself of this forum for purposes of litigating a patent dispute. In particular, Eli Lilly submitted to this Court's jurisdiction, by "admit[ting] that it is subject to this Court's personal jurisdiction," and by filing counterclaims in *Datatern, Inc. v. Eli Lilly and Co.*, 2:10-cv-00413, Dkt. No. 66 at 3, 16-25 (E.D. Tex. Mar. 28, 2011).

- 13. Brookshire Brothers is a Texas Corporation that has been registered with the Texas Secretary of State since 1997 and is headquartered in Lufkin, Texas. It has appointed Jerry A. Johnson, 1201 Ellen Trout Dr., Lufkin, TX 75904, as its registered agent.
- 14. Brookshire Brothers operates 29 pharmacies within this District which are licensed by the State of Texas, and has established contacts with sales representatives, distributors, insurers, physicians, and consumers within this District, to further sales of its products, including at least Cialis® for treatment of BPH.
- 15. This Court further has personal jurisdiction over Defendants by virtue of their systematic and continuous contacts with this jurisdiction.

BACKGROUND

16. UroPep was founded in 1997 by leading physicians and biomedical research scientists working in the Department of Urology at Hannover Medical School ("MHH"). Prof. Dr. med. Udo Jonas was the Chairman of the MHH Department of Urology from 1987 until 2008. Prof. Dr. med. Wolf-Georg Forssmann was Chairman at the Center of Pharmacology and Head of the Research Group on Experimental and Clinical Peptide Chemistry at MHH from 1990 until 2009. Prof. Dr. rer. biol. hum. Stefan Ückert is presently a Professor within the Department of Urology at MHH, and is also the Director of the Urological Research Unit there. Since 1995 Prof. Dr. med. Michael Carsten Truß has been a member of the MHH Department of Urology senior staff, and in 2005 became Director of the Urology Clinic at the Klinikum Dortmund. Prof. Dr. med. Christian Stief has also been a member of the MHH Department of Urology senior staff, and in 2004 became the Clinical Director of Urology at the Klinikum of the Ludwig-Maximilian-University Munich. Each of these five individuals—Prof. Dr. med. Wolf-Georg Forssmann, Prof. Dr. med. Christian Stief, Prof. Dr. med. Michael Carsten Truß, Prof. Dr. rer. biol. hum.

Stefan Ückert, and Prof. Dr. med. Udo Jonas—is listed as an inventor on the face of the '124 Patent.

- 17. On July 29, 2014, the United States Patent and Trademark Office duly and legally issued the '124 Patent, entitled Use of Phosphodiesterase Inhibitors in the Treatment of Prostatic Diseases.² The '124 Patent claims priority to an application filed on July 9, 1997. UroPep is the owner by assignment of all right, title, and interest in the '124 Patent, including the right to recover past and future damages. UroPep has owned all rights to the '124 Patent necessary to bring this action throughout the period of Defendants' infringement and still owns those rights to the '124 Patent. A true and correct copy of the '124 Patent is attached hereto as **Exhibit A**.
 - 18. The '124 Patent is valid and enforceable.
- 19. In January 2008, Eli Lilly announced that the U.S. Food and Drug Administration ("FDA") had approved the use of Cialis® to treat erectile dysfunction ("ED").
- 20. On December 3, 2010 Eli Lilly filed a supplemental application with the FDA proposing new indications for Cialis®, including the treatment of the signs and symptoms of BPH, as well as the signs and symptoms of BPH when occurring simultaneously with the signs and symptoms of ED.
- 21. On October 6, 2011 the U.S. Food and Drug Administration approved Cialis® to treat the signs and symptoms of BPH, as well as the signs and symptoms of BPH when occurring simultaneously with ED.
- 22. On July 26, 2011, co-inventor Dr. Stefan Ückert emailed Mr. Frank Boess, a Senior Clinical Research Scientist at Eli Lilly, referencing a conversation they had on June 5, 2011,

² The title of the '124 Patent is in fact "Use of Phosphordiesterase Inhibitors in the Treatment of Prostatic Diseases."

identifying the then-pending U.S. Patent application which would eventually issue as the '124 Patent as well as the corresponding Canadian patent, and requesting assistance contacting someone at Eli Lilly responsible for intellectual property acquisitions. Mr. Boess responded to Dr. Ückert via email on July 28, 2011, providing Dr. Ückert with the contact information for Mr. Dan L. Wood, Patent Counsel at Eli Lilly.

- 23. On October 9, 2014, Mr. Kim Larsen, attorney for UroPep, sent a letter via Certified Mail to Messrs. Dan L. Wood and Michael Harrington, Senior Vice President and General Counsel of Eli Lilly, "not[ing] that sale of Cialis for BPH appears to require a license of the '124 Patent."
- 24. Neither Mr. Wood nor Mr. Harrington, nor anyone else by or on behalf of Eli Lilly, ever responded to the above-described correspondence concerning the '124 Patent. Nevertheless, on information and belief, Eli Lilly has been placed on actual notice of the '124 Patent. On information and belief, at a minimum, in accordance with 35 U.S.C. § 287, Eli Lilly has had knowledge of the '124 Patent at least since it issued. Despite such notice, Eli Lilly continues to make, use, market, advertise, distribute, offer for sale, sell, and/or import into the United States Cialis® for treatment of BPH, which infringes the '124 Patent.
- 25. On information and belief, Brookshire Brothers has actual notice of the '124 Patent at least as early as the filing of this Original Complaint. Brookshire Brothers continues to advertise, market, distribute, offer to sell and/or sell Cialis® for treatment of BPH.

COUNT I: INFRINGEMENT OF THE '124 PATENT

- 26. Paragraphs 1-25 are herein incorporated in their entirety, as set forth above.
- 27. Eli Lilly directly infringes and/or induces infringement of the '124 Patent by making, using, selling, offering for sale, and/or importing into the United States products and/or methods covered by one or more claims of the '124 Patent, including Cialis® for treatment of BPH.

28. Eli Lilly indirectly infringes the '124 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as distributors, sales representatives, pharmacies, insurers, physicians, and/or consumers, in this District and elsewhere in the United States. For example, pharmacies and physicians directly infringe.

29. Eli Lilly's affirmative acts of: 1) manufacturing, selling, distributing, and/or otherwise making available Cialis® for treatment of BPH; 2) causing others to manufacture, sell, distribute and/or make available Cialis® for treatment of BPH; and/or 3) providing instructions, documentation, and/or other information regarding the use of Cialis® for treatment of BPH, including notices required by the Food and Drug Administration, advertising, marketing materials, prescribing information, and research to distributors, sales representatives, pharmacies, insurers, physicians, and/or consumers induces distributors, sales representatives, pharmacies, insurers, physicians, and consumers to make, use, sell, and/or offer to sell Cialis® for treatment of BPH in the way that Eli Lilly intends, and in doing so, to directly infringe the '124 Patent. Eli Lilly has performed and continues to perform these affirmative acts with knowledge of the '124 Patent and with knowledge or willful blindness that the induced acts directly infringe the '124 Patent.

30. Eli Lilly's infringement of the '124 Patent has been and continues to be willful. On information and belief, Eli Lilly knew or should have known that it was directly infringing and/or was inducing others to directly infringe the '124 Patent. UroPep has attempted discussions with Eli Lilly regarding the '124 Patent, and on information and belief, Eli Lilly had knowledge of the '124 Patent based on these discussion and any additional investigations that Eli Lilly may have performed. Eli Lilly also received notice of the '124 Patent as of the date this lawsuit was filed and/or the date the Original Complaint was served of Eli Lilly.

- 31. Brookshire Brothers directly infringes and/or induces infringement of the '124 Patent by making, using, selling, offering for sale, and/or importing into the United States products and/or methods covered by one or more claims of the '124 Patent, including Cialis® for treatment of BPH, such as when Brookshire Brothers sells Cialis® for treatment of BPH.
- 32. Brookshire Brothers indirectly infringes the '124 Patent, as provided by 35 U.S.C. § 271(b), by inducing infringement by consumers within this District. For example, Brookshire Brothers induces infringement by selling Cialis® for treatment of BPH to consumers.
- 33. Brookshire Brothers' affirmative acts of: 1) marketing, advertising, selling, distributing, and/or otherwise making available Cialis® for treatment of BPH; 2) causing others to market, advertise, sell, distribute and/or make available Cialis® for treatment of BPH; and/or 3) providing instructions, documentation, and/or other information regarding the use of Cialis® for treatment of BPH, including notices required by the Food and Drug Administration, advertising, marketing materials, and prescribing information to consumers induces consumers to use Cialis® for treatment of BPH in the way that Brookshire Brothers intends, in order to directly infringe the '124 Patent. Brookshire Brothers has performed and continues to perform these affirmative acts.
- 34. Brookshire Brothers directly infringes and/or induces infringement of the '124 Patent by providing "[p]rofessional pharmacy solutions with a personal approach . . . [with] pharmacy experts, who . . . deliver individualized advice and support." BROOKSHIRE BROTHERS PHARMACY, http://www.brookshirebrothers.com/about-us/our-banners/brookshire-brothers-pharmacy (last visited May 27, 2015). Additionally Brookshire Brothers "pharmacy staff . . . offer[] wellness counseling [and] recommendations on medication management" that induces consumers to use Cialis® for treatment of BPH in the way that Brookshire Brothers intends. *Id*.

JOINDER OF THE PARTIES

- 35. Paragraphs 1-34 are herein incorporated in their entirety, as set forth above.
- 36. On information and belief, Eli Lilly and Brookshire Brothers each distribute Cialis® for treatment of BPH, notices required by the Food and Drug Administration, advertising, marketing materials, prescribing information, and/or research to distributors, sales representatives, pharmacies, insurers, physicians, and/or consumers that are the subject of Count I (or some subset thereof). Thus, for this Count, the right of relief against Eli Lilly is asserted jointly and severally with Brookshire Brothers.
- 37. The alleged infringements set forth in Count I arise out of the same transaction, occurrence, or series of transactions or occurrences relating to the making, use, sale, offer for sale, and/or importing of Cialis® for treatment of BPH that are the subject of Count I.
- 38. Questions of fact common to all Defendants will arise in this action including, for example, direct infringement by pharmacies.
- 39. Thus, joinder of Eli Lilly and Brookshire Brothers is proper in this litigation pursuant to 35 U.S.C. § 299(a).

ATTORNEYS' FEES

40. UroPep is entitled to recover reasonable and necessary attorneys' fees under applicable law.

JURY DEMAND

41. UroPep hereby respectfully demands a jury trial on all issues appropriately triable by a jury.

PRAYER FOR RELIEF

- 42. **WHEREFORE**, UroPep respectfully requests that this Court enter judgment in its favor and grant the following relief:
 - a. Adjudged that Eli Lilly infringes the '124 Patent;
 - b. Adjudicated that Brookshire Brothers infringe the '124 Patent;
 - c. Adjudged that Eli Lilly's infringement of the '124 Patent was willful, and that Eli Lilly's continued infringement of the '124 Patent is willful;
 - d. Award UroPep damages in an amount adequate to compensate UroPep for Eli Lilly's infringement of the '124 Patent, but in no event less than a reasonable royalty under 35 U.S.C. § 284;
 - e. Award UroPep damages in an amount adequate to compensate UroPep for Brookshire Brothers' infringement of the '124 Patent, but in no event less than a reasonable royalty under 35 U.S.C. § 284;
 - f. Award enhanced damages pursuant to 35 U.S.C. § 284;
 - g. Award UroPep pre-judgment and post-judgment interest to the full extent allowed under the law, as well as its costs;
 - Enter an injunction enjoining Eli Lilly, and all others in active concert with Eli
 Lilly, from further infringing the '124 Patent;
 - Enter an injunction enjoining Brookshire Brothers, and all others in active concert with Brookshire Brothers, from further infringing the '124 Patent;
 - j. In lieu of an injunction, award a mandatory future royalty payable on each future product sold by Eli Lilly that is found to infringe the '124 Patent, and on all future products which are not colorably different from products found to infringe;

- k. In lieu of an injunction, award a mandatory future royalty payable on each future product sold by Brookshire Brothers that is found to infringe the '124 Patent, and on all future products which are not colorably different from the products found to infringe;
- 1. Enter an order finding this an exceptional case and award UroPep its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;
- m. Order an accounting of damages;
- n. Award UroPep its costs of suit; and
- Award such other relief as the Court may deem appropriate and just under the circumstances.

Date: July 1, 2015 Respectfully submitted,

FISH & RICHARDSON P.C.

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