In the United States Court of Federal Claims

No. 20-499C

(Filed: July 29, 2021)

GILEAD SCIENCES, INC., Plaintiff, **v.** **UNITED STATES,** Defendant.	Breach of contract allegations; motion to dismiss; statute of limitations; 28 U.S.C. § 2501; damage claims not alleged in pending district court suit; 28 U.S.C. § 1500

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OPINION AND ORDER

LETTOW, Senior Judge.

Gilead Sciences, Inc. ("Gilead") has sued the United States for breach of contract, alleging that the Centers for Disease Control and Prevention ("CDC") controverted the terms of four Material Transfer Agreements ("MTAs") and two Clinical Trial Agreements ("CTAs"). *See* First Am. Compl., ECF No. 33. Pending before the court is defendant's second motion to dismiss. *See* Def.'s Mot. to Dismiss, ECF No. 37. This motion addresses Count VI of plaintiff's first amended complaint, which alleges breach of the "4323 CTA." *See id.* at 1-2. The government alleges that Count VI is jurisdictionally barred and that Gilead has failed to state a claim upon which relief can be granted. *See id.* After briefing was completed, *see* Pl.'s Resp., ECF No. 38; Def.'s Reply, ECF No. 44, the court held a hearing on July 13, 2021.

BACKGROUND[1]

Gilead, a biopharmaceutical company "at the forefront of scientific efforts to identify and develop effective treatments for HIV," has collaborated with the CDC "on various research studies relating to the use of antiretroviral agents for prevention of HIV-1." First Am. Compl. ¶¶ 3-4. Gilead's lawsuit "arises out of a specific series of interactions and two sets of contracts" in its ongoing collaboration with the CDC. First Am. Compl. ¶ 5. The MTAs stipulated that Gilead would provide the CDC "with significant quantities of Gilead compounds free of charge." First Am. Compl. ¶ 6; *see also* First Am. Compl. Exs. 4-7, ECF Nos. 34-4 to 34-7. The government, in turn, agreed to "promptly notify" Gilead of "any Inventions" derived from work performed under the agreements. *E.g.*, First Am. Compl. Ex. 4 at 3. Each MTA defined "Inventions" as "any inventions, discoveries and ideas that are made, conceived or reduced to practice." *E.g.*, First Am. Compl. Ex. 4 at 3. The first CTA, dated August 6, 2004, stated that Gilead would provide antiviral products for a clinical trial in the United States called CDC 4323. First Am. Compl. Ex. 27, ECF No. 34-27. The second CTA, dated November 18, 2004, set forth the terms for providing antiviral products for a clinical trial in Botswana. First Am. Compl. Ex. 13, ECF No. 34-13. The CDC agreed "to put the results of the Trial[s], patentable or otherwise, in the public domain for all to use without obligation or compensation to [the] CDC." *E.g.*, First Am. Compl. Ex. 27 at 2. The CTAs further specified that the CDC would "not . . . seek patent protection in connection with any inventions that derive from the use of the Study Drug[s] in the Trial[s]." First Am. Compl. Ex. 27 at 2.

On February 3, 2006, the CDC filed Provisional Patent Application No. 60/764,811 (the "'811 Provisional") with the U.S. Patent and Trademark Office ("PTO"). First Am. Compl. ¶ 11. This Provisional "related to purported inventions that [the] CDC made in the course of the research conducted under the MTAs, . . . using the compounds that Gilead provided under the MTAs." First. Am. Compl. ¶ 11. The following year, the CDC filed non-provisional Patent Application No. 11/669,547 (the "'547 Application"), claiming priority to the '811 Provisional. First Am. Compl. ¶ 11. Still years later, on June 2, 2015, the PTO issued U.S. Patent No. 9,044,509 (the "'509 Patent") based on the non-provisional '547 Application. First Am. Compl. ¶ 12. Three other patents claiming priority to the '811 Provisional and the '547 Application have since issued. First Am. Compl. ¶ 12.[2] Gilead asserts that "[e]ach of the[se] . . . Patents claims methods of using tenofovir-based HIV pre-exposure prophylaxis in humans, which was shown to be safe, in part, by the CDC 4323 clinical trial." First Am. Compl. ¶ 12. Gilead further alleges that the CDC failed to "promptly notify" Gilead of any "Inventions" arising from the MTAs and CTAs or plans to seek patent protection until October 2014 at the earliest. First Am. Compl. ¶ 13.

On July 16, 2012, after the CDC had filed the '811 Provisional and the '547 Application but prior to the issuance of the relevant patents, Gilead obtained approval from the FDA to market its drug Truvada for HIV-1 pre-exposure prophylaxis ("PrEP"). *See* First Am. Compl. ¶

[1] The recitations that follow do not constitute findings of fact, but rather are recitals attendant to the pending motions and reflect matters drawn from the complaint, the parties' briefs, and records and documents appended to the complaint and briefs.

[2] Those patents are Nos. 9,579,333 (issued Feb. 28, 2017); 9,937,191 (issued Apr. 10, 2018); and 10,335,423 (issued July 2, 2019). *See* First Am. Compl. ¶ 12.

15. A few years later, on March 11, 2016, however, the government notified Gilead that Truvada "may be covered" by patents "recently obtained" by the CDC. First Am. Compl. Ex. 26 at 1, ECF No. 34-26. Gilead countered that the government had breached the MTAs and that the patents were not valid. First Am. Compl. ¶ 110. On November 6, 2019, the government filed suit against Gilead in the United States District Court for the District of Delaware. *See United States v. Gilead Sciences, Inc*., No 19-2103MN (D. Del., filed Nov. 6, 2019). The government alleges in the Delaware lawsuit that Gilead infringed its patents by selling and promoting Truvada and a related drug, Descovy, for HIV PrEP. First Am. Compl. ¶ 115.

On April 24, 2020, Gilead filed suit in this court, alleging breach of the MTAs and CTAs. *See* Compl., ECF No. 1. The government then moved to dismiss pursuant to Rules 12(b)(1) and 12(b)(6) of the Rules of the United States Court of Federal Claims ("RCFC"). *See* ECF No. 11. This court, however, held that it possesses jurisdiction over Gilead's claims and that Gilead had pled viable breach of contract claims. *See Gilead Sciences, Inc. v. United States*, 151 Fed. Cl. 742, 745 (2020). Following that ruling, Gilead discovered that the 4323 CTA "include[d] the exact same contract language" as the CTA alleged in Count V of the original complaint. Pl.'s Resp. at 1. Gilead subsequently filed its first amended complaint on April 21, 2021, adding Count VI to address the 4323 CTA. *See* First Am. Compl. ¶¶ 156-60. One month later, the government filed the pending motion to dismiss Count VI pursuant to RCFC 12(b)(1) and 12(b)(6). *See* Def.'s Mot.

STANDARDS FOR DECISION

A. Rule 12(b)(1) – Lack of Subject-Matter Jurisdiction

The Tucker Act provides this court with jurisdiction over "any claim against the United States founded either upon the Constitution, or any Act of Congress or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort." 28 U.S.C. § 1491(a)(1). To establish this court's jurisdiction under the Tucker Act, Gilead must "identify a substantive right for money damages against the United States separate from the Tucker Act." *Todd v. United States*, 386 F.3d 1091, 1094 (Fed. Cir. 2004) (citations omitted).

Gilead, as plaintiff, must establish jurisdiction by a preponderance of the evidence. *See Trusted Integration, Inc. v. United States*, 659 F.3d 1159, 1163 (Fed. Cir. 2011) (citing *Reynolds v. Army & Air Force Exch. Serv.*, 846 F.2d 746, 748 (Fed. Cir. 1988)). When ruling on the government's motion to dismiss for lack of jurisdiction, the court must "accept as true all undisputed facts asserted in the plaintiff's complaint and draw all reasonable inferences in favor of the plaintiff." *Id.* (citing *Henke v. United States*, 60 F.3d 795, 797 (Fed. Cir. 1995)). Moreover, "[e]very claim of which the United States Court of Federal Claims has jurisdiction shall be barred unless the petition thereon is filed within six years after such claim first accrues." 28 U.S.C. § 2501. This six-year statute of limitations "is a jurisdictional requirement attached by Congress as a condition of the government's waiver of sovereign immunity and, as such, must be strictly construed." *Dalles Irrigation Dist. v. United States*, 71 Fed. Cl. 344, 350 (2006) (quoting *Hopland Band of Pomo Indians v. United States*, 855 F.2d 1573, 1576-77 (Fed. Cir. 1988)). A breach of contract claim accrues under Section 2501 "when all events have occurred to fix the [g]overnment's alleged liability," including the incurrence of damages. *Gilead Sciences*, 151

Fed. Cl. at 748 (alteration in original) (quoting *Nager Elec. Co. v. United States*, 177 Ct. Cl. 234, 240 (1966)).

Additionally, this court lacks jurisdiction over "any claim for or in respect to which the plaintiff . . . has pending in any other court." 28 U.S.C. § 1500. This statute imposes a "significant jurisdictional limitation" on this court. *United States v. Tohono O'Odham Nation*, 563 U.S. 307, 314 (2011). Section 1500 applies when the earlier-filed suit and the action in this court "are based on substantially the same operative facts, regardless of the relief sought in each suit." *Id.* at 317. "Thus, similarities or the same general subject matter do not suffice to trigger Section 1500. Rather, the specific facts at issue in the cases are determinative." *Oklahoma v. United States*, 144 Fed. Cl. 263, 272 (2019) (citing *Tohono*, 563 U.S. at 317) (additional citations omitted). Two requirements must be met for Section 1500 to divest this court of jurisdiction: (1) there must be "an earlier-filed 'suit or process' pending in another court," and (2) "the claims asserted in the earlier-filed case" must be "'for or in respect to' the same claim(s) asserted in the later-filed Court of Federal Claims action." *Brandt v. United States*, 710 F.3d 1369, 1374 (Fed. Cir. 2013) (citing *Trusted Integration, Inc.*, 659 F.3d at 1163-64); *see also Gilead Sciences*, 151 Fed. Cl. at 749-50 (applying *Brandt*'s "two-step inquiry").

B. Rule 12(b)(6) – Failure to State a Claim Upon Which Relief Can Be Granted

Under RCFC 12(b)(6), a complaint will survive a motion to dismiss if it "contain[s] 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, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "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.* The factual matters alleged "must 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)." *Twombly*, 550 U.S. at 555-56 (citations omitted).

When reviewing the complaint, "the court must accept as true the complaint's undisputed factual allegations and should construe them in a light most favorable to the plaintiff." *Cambridge v. United* States, 558 F.3d 1331, 1335 (Fed. Cir. 2009) (citing *Papasan v. Allain*, 478 U.S. 265, 283 (1986)) (additional citation omitted). Conclusory statements of law and fact, however, "are not entitled to the assumption of truth" and "must be supported by factual allegations." *Iqbal*, 556 U.S. at 679. "'[N]aked assertion[s]' devoid of 'further factual enhancement'" are insufficient to state a claim. *Id.* at 678 (quoting *Twombly*, 550 U.S. at 557); *accord Bradley v. Chiron Corp.*, 136 F.3d 1317, 1322 (Fed. Cir. 1998) ("Conclusory allegations of law and unwarranted inferences of fact do not suffice to support a claim.").

ANALYSIS

A. Gilead's Claim for Breach of the 4323 CTA is Adequately Pled

Most of the government's arguments to dismiss echo its first motion, but it asserts for the first time in the pending motion that the patents at issue do not derive from the 4323 CTA. *See* Def.'s Mot. at 12-13. In contrasting Gilead's claims regarding the two CTAs, the government avers that Count VI "contains no allegation that the CDC relied on any information from the 4323 study during prosecution of the '547 Application, nor included it in the HHS Patents." *Id.*

at 13. Given that the 4323 CTA covered a single-drug, tenofovir-based PrEP, while the patents claimed a dual-drug regimen, the government claims that "there is no basis to extend the scope of the 4323 CTA to cover any and all tenofovir-based regimens." Def.'s Reply at 2.

Gilead, however, "has pleaded facts alleging that the subject matter claimed in the HHS Patents derives from the . . . 4323 clinical trial and is governed by the . . . CTA." Pl.'s Resp. at 12. Specifically, the company alleged in its amended complaint that "[t]he results of the CDC 4323 safety study provided the foundation for tenofovir-based PrEP in humans, including PrEP regimens that use tenofovir-based agents in combination with other agents (like emtricitabine), because the results helped to demonstrate that TDF can safely be taken for PrEP." First Am. Compl. ¶ 85. The government is correct that the 4323 clinical trial "was a safety study on the use of ten[o]fovir disoproxil fumarate (TDF) alone," Def.'s Mot. at 2-3, but its argument overlooks the apparent link between the trial and the patent applications: if tenofovir-based PrEP had proven unsafe in the trial, the safety of the dual-drug regimen utilizing tenofovir would have been questionable and the dual-drug regimen might have been unavailable for testing, *see* Pl.'s Resp. at 12. These factual allegations "allow[] the court to draw the reasonable inference that" the government breached the 4323 CTA's prohibition on seeking patent protection for inventions deriving from the trial. *Iqbal*, 556 U.S. at 678 (citation omitted). Gilead's claim for breach of the 4323 CTA thus does not warrant dismissal under RCFC 12(b)(6).

B. Count VI is Not Barred by 28 U.S.C. § 2501

The government reiterates its first motion to dismiss by asserting that Count VI is untimely under 28 U.S.C. § 2501. *See* Def.'s Mot. at 6-8. According to the government, Gilead's claim regarding the 4323 CTA accrued once the patent applications were filed "and either Gilead was aware . . . or should have been aware of" the applications. Hr'g Tr. 12:20-21 (July 13, 2021). The government further asserts that Gilead could have known of these applications in January 2008 when the CDC published a technologies brochure that included a brief reference to an "invention [that] discloses the use of a Tenofovir/FTC combination to prevent rectal HIV transmission." Def.'s Mot. at 7 (alteration in original) (quoting *id*. Ex. 3 at 43, ECF No. 37-3).[3] The government also points to a 2008 disclosure form provided by Dr. Robert Janssen to Gilead as proof that Gilead could have known of the government's patent application. Def.'s Mot. at 8; *see also id.* Ex. 5 at 8-9, ECF No. 37-5.[4] Gilead, in turn, argues that the government failed to provide notice of the "purported invention or its patent application" until October 2014 at the earliest. Pl.'s Resp. at 3.

All four elements of Gilead's claim for breach of the 4323 CTA must be present for its claim to accrue: "1) a valid contract between the parties; 2) an obligation or duty arising from that contract; 3) a breach of that duty; and 4) damages caused by that breach." *Claude Mayo*

[3] The government points out that the brochure was "available on the internet," as was a comparable brochure provided the following year. Hr'g Tr. 41:22-23 (July 13, 2021).

[4] Dr. Janssen included in an application for employment a reference to a prior invention listed as an international patent application filed under the Patent and Cooperation Treaty ("PCT"), not applicable to the United States: "(WD/2007/092326) Inhibition of HIV Infection through chemprophylaxis pending." Def.'s Mot. Ex. 5 at 9. This reference is relatively opaque as to the means employed regarding inhibition of HIV. *See* Hr'g Tr. 27:1-7 (July 13, 2021).

Constr. Co. v. United States, 132 Fed. Cl. 634, 637 (2017) (citing *San Carlos Irrigation & Drainage Dist. v. United States*, 877 F.2d 957, 959 (Fed. Cir. 1989)). As noted in this court's previous opinion, "the timeliness of Gilead's claims turns on the incurrence of damages." *Gilead Sciences*, 151 Fed. Cl. at 748; *see also Lake Borgne Basin Levee Dist. v. United States*, 127 Fed. Cl. 321, 335 (2016) (citation omitted) ("Because damages are a necessary element of a claim for breach of contract, plaintiffs' causes of action against defendant would not have accrued until plaintiffs had suffered such damages.").

While the government suggests that Gilead incurred damages from the moment the company could have licensed the patent applications, *see* Hr'g Tr. 13:8-15 (July 13, 2021), this argument overlooks the fact that the government's patent rights were not enforceable against Gilead until June 2, 2015, when the PTO issued the '509 Patent, *see Gilead Sciences*, 151 Fed. Cl. at 748. Gilead's claimed damages include licensing costs, *see* First Am. Compl. ¶ 22, but it does not follow that Gilead began incurring these damages upon the filing of the patent applications. The company only began to incur damages in the form of licensing costs once the PTO had issued the patents. *See* DAVID M. EPSTEIN, ECKSTROM'S LICENSING IN FOREIGN AND DOMESTIC OPERATIONS § 4:2 (2021) ("[T]he owner or licensee of patent rights or applications may not bring an action until after the patent issues. Nor may he or she recover damages for pre-issuance activities which were within the scope of the subsequently issued patent."). Gilead's claim regarding the 4323 CTA accrued "either on June 2, 2015, the date of [the] first patent issuance, or on March 11, 2016, the date when the CDC first asserted its patent rights." *Gilead Sciences*, 151 Fed. Cl. at 748. Count VI thus falls within the six-year statute of limitations set by 28 U.S.C. § 2501.

C. Neither 28 U.S.C. § 1500 Nor Gilead's Requests for Attorneys' Fees Bar Count VI

In another revival of its prior motion to dismiss, the government avers that 28 U.S.C. § 1500 precludes this court from exercising jurisdiction over Count VI. Def.'s Mot. at 11-12. Under the government's reading of Section 1500, Count VI is barred because Gilead's claim in this suit "mirrors its amendments to its Third Amended Answer in Delaware." *Id.* To be sure, this court's jurisdiction does not extend to "any claim for or in respect to which" Gilead "has pending in any other court." 28 U.S.C. § 1500. As noted in this court's previous opinion, however, "Section 1500 speaks in terms of a 'claim,' not a defense." *Gilead Sciences*, 151 Fed. Cl. at 749. Gilead's amended complaint in this case mirrors its answer in the Delaware lawsuit in that both filings depict the patents as unenforceable. *See* First Am. Compl. ¶ 27. Yet the jurisdictional bar imposed by Section 1500 does not encompass affirmative defenses brought "in any other court," namely Gilead's defense of unclean hands in the Delaware lawsuit. *See Gilead Sciences*, 151 Fed. Cl. at 749.

The government further argues that Gilead's claim for attorneys' fees incurred in the Delaware lawsuit is jurisdictionally "barred by double recovery and by 35 U.S.C. § 285." Def.'s Mot. at 9. As maintained by the government, Gilead's claim for attorneys' fees pursuant to 35 U.S.C. § 285 in the Delaware lawsuit "preempts the general terms of the Tucker Act" and thus prevents the company from seeking attorneys' fees in this court. *Id*. at 10. Gilead points to this court's previous opinion in countering that attorneys' fees are appropriate damages in this case. *See* Pl.'s Resp. at 9-10. The government overlooks the fact that a claim under Section 285 and a claim for attorneys' fees under the Tucker Act have distinct elements. An award of attorneys' fees under Section 285 "involves a two-part determination. First, a district court must determine

whether the prevailing party has proven an exceptional case by clear and convincing evidence." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1380 (Fed. Cir. 2005) (citation omitted); *see also* 35 U.S.C. § 285 ("The court in exceptional cases may award reasonable attorney fees to the prevailing party."). If the court "finds the case exceptional," it may then consider factors "such as the closeness of the case, the tactics of counsel, the flagrant or good faith character of the parties' conduct, and any other factors contributing to imposition of punitive sanctions or to fair allocation of the burdens of litigation." *Perricone*, 432 F.3d at 1380-81 (citation omitted). By contrast, Gilead may recover attorneys' fees under the Tucker Act if it proves that such fees are compensatory damages. *See Connecticut Yankee Atomic Power Co. v. United States*, 143 Fed. Cl. 172, 178 (2019) ("[A]ttorney's fees[,] when properly categorized as compensatory damages for a contract breached by the United States and not incurred in litigation, may be recovered." (internal quotation marks omitted)). Given that Gilead's counterclaim for attorneys' fees in the Delaware lawsuit requires proof of different elements than its claim for attorneys' fees this case, the government's concerns regarding a "double recovery" are misplaced at this juncture.

D. Gilead Cannot Recover Damages for Reputational Harm

In addition to attorneys' fees, Gilead alleges "reputational harm due to the Delaware Litigation in an amount to be determined at trial." First Am. Compl. ¶ 160. The government points out that this request is in conflict with the Tucker Act's jurisdictional bar against claims "sounding in tort." Def.'s Mot. at 8-9 (quoting 28 U.S.C. § 1491(a)(1)). To be sure, "[t]he mere mention of types of damages that may not be recoverable in this suit does not invalidate Gilead's claims for breach of contract." *Gilead Sciences*, 151 Fed. Cl. at 750. Nonetheless, "[l]oss of business reputation is not a compensable damage claim" in this court "because it sounds in tort and is speculative." *Lucas v. United States*, 25 Cl. Ct. 298, 310 (1992) (citation omitted). Gilead's claim for reputational damages thus falls outside of this court's jurisdiction.

CONCLUSION

For the reasons set forth above, the government's motion to dismiss is GRANTED IN PART AND DENIED IN PART. Gilead's claim for reputational damages under Count VI is DISMISSED for lack of jurisdiction. The remainder of Count VI, however, falls within this court's jurisdiction, and Gilead has sufficiently pled its claim for breach of the 4323 CTA to survive the government's motion to dismiss under RCFC 12(b)(6). The United States shall file an answer to the amended complaint regarding the claims for breach of contract on or before August 26, 2021.

It is so **ORDERED**.

s/ Charles F. Lettow
Charles F. Lettow
Senior Judge