UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
LEXINGTON

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

*** *** *** ***

This matter is before the Court on Plaintiffs Harris FRC Corporation, Research Corporation Technologies, Inc., UCB Biopharma SPRL, and UCB, Inc.'s Motion for a Preliminary Injunction. [R. 4.] For the reasons that follow, Plaintiffs' request for a preliminary injunction will be **DENIED**.

I

The facts in this case are straightforward and are largely not in dispute. On July 6, 2004, the U.S. Patent Office issued a patent to Dr. Harold Kohn, which described the invention of "anticonvulsant enantiomeric amino acid derivatives,"[1] known as the chemical compound lacosamide. [*See* R. 4-3.] Dr. Kohn assigned the Patent to Plaintiff RCT, Inc. [*Id.*] Lacosamide is the active pharmaceutical ingredient ("API") in Plaintiffs' VIMPAT® drug product.[2] Plaintiff UCB. Inc., a biopharmaceutical company, holds various approved New Drug Applications

[1] U.S. Patent No. RE38,551 (the " '551 Patent").
[2] VIMPAT® is an antiepilectic drug that prevents "seizures associated with epilepsy … or related central nervous system disorders." [R. 4-1 at 7.]

("NDAs") for VIMPAT® in various dosage forms. [R. 4-1 at 7.]

Defendant Catalent Pharma Solutions, LLC is a "contract development and manufacturing organization … that provides various services to its pharmaceutical company customers, including the development of different delivery technologies (sometimes called "dosage forms") for APIs developed by those customers and the manufacture of the final dosage form for its customers' drugs." [R. 36-1 at 1.] Between April of 2019 and September of 2020, Catalent imported 479 kgs of lacosamide to its Winchester, Kentucky facility.[3] [R. 36-3 at 4.] Catalent was importing lacosamide in order to perform on a series of contracts it had entered into with Customer A. [*See* 36-1 at 3.] Pursuant to the contract, Catalent would provide manufacturing and testing services on lacosamide products in support of Customer A's anticipated 505(b)(2) application with the FDA. [*Id.*]

Plaintiffs brought the present preliminary injunction motion, seeking to have Defendants enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States the chemical compound lacosamide or products comprising lacosamide, among other requests for relief. [R. 4-2.] Defendants responded by acknowledging their importation of lacosamide, but claiming protection under the Safe Harbor provision of the Hatch-Waxman Act. Plaintiffs argue that the Defendants are not parties eligible for protection under the Safe Harbor provision.[4] As a note, even though the parties, at this stage, do not dispute the factual record as outlined above, the parties are advised that they are "not required to prove

[3] According to Catalent's DEA Compliance Supervisor Josh Stephenson, Catalent's records "account for the use or destruction of 487.5 kg, or 99.9% of the amount of lacosamide API delivered [to Catalent]." [R. 46-3 at 4–5.]
[4] Plaintiffs also claim that the amounts of lacosamide that Catalent has imported show a use of the compound that is not "solely for uses reasonably related to the development and submission of information under a Federal law …." [R. 45 at 12] (citing 35 U.S.C. § 271(e)(1)). Given the declaration of various Catalent officials, including Catalent's DEA Compliance Supervisor, however, this Court is sufficiently confident at this stage that the amounts of lacosamide imported by Catalent is for testing and not the mass-manufacturing of lacosamide products. [R. 36-1; R. 36-2; R. 36-3.]

[their] case in full at a preliminary injunction hearing … and the findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits." *U. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) (citing *Indus. Bank of Washington v. Tobriner*, 405 F.2d 1321, 1324 (1968) and *Hamilton Watch Co. v. Benrus Watch Co.*, 206 F.2d 738, 742 (2nd Cir. 1953)); *see also AtriCure v. Jian Meng*, 842 Fed.Appx. 974, 979 (6th Cir. 2021). Consequently, this Court will consider the facts presented by the parties for the limited purpose of "preserv[ing] the relative positions of the parties until a trial on the merits can be held." *Id.*

II

"The decision to grant or deny ... injunctive relief is an act of equitable discretion by the district court." *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391, 126 S.Ct. 1837, 164 L.Ed.2d 641 (2006); *see also* 35 U.S.C. § 283 (generally providing that courts "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable"). Injunctive relief, however, remains " 'an extraordinary remedy never awarded as of right.' " *Wind Tower Trade Coalition v. United States*, 741 F.3d 89, 95 (Fed. Cir. 2014) (citations omitted). A party seeking a preliminary injunction must therefore demonstrate: (1) a reasonable likelihood of success on the merits; (2) the prospect of irreparable harm in the absence of an injunction; (3) that this harm would exceed harm to the opposing party; and (4) that the public interest favors such relief. *See, e.g., Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259 (Fed. Cir. 2012); *Antares Pharma, Inc. v. Medac Pharma, Inc.*, 55 F.Supp.3d 526, 529–30, 2014 WL 3374614, at *2 (D. Del. 2014).

A

First, the Court must consider whether Plaintiffs have demonstrated a likelihood of

success on the merits of its claim that Defendants: (1) have infringed their patent; and (2) are not protected under the Safe Harbor provision. [*See* R. 45.] Generally, any unauthorized use of a patented invention in the United States constitutes an act of infringement. 35 U.S.C.A. § 271(a). As such, a potential infringer may not make, use, or test a product that is protected by a patent, such as lacosamide, before the patent expires. In 1984, however, Congress codified a limited use exception in 35 U.S.C.A. § 271(e)(1), which read in relevant part:

> 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.A. § 271(e)(1). The limited exception is part of a legislative compromise, which seeks to both: (1) "alleviate the unintended effects of the FDA approval process on the length of pharmaceutical patent terms" by giving potential competitors a head-start in the FDA approval process; while still (2) encouraging new research and development by allowing "patent holders to extend the term of their patent up to five years for delays caused by FDA approval." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 3 F.Supp.2d 104, 107 (D. Mass. 1998) (citing 35 U.S.C. § 156(g)(6)(A)); *see Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 *amended by*, 131 F.3d 1009 (Fed. Cir. 1997). At the preliminary injunction hearing, both parties seemed to acknowledge that Catalent's importation of lacosamide to the Winchester, Kentucky facility, if not otherwise excepted, would constitute patent infringement under Section 271(a) of the United States Patent Act,[5] and this Court agrees. The pivotal question then becomes whether or not Catalent's importation of lacosamide is protected under the Safe Harbor provision.

[5] The provision, in relevant part, states: "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) (emphasis added).

UCB and Catalent rely primarily on two cases in arguing whether or not Catalent falls under the Safe Harbor provision. First, UCB argues that *Proveris* stands for the proposition that the Safe Harbor does not exempt infringing parties "whose *own* commercial services/products are *not* subject to regulatory approval." [R. 45 at 4] (citing *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265–6 (Fed. Cir. 2008)) (emphasis in original). UCB argues that *Proveris* reveals a clear example of the Federal Circuit declining to extend Safe Harbor protection downstream to a supplier of tools *because* that supplier was not the party seeking FDA approval. [*Id.* at 4–5.] On closer inspection, however, the *Proveris* Court declines to extend Safe Harbor protection to Proveris because the company "is not a patentee who would have been faced with a reduction of effective patent life caused by the FDA approval process, the reason being that *the invention claimed in the … patent is not subject to the premarket approval required by the FDCA*." *Proveris*, 536 F.3d at *1265 (emphasis added). The *Proveris* Court contrasted the patented device in question, an Optical Spray Analyzer that measured the physical parameters of aerosol sprays used in nasal spray drug delivery devices, with the "aerosol drug delivery product whose spray plume characteristics the OSA measures." *Id.* The latter might fall under the Safe Harbor provision as a product that requires FDA premarket approval, while the OSA, categorically, would not. *Id.* Consequently, *Proveris* is distinguishable from the present case and UCB's downstream supplier argument does not carry merit.

In contrast, the facts underlying *Shire LLC v. Amneal Pharms. LLC*, 802 F.3d 1301 (Fed. Cir. 2015), as presented by Catalent, more closely resemble the facts at hand. In *Shire*, the Federal Circuit found that Johnson Matthey, a third party who had supplied API to a drug company preparing for an ANDA filing, was protected by the safe harbor of § 271(e)(1) because the drug was used for purposes "reasonably related to the submission of the ANDA." *Shire*, 802

F.3d at 1310. UCB argues that *Shire* is distinguished from the present case because *Shire* involved potential indirect infringement by Johnson Matthey, as opposed to the direct infringement of Catalent here. [R. 45 at 6.] This Court, however, interprets *Shire* as offering two conclusions, in the alternative, as to why Johnson Matthey was not liable for its sale of API to the drug company. The *Shire* Court first states:

> Johnson Matthey is correct that it cannot be liable for the API it sold the ANDA defendants up to this point. Johnson Matthey, as an API supplier, has thus far done nothing more than provide material for use by the ANDA defendants in obtaining FDA approval. As the district court found, these sales, and the ANDA defendants' use of the API for filing the ANDA, were "reasonably related to the submission of an ANDA." Op. at *12. As such, Johnson Matthey's activities are protected by the safe harbor of § 271(e)(1)

Shire, 802 F.3d at 1310. In this instance, the *Shire* Court acknowledges that the third-party Johnson Matthey cannot be liable for selling API to the drug company *because* the API was used for purposes "reasonably related to the submission of an ANDA." *Id.* Consequently, the Court concluded that Johnson Matthey was protected under the Safe Harbor provision. *Id.* After concluding that Johnson Matthey was, in fact, protected under the Safe Harbor provision, the Court went on to say "*[m]oreover*, as Johnson Matthey did not submit an ANDA, it cannot be liable for infringement under § 271(e)(2)." *Id.* (emphasis added). This conclusion, reached in the alternative, briefly addresses the issue of infringement. The Court's conclusions as to infringement, however, do not affect its prior conclusion that Johnson Matthey's actions fall under the Safe Harbor provision. Consequently, *Shire* supports the notion that a third-party who uses a patented API in a way that's "reasonably related" to a drug company's FDA submission retains the protection of the Safe Harbor provision.

To that end, it is opinion of this Court that Catalent's actions of importing, testing, and manufacturing lacosamide products in the present case were reasonably related to the submission

of Customer A's 505(b)(2) drug application with the FDA. Various officials of both Catalent and Customer A have attested to that fact.[6] Further, " ' reasonably related' … does not mean that the use of the patented invention must necessarily result in submission of information to the FDA." *Momenta Pharms. V. Amphastar Pharms.*, 686 F.3d 1348 (Fed. Cir. 2012) (citing *Merck KGaA*, 545 U.S. at 206). Instead, the Supreme Court has explained that "the safe harbor 'exempted from infringement *all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs." *Id.* (emphasis in original). Significantly, "[a]s long as the accused infringer 'has a reasonable basis for believing' that use of the patented invention might yield information that 'would be appropriate to include in a submission to the FDA, that use is 'reasonably related' to the 'development and submission of information under … Federal law." *Id.* at 1356–7. The evidence before the Court reveals that Catalent held a reasonable basis for believing that its use of the lacosamide compound would yield information to be used in furtherance of Customer A's FDA submission. In the present case, Catalent falls within the protection of the Safe Harbor provision and has not infringed on UCB's '551 Patent. Because UCB has not shown "that it will likely prove infringement . . . ," it has not established a likelihood of success on the merits. *Titan Tire v. Case New Holland*, 566 F.3d 1372, 1376 (Fed. Cir. 2009).

[6] [*See, e.g.,* R. 36-1 at 3] ("[Customer A] has informed Catalent, and it is Catalent's understanding, that Catalent's manufacturing and testing services concerning the lacosamide product are all related to [Customer A's] planned filing of an application with FDA for approval of that product under what is known as the 505(b)(2) regulatory pathway"); [*see also Id.* at 3 –4] ("[b]ased on my experience in the pharmaceutical industry, the quantities of lacosamide API delivered to Catalent are not consistent with ongoing commercial-scale manufacturing, but instead are consistent with manufacturing and testing related to a submission for FDA approval"); [R. 36-4 at 1–2] ("[Customer A] does not intend to file the new drug application … with the [FDA] for its new Lacosamide[] formulation until after March 17, 2022").

B

The prospect of irreparable harm in the absence of an injunction weighs in favor of Catalent. Simply put, Catalent has failed to show that UCB is infringing the '551 Patent. Catalent is lawfully importing and using lacosamide in a way that is "reasonably related" to a drug company's FDA submission, and is therefore within the category of entities that the Hatch-Waxman Act seeks to give Safe Harbor. As a result, UCB has not only failed to show the prospect of irreparable harm, but has shown no harm at all.

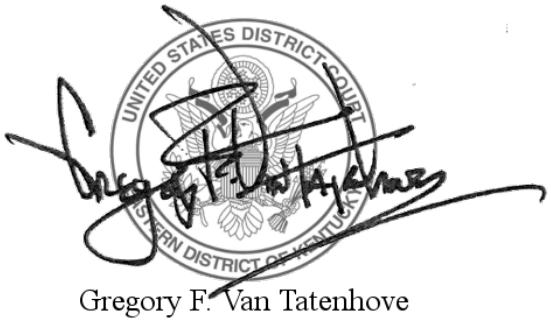
C

Because UCB was unable to show a reasonable likelihood of success on the merits, the balancing of the equities and the public interest factors are foreclosed. *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 77 F.3d 1364 (Fed. Cir. 1996) ("[n]either the public interest nor equity favors grant of an injunction against one who does not infringe"). Consequently, both factors weigh in favor of denying the present injunction.

III

Accordingly, and the Court being sufficiently advised, it is hereby **ORDERED** that Plaintiffs' Motion for a Preliminary Injunction [**R. 4**] is **DENIED**.

This is the 12th day of May, 2021.



Gregory F. Van Tatenhove
United States District Judge