IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

BIOMUNE COMPANY, Plaintiff,	)	
v.	)	Case No. 14-2567-JWL
MERIAL LIMITED and MERIAL LLC, Defendants.	)	

MEMORANDUM AND ORDER

By this action, plaintiff Biomune Company seeks a declaratory judgment to the effect that its animal vaccine does not infringe two patents held by defendants Merial Limited and Merial LLC and that those patents are invalid. This matter comes before the Court on defendants' motion to dismiss (Doc. # 16). For the reasons set forth below, the Court concludes that no case or controversy exists here under Article III of the Constitution and that it therefore lacks subject matter jurisdiction. The Court therefore **grants** the motion, and this action is hereby dismissed.[1]

"The burden is on the party claiming declaratory relief . . . to establish that an Article III case or controversy existed at the time that the claim for declaratory relief was

[1]In light of this ruling, the Court does not address defendants' alternative argument for dismissal based on a lack of personal jurisdiction. The Court also denies plaintiff's request for oral argument on this motion (Doc. # 26).

filed and that it has continued since." *See Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1329 (Fed. Cir. 2014).[2] "[T]he proper test of when an action for declaratory judgment presents a justiciable controversy is 'whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *See Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1356 (Fed. Cir. 2013) (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)). The test is an objective one: "it is the objective words and actions of the patentee that are controlling," and "conduct that can be reasonably inferred as demonstrating intent to enforce a patent can create declaratory judgment jurisdiction." *See Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358, 1363 (Fed. Cir. 2009). There is no bright-line test; rather the Court considers the totality of the circumstances in determining whether a case or controversy exists. *See Danisco*, 744 F.3d at 1331-32.

In its opposition brief, plaintiff disputes that it must show jurisdiction arising from an affirmative act by defendants, but the Federal Circuit has repeatedly stated that such an act is required. "[D]eclaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by

[2]This issue of whether a case or controversy exists in this case is governed by Federal Circuit law. *See 3M Co. v. Avery Dennison Corp.*, 673 F.3d 1372, 1377 (Fed. Cir. 2012).

the patentee." *See SanDisk Corp. v. ST Microelectronics, Inc.*, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007); *see also Hewlett-Packard*, 587 F.3d at 1364 (quoting and applying *SanDisk*'s requirement of an affirmative act by the patentee); *Prasco, LLC v. Medicis Pharmaceutical Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008) (same). The governing objective standard "cannot be met by a purely subjective or speculative fear of future harm" by the plaintiff; rather "a case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants*." *See Prasco*, 537 F.3d at 1339 (emphasis in original). Plaintiff notes that in *Danisco* the Federal Circuit held that the defendant need not specifically have "threatened litigation or otherwise taken action to enforce its rights." *See Danisco*, 744 F.3d at 1330. The Federal Circuit did not state in that case, however, that the declaratory judgment plaintiff need not point to some affirmative act by the defendant that gives rise to the reasonable belief that the defendant will enforce its patent against the plaintiff. In finding jurisdiction in *Danisco*, the court relied on the defendant's "posturing" and its "activities"—specifically, defendant's claim that its patent covered the compound used by the plaintiff and the "war" over patents that the parties had been waging—that demonstrated that the defendant had "engaged in a course of conduct that shows a preparedness and a willingness to enforce its patent rights." *See id.* at 1332 (quoting *SanDisk*, 480 F.3d at 1383). Thus, the Federal Circuit has consistently required that declaratory judgment jurisdiction arise from an affirmative act of the defendant.

In asserting jurisdiction in its complaint and in its opposition brief, plaintiff relies

solely on defendants' refusal to enter into license negotiations on one occasion and various patent infringement suits filed by defendants. The Court will consider those alleged affirmative acts by defendants in turn.

In Paragraph 19 of its complaint, plaintiff alleges as follows:

> On or about October 24, 2011, Ceva Sante Animale [plaintiff's parent company] employee Bernard Emery contacted Merial's Vice President of Business Development, Mr. Peter Selover, to discuss a potential license with respect to Merial's patent rights related to PCV-2 in an effort to remove any uncertainty concerning Biomune's vaccine. On or about November 3, 2011, Merial, by and through its representative, Mr. Selover, refused to enter into license negotiations with Ceva related to Merial's PCV-2 [patents].[3]

Plaintiff argues that defendants' refusal to enter into license negotiations at that time gives rise or contributes to a reasonable inference that defendants did intend to enforce their patents against plaintiff's vaccine. The Court disagrees.

Plaintiff has not cited any case in which a court has relied on such a refusal in finding jurisdiction under the *MedImmune* test. In *Prasco*, the Federal Circuit rejected the plaintiff's argument based on the defendant's refusal to sign a covenant not to sue after being sent samples of the product. *See Prasco*, 537 F.3d at 1341. The court noted that although a refusal to give assurances of non-enforcement may be relevant, it is not dispositive, and that a patentee is not obliged to test a competitor's product or to make

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[3]The last word of this paragraph as alleged in the complaint is actually "products", but plaintiff insists in its brief that the use of that word was a typographical error and that "patents" was intended (and plaintiff is willing to amend to fix the error if necessary). Because the Court does not believe that the issue of jurisdiction turns on this word, the Court will consider the allegation as restated by plaintiff.

a definitive determination regarding enforcement at a time of the competitor's choosing. *See id.* The court further stated that the patentee's silence is not sufficient by itself to create an actual controversy and that "affirmative" actions by the patentee are also generally necessary. *See id.*

Similarly here, the Court gives minimal weight in evaluating the totality of the circumstances to defendants' alleged refusal to enter into license negotiations with plaintiff. Plaintiff's allegation does not include any detail about the conversations between the parties or defendants' stated reasons (if any) for refusing to enter into negotiations. Moreover, plaintiff does not allege that defendants refused to grant them some specific license; rather, plaintiff merely alleges that defendants refused to discuss the subject at all (indeed, defendants provide evidence that Mr. Selover had no authority to grant a license). The fact that defendants did not wish to talk about a license does not necessarily imply any intent to enforce their patents against any particular product. Finally, as defendants note, the alleged conversations took place well before plaintiff even sought regulatory approval for the vaccine in 2012, and more than three years before plaintiff filed the present suit; thus, the conversations in themselves say little about defendants' intent to enforce their patents against plaintiff's vaccine in late 2014 when plaintiff filed this suit.

Plaintiff also relies on defendants' history of patent infringement litigation in arguing for jurisdiction here. In Paragraph 18 of its complaint, plaintiff alleges that defendants have a "history" of enforcing their patents "against Biomune." Plaintiff has

not identified any such litigation between these parties, however. In Paragraph 18, plaintiff proceeds to allege that defendants sued another subsidiary of plaintiff's parent company for infringement of patents related to flea control products. Thus, defendants did not sue plaintiff, but rather sued a related company, and the suit involved a different type of product. In Paragraph 17 of its complaint, plaintiff also alleges that defendants have "a history of aggressively asserting its PCV-2 related patents to stop competitors from bringing PCV-2 vaccine products to market." In support of that allegation, in its complaint and in its brief, plaintiff identifies only a series of related cases brought by defendants against two companies between 2005 and 2009.

The Court concludes that these allegations are not sufficient to give rise to a case or controversy under Article III. The Federal Circuit has noted that "a history, or lack thereof, of litigating in the industry" can be a factor to be considered in this analysis. *See Hewlett-Packard*, 587 F.3d at 1364 n.1 (citing *Prasco*, 537 F.3d at 1341). That court has generally given weight, however, to suits involving the same parties and the same or related technology or patents. *See Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) ("related litigation involving the same technology and the same parties is relevant in determining whether a justiciable controversy exists on other related patents"). In this case, there is no history of litigation between these parties, and the suit by defendants against a company related to plaintiff involved an unrelated product. Defendants brought a series of suits against two companies unrelated to plaintiff involving this same type of product, but that

litigation was initiated many years before plaintiff filed this suit. In the absence of other conduct by defendants, these suits do not give rise to a reasonable inference that defendants have the intent to enforce their patents against plaintiff and its vaccine. *See Prasco*, 537 F.3d at 1341 (one prior suit between the parties concerning different products did not constitute "the type of pattern of prior conduct that makes reasonable an assumption that [the patentee] will also take action against [the plaintiff] regarding its new product"); *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1382 (Fed. Cir. 2010) ("Thus while prior litigation is a circumstance to be considered in assessing the totality of circumstances, the fact that [the patentee] had filed infringement suits against other parties for other products does not, in the absence of any act directed toward [the plaintiff], meet the minimum standard discussed in *MedImmune*.").

In support of their motion, defendants have provided evidence that they were unaware of plaintiff's vaccine until plaintiff filed this suit. In *Hewlett-Packard*, the Federal Circuit stated that it was irrelevant whether the patentee defendant had conducted an adequate investigation or whether it subjectively believed the plaintiff was infringing. *See Hewlett-Packard*, 587 F.3d at 1363. Similarly, defendants' claim that they did not even know about this product does not automatically mean that no controversy can exist here. Nevertheless, as explained above, an affirmative act by the patentee is required to give rise to a controversy, and defendants' insistence that they did not know about the vaccine is consistent with the lack of any evidence or allegation that defendants performed any affirmative act specifically relating to this product and these

patents. Apropos here is the following conclusion by the Federal Circuit in *Prasco*:

> In contrast [to other cases], here the defendants have not accused [the plaintiff] of infringement or asserted any rights to [the plaintiff's product], nor have they taken any actions which imply such claims. Instead, all we have before us is [the plaintiff's] allegation that its product does not infringe the defendants' patents. The defendants' lack of any "concrete claim of a specific right" is an important factor weighing against a finding of an actual controversy, particularly given that there has been no actual injury. The lack of any evidence that the defendants believe or plan to assert that the plaintiff's product infringes their patents creates a high barrier to proving that [the plaintiff] faces an imminent risk of injury. Moreover, not only have the defendants not taken a concrete position adverse to [plaintiff's], but they also have taken no affirmative actions at all related to [the plaintiff's] current product.

See Prasco, 537 F.3d at 1340 (footnote omitted). Plaintiff has not identified any cases in which an actual controversy was found on so little evidence of acts by the patentee relating to the product at issue as has been alleged here. Accordingly, the Court concludes from the totality of the circumstances that no case or controversy exists here as required under Article III.

Finally, the Court rejects plaintiff's apparent argument that a controversy arises here under 35 U.S.C. § 271(e)(2)(B). That paragraph of Section 271 makes it a technical act of infringement to submit an application for regulatory approval of certain products that are claimed in a patent. *See id.* Under that statute, an applicant may certify that such a patent is invalid or will not be infringed, and it may then give notice of that certification to the patentee, who then has a limited time in which to sue for infringement. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568-69 (Fed. Cir. 1997). Section 271(e)(2) provides a defined act of infringement to create a case or

controversy in that situation. *See id.* In this case, however, plaintiff has not alleged or argued that it made a certification under Section 271 and gave such notice to defendants, such that defendants would be required to assert any claims of infringement at this time. Plaintiff has not cited any authority suggesting that, if no such certification has been made, a case or controversy is created for purposes of Article III merely by applying for regulatory approval, without consideration of the *MedImmune* standard and the Federal Circuit caselaw applied above. In the absence of such authority, the Court cannot conclude that plaintiff's mere act in applying for regulatory approval creates a justiciable controversy in this case.

Accordingly, because no case or controversy exists here, the Court grants defendants' motion and hereby dismisses this action for lack of subject matter jurisdiction.

IT IS THEREFORE ORDERED BY THE COURT THAT defendants' motion to dismiss for lack of subject matter jurisdiction (Doc. # 16) is **granted**, and this action is hereby dismissed.

IT IS FURTHER ORDERED BY THE COURT THAT plaintiff's request for oral argument on the motion to dismiss (Doc. # 26) is **denied**.

IT IS SO ORDERED.

Dated this 26th day of June, 2015, in Kansas City, Kansas.

s/ John W. Lungstrum
John W. Lungstrum
United States District Judge