In the United States Court of Federal Claims

No. 20-499C

(Filed: December 30, 2020)

GILEAD SCIENCES, INC. Plaintiff, **v.** **UNITED STATES,** Defendant.	Suit based on alleged breach of contracts; motion to dismiss in which government points to defenses asserted by plaintiff in earlier action filed by government against plaintiff; 28 U.S.C. § 1500; pleading a claim

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OPINION AND ORDER

LETTOW, Senior Judge.

This case arises out of five contracts between plaintiff, Gilead Sciences, Inc. ("Gilead"), and the Centers for Disease Control and Prevention ("CDC"), acting on behalf of the federal government.[1] These contracts consist of four Material Transfer Agreements ("MTAs") and one Clinical Trial Agreement ("CTA"). Gilead and the CDC entered into these agreements as part of an ongoing collaboration on research "relating to the use of antiretroviral agents for prevention of HIV-1." Compl. ¶ 4. Gilead alleges that "the [g]overnment is asserting patents that it secretly obtained in violation of the collaboration agreements," Compl. ¶ 2, and that "[t]he [g]overnment

[1] References to the "United States," the "government," and the "CDC" all refer to defendant and its collective entities.

breached its obligations under both the MTAs and the CTA," Compl. ¶ 10. The context in which this case arises includes a suit filed by the government against Gilead for infringement of the relevant patents. *See United States v. Gilead Sciences, Inc*., No 19-2103MN (D. Del., filed Nov. 6, 2019). That action was instituted approximately five months before Gilead filed this suit.[2]

Pending before the court is the government's motion to dismiss the complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Rules of the Court of Federal Claims ("RCFC"). *See* Def.'s Mot. to Dismiss ("Def.'s Mot."), ECF No. 11. After briefing, *see* Pl.'s Resp. to Def.'s Mot. ("Pl.'s Resp."), ECF No. 12; Def.'s Reply to Pl.'s Resp. ("Def.'s Reply"), ECF No. 15; Pl.'s Sur-Reply to Def.'s Reply ("Pl.'s Sur-Reply"), ECF No. 18, the court held a hearing on Monday, December 14, 2020. The government's motion to dismiss this action is based on lack of subject-matter jurisdiction and failure to state a claim. *See* Def.'s Mot. at 2.

The court concludes that Gilead's claims for breach of contract are timely under 28 U.S.C. § 2501, as they accrued within six years of Gilead's filing suit in this court. Furthermore, Gilead's claims are not barred by 28 U.S.C. § 1500 because Gilead has only asserted defenses in the Delaware action, and relatedly the statute speaks in terms of a "claim," not a defense. Lastly, Gilead has pled viable breach of contract claims to avoid dismissal under RCFC 12(b)(6). Accordingly, the government's motion is DENIED.

BACKGROUND[3]

Gilead "has brought to market more than a dozen products that have been approved by the FDA for the treatment and prevention of HIV." Compl. ¶ 28. The company "has a long history of working with the scientific community," including the CDC, "to promote basic scientific and clinical research on HIV, HIV treatment, and HIV prevention." Compl. ¶ 39. The collaborations between Gilead and the CDC have taken the form of "many material transfer and related agreements over the past three decades." Compl. ¶ 42.

The MTAs at issue in this case span from 2004 to 2014. Compl. ¶ 44. In each of these MTAs, "Gilead agreed to provide" certain compounds to the CDC "at no cost, to be used in HIV-1 research." Compl. ¶ 45. "[U]nder each of the four MTAs," Compl. ¶ 45, the government agreed to, *inter alia*, "promptly notify" Gilead of "any Inventions" derived from work performed under the agreements. *E.g.*, 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.*, Compl. Ex. 4 at 3. The government also agreed "to give serious and reasonable consideration to [Gilead's] request for a non-exclusive or exclusive license on commercially reasonable terms under [the government's] intellectual property rights in or to any Inventions." *E.g.*, Compl. Ex. 4 at 3. The MTAs at issue were amended as the collaborations progressed. *See, e.g.*, Compl. Ex. 8.

[2] This case was filed on April 24, 2020.

[3] 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.

Also at issue in this case is a CTA, which the CDC and Gilead entered into on November 1, 2004. *See* Compl. Ex. 13 at 1. That agreement was amended three times beginning in October 2006. Compl. ¶¶ 54-56. Pursuant to this agreement, Gilead was to provide antiretroviral products to the CDC for a clinical trial in Botswana. *See* Compl. Ex. 13 at 2-3. The CDC agreed in turn "not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial." Compl. Ex. 13 at 2. As outlined in the amended CTA, Gilead provided the CDC with the pre-exposure prophylaxis drug Truvada and matching placebos. *See* Compl. ¶ 57.

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"). *See* Compl. Ex. 18. The '811 Provisional "related to purported inventions that [the] CDC made in the course of the research conducted under the MTAs[] and using the compounds that Gilead provided under the MTAs." Compl. ¶ 11. On January 31, 2007, the government filed non-provisional Patent Application No. 11/669,547 ("the '547 Application"). *See* Compl. Ex. 19. Gilead alleges that the "CDC relied on information derived from the Botswana clinical trial to make decisions concerning the prosecution of the '547 Application." Compl. ¶ 11. On February 1, 2008, the CDC sent Gilead a draft of an article which outlined the study described by the '649 MTA. Compl. ¶ 76. This article disclosed that five of the authors were "named in a US [g]overnment patent application related to methods for HIV prophylaxis." Compl. Ex. 20 at 1.

In January 2011, "the CDC provided interim guidelines that explicitly directed physicians to prescribe the use of" Gilead's Truvada, the drug used in the Botswana clinical trial, for pre-exposure prophylaxis. Compl. ¶ 81. A year later, in 2012, "with the encouragement and support of the [g]overnment," Gilead sought and obtained approval from the FDA to market Truvada for HIV-1 pre-exposure prophylaxis. Compl. ¶ 82. Thereafter Gilead alleges that it was not until October 2014 that CDC provided "notice to Gilead of the purported invention(s) described in the '811 Provisional and/or the '547 Application." Compl. ¶ 75; *see* Compl. Ex. 23. Subsequently, on June 2, 2015, the Patent and Trademark Office issued the first of the relevant patents, U.S. Patent No. 9,044,509 ("the '509 Patent"), from the non-provisional '547 Application. *See* Compl. ¶ 12. The government also filed U.S. Patent Application No. 15/913,750 on March 6, 2018 ("the '750 Application"). Compl. ¶ 106. Three other patents "that claim priority to the same provisional and non-provisional applications have . . . issued" since the issuance of the '509 Patent. Compl. ¶ 12.[4]

Gilead alleges that "[a]t no time during any of the communications in the course of executing the parties' obligations under the MTAs or . . . amendments was there any mention by [the] CDC of any purported invention . . . or any plan to seek patent protection as a result of the research performed . . . ." Compl. ¶ 48. Gilead further alleges that the CDC's failure to mention any "purported invention" or "any plan to seek patent protection" contravened the express terms of the CTA. Compl. ¶ 60. In 2016, after the first patent had issued, the CDC notified Gilead that it believed Truvada "may be covered by" patents "recently obtained" by the CDC. Compl. Ex. 26. The CDC suggested that Gilead apply for a non-exclusive license of the invention covered

[4] 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).

by its patents. Compl. Ex. 26. Gilead responded that the government had breached the MTAs and that it did not believe the patents to be valid. Compl. ¶ 102.

On November 6, 2019, the government filed suit against Gilead in the United States District Court for the District of Delaware. Compl. ¶ 107. The government alleges in the Delaware lawsuit that Gilead infringed its patents by selling and promoting the products Truvada and a related drug, Descovy. Compl. ¶ 107. Gilead has asserted several defenses in the Delaware lawsuit, including "the equitable doctrine of unclean hands due to, among other things, the [g]overnment's breaches of the MTAs and the CTA." Compl. ¶ 27.

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)).

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 two suits "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).

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 Claims Fall Within the Six-Year Statute of Limitations Set by 28 U.S.C. § 2501

In its motion to dismiss, the government contends that Gilead's claims fall outside the six-year statute of limitations set by 28 U.S.C. § 2501. Def.'s Mot. at 8-13. It argues that Gilead's claims accrued on February 3, 2006, when the CDC filed the provisional patent application. *See id.* at 10-11. Gilead counters that its claims could not have accrued until the PTO issued the patents to the CDC. *See* Pl.'s Resp. at 9.

A claim accrues under 28 U.S.C. § 2501 "when all events have occurred to fix the [g]overnment's alleged liability, entitling the claimant to demand payment and sue here for his money." *Nager Elec. Co. v. United States*, 177 Ct. Cl. 234, 240 (1966) (footnote omitted). A viable breach of contract claim requires "four elements: 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 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)).

While the government filed its provisional patent application in 2006, *see* Compl. Ex. 18, and mentioned its pursuit of a patent in a draft article sent to Gilead in 2008, *see* Compl. Ex. 20, the timeliness of Gilead's claims turns on the incurrence of damages. "Because damages are a necessary element of a claim for breach of contract," Gilead's claims did not accrue until it "suffered such damages." *Lake Borgne Basin Levee Dist. v. United States*, 127 Fed. Cl. 321, 335 (2016) (citing *Terteling v. United States*, 167 Ct. Cl. 331, 338 (1964)).

Gilead alleges that "the [g]overnment's actions increased the cost of a potential license and exposed Gilead to the risk of patent-infringement damages." Compl. ¶ 110. These damages

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