

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

ERFINDERGEMEINSCHAFT UROPEP  
GbR,

*Plaintiff,*

v.

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

*Defendants.*

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Case No. 2:15-CV-1202-WCB

**MEMORANDUM OPINION AND ORDER**

Before the Court is the motion by defendant Brookshire Brothers, Inc. to dismiss the complaint for failure to state a claim upon which relief can be granted. Dkt. No. 37. The Court heard argument on Brookshire’s motion on February 11, 2016. For the reasons set forth below, Brookshire’s motion to dismiss is DENIED.

**BACKGROUND**

This case concerns allegations that Brookshire infringes U.S. Patent No. 8,791,124 (“the ’124 patent”) when Brookshire’s pharmacists dispense the drug Cialis. Complaint, Dkt. No. 1, at ¶¶ 31-34 (listing direct and indirect infringement allegations against Brookshire). The ’124 patent only has one independent claim:

1. A method for prophylaxis or treatment of benign prostatic hyperplasia comprising administering to a person in need thereof an effective amount of an inhibitor of phosphodiesterase (PDE) V excluding a compound selected from the group consisting of
  - dipyridamole,
  - 2-(N-(4-carboxypiperidine)-6-chloro-4(3,4-methylenedioxy)benzyl)amino)quinzalone

2,3-dihydro-8-hydroxy-7-nitro-1,4-benzodioxine-2-methanol,  
alpha-nitrate.

4((3,4-(methylenedioxy)benzyl 1)amino)-6,7,8-trimethoxy-  
quinazoline,

1-methyl-3-propyl-6-(5-(N-(4-methylmorpholino)sulfonyl)-2-  
ethoxyphenyl)pyrazole [4,5]pyrimidin-4(5H)one, 2-n-butyl-5-  
chloro-1-(2-chlorobenzyl)-4-methylacetate-imidazole,

1-cyclopentyl-3-methyl-6-(4-pyridinyl)pyrazolo(3,4-d)pyrimidin-  
4(5H)-one,

7-(3-(4-acetyl-3-hydroxy-2-propyl-phenoxy)-2-hydroxy-propoxy)-  
2-carboxy-2,3-didehydro-chro nan-4-one,

1-methyl-3-propyl-6-(5-(N-(4-methylmorpholino)sulfonyl)-2-  
ethoxyphenyl)pyrazole[4,5]pyrimidin-4(5H)one,

and pharmacologically compatible salts thereof.

The parties do not dispute that Cialis is an “inhibitor of phosphodiesterase (PDE) V” that treats benign prostatic hyperplasia (“BPH”). The focus of the motion to dismiss is on the underscored language of the claim, “administering to a person in need thereof.”

Brookshire asks the Court to dismiss UroPep’s claims of direct and indirect patent infringement. As to direct infringement, Brookshire asserts that UroPep’s complaint “makes no allegation that Brookshire administers Cialis to patients, and the allegation that Brookshire sells Cialis to patients does not constitute direct infringement as a matter of law.” Brookshire Motion at 8. As to induced infringement, Brookshire asserts that the complaint “alleges no facts that satisfy the requirement of specific intent.” *Id.* UroPep responds that its complaint adequately pleads both direct and indirect infringement.

#### **APPLICABLE LAW**

Rule 12(b)(6) of the Federal Rules of Civil Procedure authorizes a court to dismiss a complaint if the complaint “fail[s] to state a claim upon which relief can be granted.” The question resolved on a Rule 12(b)(6) motion to dismiss is not whether the plaintiff will

ultimately prevail, “but whether [the] complaint was sufficient to cross the federal court’s threshold.” Skinner v. Switzer, 562 U.S. 521, 530 (2011). When considering a motion to dismiss under Rule 12(b)(6), a court “accept[s] all well-pleaded facts as true, and view[s] those facts in the light most favorable to the plaintiff.” Bustos v. Martini Club, Inc., 599 F.3d 458, 461 (5th Cir. 2010). The court may consider “the complaint, any documents attached to the complaint, and any documents attached to the motion to dismiss that are central to the claim and referenced by the complaint.” Lone Star Fund V (U.S.) L.P. v. Barclays Bank PLC, 594 F.3d 383, 387 (5th Cir. 2010).

Upon viewing the facts most favorably to the plaintiff, the court must decide whether those facts state a claim for relief that is plausible on its face. Bowlby, 681 F.3d 215, 217 (5th Cir. 2012). “A claim is plausible if ‘the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.” United States v. Bollinger Shipyards, Inc., 775 F.3d 255, 260 (5th Cir. 2014) (citing Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). Instead, the standard “simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of [the claim].” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 545 (2007). “The factual allegations in the complaint need only ‘be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact).’” Wooten v. McDonald Transit Associates, Inc., 788 F.3d 490, 498 (5th Cir. 2015) (quoting Twombly, 550 U.S. at 555)).

## DISCUSSION

### I. Direct Infringement

Brookshire’s argument that the complaint does not state a plausible claim of direct infringement is based on the contention that its pharmacists do not “administer[] to a person in need thereof an effective amount of an inhibitor of phosphodiesterase (PDE) V.”<sup>1</sup> Because Brookshire’s argument constitutes a head-on challenge to UroPep’s theory of infringement, the briefing focuses on the proper construction of the claim term “administering” and whether, under the proper construction of that term, the actions of Brookshire’s pharmacists could be found to constitute infringement. In Brookshire’s view, someone—presumably a physician—may administer a drug to the patient. But, according to Brookshire, a pharmacist who only sells the drug to the patient cannot be regarded as “administering” the drug to the patient within the meaning of that term as used in the ’124 patent.

That argument is, in essence, a combined claim construction and non-infringement argument. Its resolution turns on how “administers” is construed and what the evidence may show about the conduct of Brookshire’s pharmacists in dispensing Cialis.<sup>2</sup> Claim construction

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<sup>1</sup> In its reply brief, Brookshire argues (Brookshire Reply at 3) that claim 1 “involves the treatment of patients for BPH,” and that UroPep “has made no plausible allegation that Brookshire actually treats patients for BPH.” But the reference to treatment appears only in the preamble of claim 1. The body of the claim provides that the “method for prophylaxis or treatment” of BHP “compris[es] administering to a person in need thereof an effective amount” of a specified class of drugs, including Cialis. Thus, all that is necessary is for the pharmacy to administer the drug for the purpose of prophylaxis or treatment of BPH; contrary to Brookshire’s assertion, it is not necessary for the pharmacy to “actually treat” the patient (Brookshire Reply at 5), whatever that may be thought to entail.

<sup>2</sup> To the extent Brookshire is arguing that the complaint alleges that Brookshire “sells” Cialis, but not that it “administers” Cialis, the argument is without merit. The complaint alleges that Brookshire uses the claimed method when it sells Cialis for treatment for BPH. The clear point of that allegation is that the selling of Cialis for the treatment of BPH is conduct that constitutes “administering to a person in need [of treatment for BPH] an effective amount” of Cialis.

proceedings have not yet been held in this case, and there is no evidence before the Court on the issue of infringement. As discussed below, the issue of possible infringement under a correct claim construction is not entirely free from doubt. The Court therefore concludes that it would be improper to resolve the dispute on procedural grounds at this point, pretermittting the claim construction process and the evidentiary presentations that may be made either on summary judgment or at trial.

The task of the Court at the Rule 12(b)(6) stage is simply to assess whether the “short and plain statement” of the plaintiff’s claims in the complaint plausibly “states a claim upon which relief can be granted.” The test at this initial stage is not one of ultimate success or even probable success on the merits. Instead, it is a threshold test that asks whether, taking all well-pleaded facts as true and viewing those facts in the light most favorable to the plaintiff, the claim is plausible, i.e., whether the claim to a right to relief rises “above the speculative level.” Twombly, 550 U.S. at 555; Shakeri v. ADT Sec. Servs., Inc., No. 10539 (5th Cir. Mar. 7, 2016); ABB Turbo Sys. AG v. Turbousa, Inc., 774 F.3d 979, 984 (Fed. Cir. 2015).

Brookshire argues that the mere sale of Cialis cannot directly infringe the ’124 patent, because “administering” the drug requires more than simply selling it to patients. Citing Joy Technologies, Inc. v. Flakt, Inc., 6 F.3d 770, 774 (Fed. Cir. 1993), Brookshire contends that the mere sale of a product that is used to perform a patented method does not constitute practicing the method. Thus, Brookshire argues, a pharmaceutical company that sells drugs to retailers cannot infringe a patent claiming a method of treating patients suffering from a particular disease. See Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1363 (Fed. Cir. 2003).

UroPep, however, does not rest its allegation of direct infringement solely on the fact that Brookshire sells Cialis to customers. Instead, it alleges that Brookshire has engaged in particular

infringing conduct in the course of selling Cialis from its pharmacies. Complaint ¶¶ 31, 24. Considered in the context of the full complaint, Brookshire's allegations set forth a plausible claim for relief.

To be sure, the mere selling of an off-the-shelf drug (e.g. aspirin) by a general employee of a drugstore does not constitute "administration" of the drug as that term is commonly understood. UroPep's complaint, however, alleges that Brookshire's pharmacists do more than simply sell prescription drugs. According to the complaint, the relationship between a patient and a Brookshire pharmacist is quite different from the relationship between a customer and a general employee who simply provides an off-the shelf medicine to the customer who asks for it. The complaint alleges that Brookshire's pharmacists not only sell Cialis to customers for the treatment of BPH, but also offer "individualized advice and support" to patients who use Cialis for prophylaxis or treatment of BPH and 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."

For purposes of this motion, Brookshire does not dispute that it engages in the conduct alleged. Brookshire does, however, dispute that its actions infringe the patent. The question on the pleadings, however, is not the probability that UroPep's claim will succeed on the merits. Instead, the question is simply whether the claim is plausible in light of the allegations of the complaint, under the forgiving standard applied to motions to dismiss. At this juncture, the Court treats the pleaded facts as true and views those facts in the light most favorable to UroPep. In that light, Brookshire's argument that UroPep's direct infringement complaint is implausible turns mainly on the meaning of the term "administer" as used in the claims.

UroPep contends that a pharmacist that provides drugs to a patient and offers counseling to the patient regarding the nature and proper use of the drugs can be said to “administer” the drugs. Given the inferences that must be credited at this stage in the case, that is not a wholly implausible characterization.

The case law addressing the term “administer” in pharmaceutical patents also indicates that this is not a wholly implausible interpretation. It is not difficult to characterize a physician’s actions in directing a patient to take particular drugs pursuant to a particular protocol as “administering” the drug, even if it is the patient who actually takes the pills. But whether a pharmacist who dispenses a drug to a patient can be regarded as “administering” the drug is a more difficult question, and one that appears to have attracted very little attention in the case law. The only case that the parties or the Court have been able to find that addresses that question is Accorda Therapeutics Inc. v. Apotex Inc., Civil Action No.07-4937, 2011 WL 4074116 (D.N.J. Sept. 6, 2011). In that case, the court construed the term “administering” to mean “giving, prescribing, dispensing, dosing, self-dosing or taking.” Accorda Therapeutics, Inc. v. Apotex Corp., Civil Action No. 07-4937, at 2 (D.N.J. July 2, 2010). In light of that construction, the court concluded that a pharmacist could be regarded as administering a drug; as the court put it, “a physician, pharmacist, or patient could alone infringe the patent.” Id. at \*27.

Other courts, although not addressing the “pharmacist” issue, have adopted similar language in defining the term “administering” as used in medical treatment patents. See Identix Pharms., Inc. v. Gilead Scis., Inc., Civil Action No. 13-1987 et al., at 15 (D. Del. Dec. 16, 2015) (defining “administering” as “making available”); MSD Consumer Prods., Inc. v. Par Pharm., Inc., Civil Action No. 10-4837, at 1 (D.N.J. Oct. 16, 2013) (“The term ‘administering’ . . . shall be construed according to its ordinary and accustomed meaning . . . (e.g. to mete out, dispense,

or give remedially).”); Bristol-Myers Squibb Co. v. Apotex, Inc., Civil Action No. 10-5810, 2013 WL 1314733, at \*10-11 (D.N.J. Mar. 28, 2013) (construing “administering” to mean “to mete out or dispense or to give remedially”); see also Gilead Scis., Inc. v. Merck & Co., Case No. 13-cv-04057, at 5-6 (N.D. Cal. Nov. 3, 2015) (patent defines administering to mean “providing a compound of the invention . . . to the individual in need”).

Taking UroPep’s allegations as true and viewing the complaint in the light most favorable to UroPep, the Court finds that UroPep has sufficiently stated a plausible, non-speculative claim of direct infringement.<sup>3</sup> It may be that the proceedings will ultimately determine that the term “administering” does not reach conduct such as the conduct alleged in the complaint, or that the evidence will show that Brookshire’s pharmacies do not engage in conduct that is sufficient to constitute “administering” Cialis. Those questions, however, are properly left for claim construction, summary judgment, or trial. The question whether the allegations in the complaint regarding Brookshire’s conduct can constitute “administering” Cialis is not so implausible as to be resolvable on a Rule 12(b)(6) motion.

## **II. Indirect Infringement**

Brookshire argues that UroPep has also failed to sufficiently plead indirect infringement by inducement of infringement. Brookshire notes that to establish induced infringement, “UroPep must allege facts showing that Brookshire had knowledge of the ’124 patent, knowledge that the alleged induced acts constitute patent infringement, and specific intent to

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<sup>3</sup> Although complaints asserting direct infringement of a patent have historically been measured against the form complaint previously found in Form 18 of the Federal Rules of Civil Procedure, the forms were removed in the latest amendment to the Federal Rules. When the Supreme Court announced the latest amendments to the Civil Rules, the Court made them mandatory only with respect to cases filed after December 1, 2015, but stated that the amendments “shall govern . . . insofar as just and practicable, all proceedings then pending.” The Court finds that it is just and practicable to apply the amended rules in this case.



encourage infringement by the one alleged to directly infringe the '124 patent.” Brookshire Motion at 8. Brookshire focuses on the element of specific intent and argues that “UroPep alleges no facts that satisfy the requirement of specific intent.”<sup>4</sup> Id. To properly plead induced infringement, Brookshire argues, UroPep’s complaint “must allege facts showing that Brookshire ‘plausibly’ knew that they were engaged in infringing actions and showing that Brookshire ‘specifically intended their customers to infringe.’” Id., citing In re Bill of Lading Transmission and Processing Sys. Patent Litig., 681 F.3d 1323, 1339 (Fed. Cir. 2012).

The complaint alleges that Brookshire induces infringement of the '124 patent when it dispenses Cialis to Brookshire’s customers and that Brookshire has the requisite knowledge and intent to make it liable for induced infringement. Complaint ¶¶ 32-34. In particular, the complaint alleges that Brookshire “engages in the acts of marketing, advertising, selling, distributing, and/or otherwise making available” Cialis for treatment of BPH, and that it “causes others to market, advertise, sell, distribute and/or make available” Cialis for treatment of BPH. In so doing, according to the complaint, Brookshire provides “instructions, documentation,

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<sup>4</sup> Although Brookshire mentions the requirement of knowledge of the patent, it does not focus on that issue. The complaint addresses the issue, alleging that Brookshire “has actual notice of the '124 Patent at least as early as the filing of tis Original Complaint. Brookshire Brothers continues to advertise, market, distribute, offer to sell, and sell Cialis for treatment of BHP.” Complaint ¶ 25. Courts in this district have repeatedly held that such allegations are sufficient to prove knowledge of the patent for purposes of indirect infringement, at least from the time of the complaint going forward. See Tierra Intelectual Borinquen, Inc. v. ASUS Computer Int’l, Inc., No. 2:13-cv-44, 2014 WL 1233040, at \*2 (E.D. Tex. Mar 24, 2014); Norman IP Holdings, LLC v. Chrysler Group LLC, No. 6:13-cv-278, Dkt. No. 216, at 5-6 (E.D. Tex. Mar. 5, 2014); Achates Reference Pub., Inc. v. Symantec Corp., No. 2:11-cv-294, 2013 WL 693955, at \*2 (E.D. Tex. Jan. 10, 2013), recommendation adopted by No. 2:11-CV-294, 2013 WL 693885 (E.D. Tex. Feb. 26, 2013); Patent Harbor, LLC v. Dreamworks Animation SKG, Inc., 6:11-cv-229, 2012 WL 9864381, at \*4 (E.D. Tex. July 27, 2012); InMotion Imaging Techs. v. Brain Damage Films, No. 2:11-cv-414, 2012 WL 3283371, at \*3 (E.D. Tex. Aug. 10, 2012); Lochner Techs., LLC v. AT Labs. Inc., 2:11-cv-242, 2012 WL 2595288, at \*3 (E.D. Tex. July 5, 2012); see also In re Bill of Lading Transmission & Processing Sys. Patent Litig., 681 F.3d at 1345-46 (noting that the complaints alleged knowledge “at the latest . . . when [the defendant] was served with the complaint”).

and/or other information” regarding the use of Cialis for treatment of BPH, “including notices required by the Food and Drug Administration [‘FDA’], advertising, marketing materials, and prescribing information to consumers.”

Those allegations are sufficient to survive Brookshire’s motion to dismiss. Viewing UroPep’s complaint under the applicable standards, the Court finds that UroPep has sufficiently stated a plausible, non-speculative claim for indirect infringement through inducement of infringement by patients who take Cialis for treatment of BPH as directed and counseled by Brookshire’s pharmacists.

Brookshire cites several cases involving retailers who were accused of inducing infringement when they sold infringing products to customers. Where the retailers were simply reselling products that would be operated in an infringing manner, the courts have generally held the retailers’ sales of the products did not constitute inducement and that they were therefore not liable for induced infringement.

In Tierra Intelectual Borinquen, Inc. v. ASUS Computer Int’l, Inc., Case No. 2:13-cv-38, 2014 WL 894805 (E.D. Tex. Mar. 4, 2014), for example, defendant Office Max was accused of inducing infringement because it sold a computer product accompanied by a user’s guide that instructed customers to perform certain acts that would infringe the plaintiff’s patents. The court dismissed the complaint against Office Max on the ground that Office Max was a prototypical “neutral reseller”; it simply resold the computer products as received, without instructing consumers about how the products could be used in an infringing manner. See also Affinity Labs of Tex., LLC v. Toyota Motor N. Am., Civil Action No. W:13-cv-365, 2014 WL 2892285 (W.D. Tex. May 12, 2014) (inducement claim against Toyota dismissed in the absence of evidence that Toyota encouraged or instructed its customers to use the sound systems installed in

its cars in an infringing manner); U.S. Ethernet Innovations, LLC v. Cirrus Logic, Inc., No. 6:12-cv-366, 2013 WL 8482270 (E.D. Tex. Mar. 6, 2013) (dismissing complaint of inducement against defendant retailer based on allegations that manufacturer's instructions encouraged use of a product sold by the retailer, in an infringing manner); Norman IP Holdings, LLC v. Chrysler Group LLC, No. 6:13-cv-278, Dkt. No. 216 (E.D. Tex. Mar. 5, 2014) (same).

In this case, Brookshire clearly knew that it was selling Cialis, a drug covered by the '124 patent. It therefore clearly had the intent to dispense the drug. The only remaining question under the patent is whether the allegations are sufficient to show that Brookshire knew the Cialis it dispensed was, at least in some instances, being used to treat BPH.

Brookshire notes that Cialis can be used to treat erectile dysfunction ("ED") in addition to BPH. Accordingly, Brookshire argues, the knowledge of the Brookshire pharmacists that Cialis is being prescribed does not necessarily translate into knowledge that it is being prescribed to treat BPH. Brookshire argues that neither the counseling nor the instructions given by Brookshire pharmacists to patients regarding how to take Cialis "give rise to an inference of intent the same drug may be taken to treat ED or BPH." Brookshire Reply at 8.

The complaint alleges that in 2008, the FDA approved the use of Cialis to treat ED, and in 2011, the FDA approved the use of Cialis to treat the signs and symptoms of BPH, as well as the signs and symptoms of BPH when they occur simultaneously with ED. The complaint further notes that Brookshire provides patients with "instructions, documentation, and/or other information regarding the use of Cialis for treatment of BPH," including the FDA-required notices regarding the drug, and that Brookshire offers counseling and recommendations to patients "that induce[] consumers to use Cialis for treatment of BPH in the way that Brookshire Brothers intends." Complaint ¶¶33, 34. Those allegations give rise to a plausible inference that

Brookshire is aware that Cialis is prescribed not only for ED, but also for BPH and for the combination of ED and BPH. Thus, given the inferences to which UroPep is entitled on a motion to dismiss, it is plausible that when Brookshire sells Cialis to its customers, it is aware that that particular customers, or at least some percentage of its customers, will use Cialis to treat BPH, and that Brookshire provides counseling or instruction on how to use Cialis for that purpose.

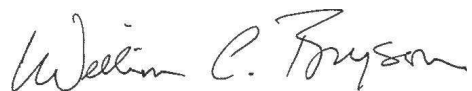
Finally, the '124 patent itself explains that the method of the patent is effective not only against BPH, but also "in the prophylaxis and treatment of prostatic diseases" generally, including various related conditions such as impotence (ED). '124 patent, col. 2, ll.17-27. Based on that information, Brookshire would have known, at least as of the time it learned about the patent, that when Cialis is administered to treat ED, it is also effective in treating or preventing BPH. For that reason as well, the allegations in the complaint are sufficient to set forth a plausible claim of specific intent to induce infringement of the '124 patent.

### **CONCLUSION**

Viewing the well-pleaded facts in UroPep's complaint in the light most favorable to UroPep, the Court concludes that UroPep's complaint meets the pleading threshold for both direct and indirect infringement. For the reasons set forth above, the Court finds that the motion to dismiss filed by Brookshire Brothers, Inc. should be DENIED.

IT IS SO ORDERED.

SIGNED this 26th day of April, 2016.



WILLIAM C. BRYSON  
UNITED STATES CIRCUIT JUDGE