

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
LEXINGTON

UCB, INC., <i>et al.</i> ,)	
)	
Plaintiffs,)	Civil No. 5:21-cv-00038-GFVT
)	
v.)	
)	MEMORANDUM OPINION
CATALENT PHARMA SOLUTIONS,)	&
INC., <i>et al.</i> ,)	ORDER
)	
Defendants.)	

*** **

This matter is before the Court on the Defendants’ (Catalent Pharma Solutions, Inc., Catalent Pharma Solutions, LLC, and Catalent, Inc. (collectively, “Catalent”)) Motion to Dismiss. [R. 48.] Plaintiffs UCB, Inc., UCB Biopharma SPRL, and Research Corporation Technologies, Inc. (collectively, “UCB”) allege that Catalent is infringing on their patent on the compound lacosamide. [See generally R. 30.] For the reasons that follow, the Defendants’ Motion to Dismiss [R. 48] is **DENIED**.

I

Each of the Plaintiffs has an interest in United States Reissued Patent No. RE38,551 (“the ‘551 Patent”), which claims the chemical compound lacosamide. [R. 30 at 6; R. 1-1.] The patent was first assigned to Research Corporation Technologies, Inc., which gave Harris FRC Corporation an exclusive right to use the compound.¹ [R. 30 at 6.] Harris FRC then granted a

¹ Harris FRC was a Plaintiff in the initial complaint [R. 1] but was not included in the Amended Complaint [R. 30] and was consequently terminated on February 27, 2021.

sublicense in the ingredient to Schwarz Pharma AG, which was acquired by UCB and its affiliates. [*Id.*] UCB uses lacosamide as the primary ingredient in its anticonvulsant medication VIMPAT®. [*Id.* at 1.]

Defendant Catalent manufactures and sells pharmaceutical products, including generic drugs. *Id.* at 4. UCB alleges Catalent is infringing on the ‘551 patent by importing lacosamide into the United States. [*Id.* at 8-9.] They specify seven instances between April 2019 and September 2020 where Catalent “caused” another corporation, MSN Pharmachem, to import “over 550 kilograms” of lacosamide. [*Id.*] MSN is a separate pharmaceutical company that was involved in prior litigation over this patent with UCB. [*Id.* at 9-10.] UCB also requested injunctive relief [R. 1 at 12], but this Court denied the preliminary injunction, finding UCB was unlikely to succeed on the merits [R. 59]. UCB filed an amended complaint, making minor changes, during the adjudication of the preliminary injunction. [R. 30.] Catalent now moves to dismiss the amended complaint, claiming the complaint does not state facts establishing a plausible claim and that UCB was required and failed to address the statutory safe harbor in their complaint. [R. 48-1 at 9-10.]

II

Dismissal of this pharmaceutical patent infringement claim turns on a simple question of civil procedure: what a complaint must include to survive a motion to dismiss. UCB’s amended complaint claims that Catalent is infringing the ‘551 Patent because it “has made, used, offered for sale, and/or sold” and “imported” lacosamide. [R. 30 at 10-12.] In response, Catalent argues the complaint should be dismissed under Rule 12(b)(6). [R. 48.] A motion to dismiss pursuant to Rule 12(b)(6) tests the sufficiency of a plaintiff’s complaint. In reviewing a Rule 12(b)(6) motion, the Court “construe[s] the complaint in the light most favorable to the plaintiff, accept[s]

its allegations as true, and draw[s] all inferences in favor of the plaintiff.” *DirectTV, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007). The Court, however, “need not accept as true legal conclusions or unwarranted factual inference.” *Id.* (quoting *Gregory v. Shelby County*, 220 F.3d 433, 446 (6th Cir. 2000)).

The Supreme Court has explained that “[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, ‘to state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)); see also *Courie v. Alcoa Wheel & Forged Products*, 577 F.3d 625, 629 (6th Cir. 2009). Stated otherwise, it is not enough for a claim to be merely possible; it must also be “plausible.” See *Courie*, 577 F.3d at 630. According to the Court, “a claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). Moreover, under limited circumstances, a claim may be rendered plausible if a plaintiff pleads its “information and belief” with supporting facts. See *Modern Holdings v. Corning Incorporated*, 2015 U.S. Dist. LEXIS 41134 at *12 (E.D. Ky. 2015) (“While pleading on information and belief cannot insulate a plaintiff at the 12(b)(6) stage, *Iqbal* did not render pleading on information entirely ineffectual.”) E.g., *Arista Records, LLC v. Doe*, 604 F.3d 110, 120 (2d Cir. 2010) (“The *Twombly* plausibility standard, which applies to all civil actions, does not prevent a plaintiff from pleading facts alleged upon information and belief where the facts are peculiarly within the possession and control of the defendant . . .”).

The underlying legal principles are especially relevant in resolving this motion to dismiss. UCB alleges Catalent is infringing on its patent by importing lacosamide into the

United States for commercial purposes. [R. 30 at 9-12.] Patent infringement is governed by 35 U.S.C. § 271, which states whoever “makes, uses, offers to sell,” sells, or imports a patented invention without authority “infringes the patent.” However, the Hatch-Waxman Act adopted an important exception, known as the safe harbor, codified at § 271(e)(1):

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e). Catalent does not argue that they are not importing lacosamide but claims their importation is protected under this safe harbor provision. [R. 48-1 at 15-19.] They move for dismissal, arguing the complaint fails to state a claim because it does not allege facts showing Catalent’s use “infringes outside the scope of the safe harbor.” [*Id.* at 15.] They claim this precludes UCB from being able to “state a plausible claim for patent infringement.” [*Id.*] They also argue the complaint fails to state a claim for patent infringement without considering application of the safe harbor because its allegations are not plausible. [*Id.* at 15-17.] In response, UCB states its complaint is sufficient to notify Catalent of the claim against it and that a plaintiff is not required to preemptively respond to an affirmative defense. [R. 57 at 8-14.]

A

To determine whether UCB’s amended complaint states a claim for patent infringement, the Court must first determine which of the complaint’s allegations are proper to consider. Much has been made in the pleadings about the effect that prior hearings and briefings in this Court, particularly those related to the preliminary injunction, have on dismissal of the complaint. [*See* R. 48-1 at 15-19; R. 57 at 9-10.] Catalent bases some of its argument on the notion that UCB should have addressed the safe harbor in its amended complaint because UCB participated in the

preliminary injunction process and was aware that Catalent intended to claim that defense. [R. 48-1 at 15.] Further, they point out alleged inconsistencies between the amended complaint and testimony submitted in relation to the preliminary injunction. [*Id.* at 16-17.]

Catalent points to *Bassett* as support for its assertion that the Court can consider these filings. [R. 48-1 at 18.] But that case, specifically the portion quoted in Catalent's motion, contradicts this assertion. This Court can consider portions of the record "so long as they are referred to in the complaint." *Bassett v. Nat'l College Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008). The preliminary injunction filings and related testimony were not referred to in the amended complaint [*see* R. 30], so the Court cannot consider them in resolving the motion to dismiss. For the same reasons, the Court will not consider the "admissions" Catalent made in the adjudication of the preliminary injunction, which UCB points to in its Response. [R. 57 at 9-20.]

In contrast, the Court will consider the information contained in the "four corners of the complaint," except for its "threadbare recitals" of the elements of a patent infringement claim. *Berry v. United States Dep't of Labor*, 832 F.3d 627, 637-38 (6th Cir. 2016). Catalent portrays the complaint as "a mishmash of bare allegations and rote recitations of claim elements." [R. 48-1 at 15.] It is true that some of the allegations in the complaint are merely conclusory or restatements of elements, which the Court does not have to accept as true. On multiple occasions, the complaint states some formulation of: "Catalent has used, manufactured, sold, and/or offered to sell lacosamide, and/or drug products comprising lacosdamide in the United States." [R. 30 at 9; *see also id.* at 5, 10-11.] These "allegations" are merely restating the patent infringement statute itself: "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented

invention during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a). The Court will not construe these conclusory statements as true.

However, the complaint does contain other allegations that are sufficiently plead to state a claim for patent infringement. UCB outlines seven instances where Catalent “caused” another corporation to import lacosamide. [R. 30 at 8-9.] These allegations include when, where and in what amount the compound was imported. [*Id.*] Though they are on “information and belief,” these statements are far from conclusory because of the specific factual allegations they contain. A court can take allegations based on information and belief as true so long as there is a sufficient factual basis for the belief. *Smith v. General Motors, LLC*, 988 F.3d 873, 885 (6th Cir. 2021) (*citing Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 878 (6th Cir. 2006)). The very specific details provided about these alleged instances of importation provide a sufficient factual basis for UCB’s belief that Catalent did in fact import lacosamide.

Catalent argues there are insufficient details to explain how Catalent “caused” the other corporation to import the substance or which Catalent entity was responsible. [R. 48-1 at 16.] UCB does not have to provide such details because the mechanics of the arrangement and Catalent’s corporate structure are not necessary to state a claim for patent infringement. Further, those facts would be “peculiarly within the possession and control of the defendant,” justifying UCB’s pleading them on information and belief. *Arista*, 604 F.3d at 120.

Assuming it is true that Catalent caused MSN to import lacosamide on the specified dates and in those amounts, UCB has stated a claim for patent infringement. The Court will note that the details of the relationship between Catalent and MSN may suggest liability under one of the non-direct forms of patent infringement, such as induced or contributory infringement. See 35 U.S.C. § 271(b), (c), (f). However, UCB contained these additional grounds for relief in their

complaint. [R. 30 at 11.] The purpose of the pleading system is to only require plaintiffs to state a “short and plain statement of the claim” that notifies the defendants of the claim and the ground on which it rests. *Conley*, 355 U.S. at 47-48. Catalent was notified by the complaint that UCB was filing suit against it for patent infringement based on certain, very specific, instances of imported lacosamide. This satisfies the modern “simplified ‘notice pleading’” standard. *Id.* Reading the amended complaint in the light most favorable to UCB, the Court finds that these allegations contain a sufficient factual basis to infer that Catalent did import or cause the importation of a patented invention. Therefore, UCB stated a plausible claim for relief which survives Catalent’s motion to dismiss. *Iqbal*, 556 U.S. at 678.

B

Catalent also argues in its motion to dismiss that UCB failed to state a claim because the amended complaint did not plead facts showing the alleged infringement is not protected by the safe harbor. [R. 48-1 at 17-19.] UCB’s Response argues both that the safe harbor does not apply in this case and that they are not required to “proactively address” Catalent’s affirmative defense in their complaint. [R. 57 at 11.] Dismissal is usually not the appropriate time for a Court to consider affirmative defenses. *Estate of Barney v. PNC Bank, Nat. Ass’n*, 714 F.3d 920, 926 (6th Cir. 2013). Otherwise, defendants would not have to prove the existence of their defense by a preponderance of the evidence. *Id.* Courts can grant a motion to dismiss on an affirmative defense in the limited circumstance where the complaint itself establishes the existence of the defense. *Id.* This is most straightforward when the defendant is protected by a statute of limitations and the complaint contains the dates that bring the claim outside of the limitations period. Put simply, the plaintiff’s own allegations, not facts or arguments raised in the defendant’s motion to dismiss, must establish the existence of the defense. *Id.*

Therefore, the Court must first determine whether the safe harbor in 35 U.S.C. § 271(e)(1) is in fact an affirmative defense. District courts around the country have convincingly held it is. *See, e.g. Allele Biotechnology and Pharmaceuticals, Inc. v. Pfizer, Inc.*, No. 20-cv-01958-H-AGS, 2021 WL 1749903, at *3 (S.D. Cal. May 4, 2021); *Enteris Biopharma, Inc. v. Clinical Pharmacology of Miami, Inc.*, No. 1:14-cv-22770-UU, 2015 WL 12085848, at *7 (S.D. Fla. Mar. 20, 2015); *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 933 F. Supp. 2d 569, 575 (D. Md. 2014); *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 273 (D. Mass. 2006). The Federal Circuit also once referred to a defendant’s “right to assert a section 271(e)(1) defense.” *Intermedics, Inc. v. Ventritex Co., Inc.*, 991 F.2d 808, 808 (Fed. Cir. 1993). This Court agrees that the safe harbor is an affirmative defense. The purpose of the safe harbor is that *otherwise infringing conduct* does not constitute infringement if it is undertaken for specific purposes. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202-08 (2005). Therefore, all the allegations in a plaintiff’s complaint alleging patent infringement can be true, establishing infringing conduct, but the defendant can allege other facts defeating that claim by showing their use was for specific, exempt purposes. *Id.* This dynamic is a quintessential affirmative defense. *See Affirmative Defense, Black’s Law Dictionary* (11th ed. 2019) (defining an affirmative defense as “a defendant’s assertion of facts and arguments that, if true, will defeat the plaintiff’s or prosecution’s claim, even if all the allegations in the complaint are true.”) Accordingly, dismissal is only appropriate if the facts alleged in the amended complaint establish the existence of the defense.

UCB’s amended complaint [R. 30] does not establish that Catalent’s conduct is protected by the safe harbor. UCB specifically alleges seven instances in which Catalent caused the importation of a patented invention, lacosamide, into the United States. [R. 30 at 8-9.] 35

U.S.C. § 271(a) clearly states importation of a patented invention infringes the patent. *See supra* pp. 6-7, discussing different potential forms of liability. Accepting the complaint's non-conclusory allegations as true, as the Court is required to do under *Iqbal*, 556 U.S. at 678, UCB stated a claim for patent infringement. If it is true that Catalent caused the importation of lacosamide as alleged, UCB would have a claim for patent infringement because the product is a patented invention and the patent term has not expired. [See R. 30; R. 1-1.] Catalent may well be able to prove the existence of an affirmative defense by showing the safe harbor applies by a preponderance of the evidence. However, the complaint does not establish this defense so it would be inappropriate for this Court to grant the motion to dismiss.

The many cases cited by Catalent allegedly supporting the Court's ability to grant their motion to dismiss actually support denial. While it is true that many courts have dismissed complaints alleging patent infringement based on the safe harbor, those complaints established the existence of the defense. *Medical Diagnostic Laboratories*, a case cited often by Catalent, granted a motion to dismiss based on the safe harbor when the allegations in the complaint specifically alleged use of a patented invention in connection with clinical trials. *Med. Diagnostic Labs. L.L.C. v. Protagonist Therapeutics, Inc.*, 298 F. Supp. 3d 1241, 1248-49 (N.D. Cal. 2018). That court specified the allegations in the complaint "leave no doubt that the purpose of [the infringing use]" was exempted under the safe harbor. *Id.* at 1248. The unpublished opinion provided in support by Catalent as Exhibit A misconstrues this case. It holds that *Med. Diagnostic Labs.* requires a plaintiff to allege facts showing the defendant's use is not protected by the safe harbor. [R. 48-2 at 14-15.] This conflicts with the language of the case itself, the weight of authorities, and a logical reading of § 271(e)(1). For example, *Enteris* granted a motion to dismiss because the complaint stated the defendants allegedly committed patent

infringement by conducting a clinical trial connected to filing a new drug application with the FDA, which is clearly protected by the safe harbor. 2015 WL 12085848, at *7-*8. *Teva* reached the same conclusion on very similar facts and was the basis for the *Enteris* court's holding. *Id.*; *Teva Pharm. USA, Inc. v. Sandoz Inc.*, No. 09-cv-10012, 2013 WL 3732867, at *4-*9 (S.D.N.Y. July 16, 2013) (“[the safe harbor] applies to precisely that activity alleged here to be infringing”). Both *Classen* cases are the same, granting motions to dismiss because the allegedly infringing conduct was “inherently tied to a regulatory approval process.” *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F. Supp. 2d 569, 577 (D. Md. 2014); *see also Classen Immunotherapies, Inc. v. Somaxon Pharmaceuticals*, No. CV 12-06643-GAF-PLA, 2013 WL 9947386 (C.D. Cal. Apr. 11, 2013).

While the Sixth Circuit has not addressed this question in the patent infringement context, it has considered the similar safe harbor provision of the Private Securities Litigation Reform Act. *Miller v. Champion Enterprises, LLC*, 346 F.3d 660, 676-89 (6th Cir. 2003). In *Miller*, the Circuit affirmed dismissal of multiple claims because the allegedly fraudulent statements fell within the PSLRA's safe harbor. *Id.* The Circuit granted dismissal at this stage because the complaint included the allegedly fraudulent statements, and analysis of the text of those statements proved their exemption. *Id.* Again, if UCB's complaint alleged facts establishing the applicability of the safe harbor, this Court could dismiss pursuant to *Miller*. The complaint does not do so, so dismissal is inappropriate.

This Court finds the Massachusetts District Court's denial of a motion to dismiss based on the safe harbor most compelling. *Amgen*, 456 F. Supp. 2d 267, 272-74. That case involved a complaint that alleged patent infringement by importation of a patented drug and a motion to dismiss claiming that importation was protected under the safe harbor, precisely the facts in the

case at hand. *Id.* at 270-71. The court held that the safe harbor is an affirmative defense and, consequently, dismissal was improper because the defendant is required to plead the existence of safe harbor protection, rather than the plaintiff having to plead its absence. *Id.* at 273. Dismissal was inappropriate because, by alleging importation of a patented drug, the plaintiff showed patent infringement.² *Id.* The defendant was then able to plead the application of the application of the safe harbor exemption, but not in their motion to dismiss. *Ventrassist* provides further support. *Ventrassist Pty Ltd. v. Heartware, Inc.*, 377 F. Supp. 2d 1278 (S.D. Fla. 2005). That court held a motion to dismiss could not be granted when the defendant's argument was that the plaintiffs failed to show their activities were not exempt under the safe harbor. *Id.* at 1286-87. Thorough analysis of federal law supported the conclusion that the safe harbor is an affirmative defense that does not have to be pre-empted in a complaint. *Id.*

By moving to dismiss based on UCB's failure to show Catalent's use was not exempt, Catalent "has attempted to foist on Plaintiffs a pleading requirement that does not exist." *Id.* at 1287. This Court will not raise the UCB's pleading requirements by asking them to pre-empt Catalent's safe harbor defense. Catalent has failed to show there is "no set of facts" entitling UCB to relief. *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). As in *Ventrassist*, "one can easily conceive of facts that would entitle [the] plaintiff to relief," namely that Catalent is infringing UCB's patent by importing lacosamide and that importation, in whole or in part, is not protected by the safe harbor. 377 F. Supp. 2d at 1285. It is not "beyond doubt" that UCB cannot succeed. *Conley*, 355 U.S. 45. To hold otherwise would allow a defendant to

² The court reached this conclusion "even if it were necessary to plead acts . . . that fall outside the Section 271(e)(1) provision. *Amgen*, 456 F. Supp. at 274. So even if the plaintiff was required to show the infringing conduct was not protected, the court would have denied the motion to dismiss because it would not conclude that all importation was protected. *Id.* That this conclusion was reached assuming a heightened pleading standard bolsters this Court's finding under the (actual) lower standard.

simply state in their motion to dismiss that their infringing use is exempt under the safe harbor, preventing the plaintiff from using the federal judicial system's robust discovery mechanisms to find otherwise and argue the provision's inapplicability. UCB's complaint includes sufficient non-conclusory allegations to state a claim and is not required to plead around the safe harbor, so dismissal is not warranted.

III

Accordingly, having considered the record, applicable law, and the arguments of the parties, the Court hereby **ORDERS** the Defendants' motion to dismiss [R. 48] is **DENIED**.

This the 24th day of November, 2021.

The image shows a handwritten signature in black ink, which appears to read "Gregory F. Van Tatenhove". The signature is written over a circular official seal. The seal contains the text "UNITED STATES DISTRICT COURT" at the top and "EASTERN DISTRICT OF KENTUCKY" at the bottom. In the center of the seal is an eagle with its wings spread, perched on a shield.

Gregory F. Van Tatenhove
United States District Judge