

**UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

AORTIC INNOVATIONS, LLC,)	
)	
Plaintiff,)	Case No. 1:21-cv-01377-JPM
v.)	
)	JURY TRIAL DEMANDED
EDWARDS LIFESCIENCES)	
CORPORATION; EDWARDS)	
LIFESCIENCES LLC; EDWARDS)	
LIFESCIENCES (U.S.) INC.,)	
)	
Defendants.)	

**ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' RULE
12(b)(6) MOTION TO DISMISS**

Before the Court is Defendants Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc.'s (collectively, "Edwards") 12(b)(6) Motion to Dismiss, filed on December 6, 2021. (ECF No. 10.) For the following reasons, the Court **GRANTS IN PART** and **DENIES IN PART** Edwards's Motion.

I. BACKGROUND

A. Factual Background

Plaintiff Aortic Innovations, LLC ("Aortic" or "AI") is incorporated in Florida, with a principal place of business in Hillsboro Beach, Florida. (ECF No. 1 ¶ 7.) Edwards is incorporated in Delaware, with a principal place of business in Irvine, California. (Id. ¶¶ 8–10.) Edwards sells the SAPIEN 3 Ultra TAVR (transcatheter aortic valve replacement), which Aortic alleges infringes one or more claims of the following of its patents: U.S. Patent No. 10,881,538 (the "'538 Patent"), U.S. Patent No. 10,966,846 (the "'846 Patent"), U.S. Patent No. 10,987,236 (the "'236 Patent"), and U.S. Patent No. 11,129,735 (the "'735 Patent"). (Id. ¶¶ 103–69.)

The patents are directed to an improvement in TAVR devices. The Complaint provides a general summary of TAVR:

TAVR is a procedure where a replacement aortic heart valve is delivered by a catheter through an artery of a patient. Prior to TAVR, patients undergoing heart valve replacement would have their chest incised in an open heart procedure called Surgical Aortic Valve Repair (“SAVR”). SAVR often led to increased complications and was not deemed suitable for high risk patients who were often determined to be inoperable. The first TAVR device was approved in the United States by the Food and Drug Administration in 2011. Since that time, TAVR has become the leading choice for aortic valve replacement compared to the SAVR approach, with the number of TAVR procedures exceeding the number of SAVR procedures for the first time in 2019.

(Id. ¶ 3.) The claims of the Asserted Patents and the accused product are improvements of the original TAVR devices.

B. Procedural Background

On September 28, 2021, Aortic filed a Complaint accusing Edwards of infringing its patents. (ECF No. 1.) Edwards filed a Motion to Dismiss (ECF No. 10) and an Opening Brief in Support (ECF No. 11) on December 6, 2021. Aortic filed a Response in Opposition on December 20, 2021. (ECF No. 13.) Edwards filed a Reply on January 3, 2022. (ECF No. 16.) The Court held a hearing on the Motion on March 10, 2022. (ECF No. 23.)

II. LEGAL STANDARD

When reviewing a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must accept the complaint’s factual allegations as true. See Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555–56 (2007). “Though ‘detailed factual allegations’ are not required, a complaint must do more than simply provide ‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action.’” Davis v. Abington Mem’l Hosp., 765 F.3d 236, 241 (3d Cir. 2014) (quoting Twombly, 550 U.S. at 555). A complainant must plead facts sufficient to show

that a claim has “substantive plausibility.” *Id.* at 247. That plausibility must be found on the face of the complaint. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

III. ANALYSIS

A. Pre-Suit Knowledge of the '735 Patent

For willful and induced infringement, the plaintiff must allege that the defendant had knowledge of the patent. See *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 988 (Fed. Cir. 2021) (“Knowledge of the asserted patent and evidence of infringement is necessary, but not sufficient, for a finding of willfulness.”); *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 639 (2015) (“[L]iability for inducing infringement attaches only if the defendant knew of the patent and that ‘the induced acts constitute patent infringement.’”) (quoting *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011)).

Edwards contends that Aortic’s Complaint fails to state a claim for willful and indirect infringement of the '735 Patent “because AI fails to allege facts supporting a plausible inference that Edwards had pre-suit knowledge of the '735 [P]atent, which issued on the *same day* that AI filed its Complaint in this action.” (ECF No. 11 at PageID 1331.) Edwards contends that “[t]his Court recently dismissed willful infringement claims under similar circumstances in *Express Mobile, Inc.*” because, in that case, “the patentee provided the defendant with express notice of the patent one day before filing its complaint.” (*Id.* at PageID 1334.) (citing *Express Mobile, Inc. v. Squarespace, Inc.*, No. 20-1163-RGA, 2021 WL 3772040, at *5 (D. Del. Aug. 25, 2021).) Edwards points out that “[u]nlike defendants in *Express Mobile, Inc.*, Edwards did not even receive one-day advance notice of the '735 patent’s existence and alleged infringement.” (*Id.*)

Edwards also contends that the email sent from Dr. Shahriari (founder of Aortic and inventor of the patents-in-suit), informing Edwards of potentially infringing activity and listing the other patents-in-suit, “does not plausibly support AI’s willful infringement allegations” because it

“does not include the ’735 patent in the list of AI’s patents, nor could it have, because the ’735 patent did not issue for more than two months after the email was sent.” (Id.) Edwards contends that these facts are similar to the dismissed allegations of willful infringement in Wrinkl, Inc. because in that case, the patent in question “did not issue until July 2020” even though the pre-suit knowledge was alleged to come from “an October 2018 email exchange.” (Id. at PageID 1335.) (citing Wrinkl, Inc. v. Facebook Inc., No. 20-cv-1345-RGA, 2021 WL 4477022, at *6 (D. Del. Sept. 30, 2021).)

In response, Aortic contends that the email from Dr. Shahriari does provide sufficient notice because “[t]hat email listed the patent number for three of the four Patents-in-Suit as well as the publication number for the application that was set to issue shortly as the fourth—the ’735 Patent.” (ECF No. 13 at PageID 1360.) Aortic contends that pre-suit knowledge of the ’735 Patent is pled when considered under the totality of the circumstances. (Id. at PageID 1361.) Aortic asserts that “case law further indicates that, within this totality of circumstances, parties can have knowledge of a patent prior to patent issuance—in particular, they can have relevant pre-suit knowledge of patent claims following a notice of allowance from the PTO.” (Id.) (citing WCM Indus., Inc. v. IPS Corp., 721 F. App’x 959, 973 (Fed. Cir. 2018).) Aortic contends that “it is highly likely—and most certainly plausible—that Edwards discovered the USPTO’s August 23, 2021 final notice of allowance prior to the filing of this suit on September 28, 2021.” (Id. at PageID 1363.)

On Reply, Edwards contends that “even where a notice of allowance has been entered, the claims of an application can still be amended and further prosecuted.” (ECF No. 16 at PageID 1561.) (citing 37 C.F.R. §§ 1.312, 1.114.) Edwards points out that “there were *three* separate notices of allowance entered for the ’735 patent’s application before it ultimately issued, and AI

amended the claims *after* the first notice of allowance was entered.” (Id.) Edwards further contends that “AI does not cite a single case holding that knowledge of a patent application is sufficient to support a plausible inference of pre-suit knowledge of an issued patent.” (Id. at PageID 1562.)

In Wrinkl, this Court found that the complaint plausibly alleged pre-suit knowledge from an email from the plaintiff to the defendant where the patent had been listed in a video presentation that was linked in the email. 2021 WL 4477022, at *5–6. The Court found that this email correspondence was insufficient, however, to plausibly allege pre-suit knowledge of the other patent-in-suit because that patent did not issue until nearly two years after the email was sent. Id. Here, while the time between issuance of the ’735 Patent and the email from Dr. Shahriari is just over a month, the email only listed the patent application, and as such, does not necessarily provide knowledge of the patent.

The Eastern District of Texas has held that knowledge of a patent application was sufficient to allege pre-suit knowledge of the patent itself because at the time the defendant had knowledge of the patent application, the patent itself had already issued. See Blitzsafe Tex., LLC v. Volkswagen Grp. of Am., Inc., No. 2:15-cv-1274-JRG-RSP, 2016 WL 4778699, at *6 (E.D. Tex. Aug. 19, 2016) (“The Court finds VWGoA could have learned of the ’786 patent when it cited the Marlowe Application in a Patent Office proceeding. The proceeding occurred a year after the ’786 patent issued.”), report and recommendation adopted, 2016 WL 4771291 (E.D. Tex. Sept. 13, 2016). Further, the Federal Circuit has indicated that it *may* be possible to have pre-suit knowledge of a patent before the patent issues. See WCM Indus., 721 F. App’x at 970 (“[H]ere, WCM provided sufficient evidence for a reasonable jury to conclude that IPS *did* know of WCM’s patents as they issued, if not earlier.”). In that same case, though, the Federal Circuit declined to decide

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