In the United States Court of Federal Claims

No. 20-499C

(Filed under seal: March 4, 2022)
(Reissued: March 9, 2022)

GILEAD SCIENCES, INC., Plaintiff, **v.** **UNITED STATES,** Defendant.	Contract case related to private support for governmental research agreements; proper scope of discovery under RCFC 30(b)(6); limitations imposed; RCFC 26(b)(2)(c)

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OPINION AND ORDER[1]

LETTOW, Senior Judge.

Pending before the court in this contract dispute is plaintiff Gilead Sciences, Inc.'s ("Gilead") motion to compel the designation of a witness under Rule 30(b)(6) of the Rules of the Court of Federal Claims ("RCFC"). Pl.'s Mot. to Compel ("Pl.'s Mot."), ECF No. 51. Gilead has sued defendant United States ("the government") for breach of contract, alleging that the Centers for Disease Control and Prevention ("CDC") violated the terms of four Material Transfer

[1] Because of the protective order entered in this case, this opinion was initially filed under seal. The parties were requested to review the decision and provide proposed redactions of any confidential or proprietary information. No redactions were requested.

Agreements ("MTAs") and two Clinical Trial Agreements ("CTAs"). *See* First Am. Compl., ECF No. 33.

This action is closely tied to a patent infringement case pending in the district of Delaware styled *United States v. Gilead Sciences Inc.,* No. 19-2103MN (D. Del., filed Nov. 5, 2019). Discovery in that action and this one has been coordinated by the parties,[2] except that the pending motion has been filed only in this court, Hr'g Tr. 22:21-22, 24:20-25.[3] The results however, would be applicable also to the district court case. [4] The motion seeks to compel the government to designate a witness or witnesses to testify regarding the topic of Gilead's Rule 30(b)(6) Notice which concerns the government's policies and procedures for tracking government obligations under MTAs, CTAs, and other similar agreements. Pl.'s Mot. at 2. The government counters that the notice was overly broad. Def.'s Opp'n to Pl.'s Mot. to Compel at 2 ("Def.'s Opp'n"), ECF No. 54. After briefing was completed, *see* Pl.'s Reply, ECF No. 58, the court held a hearing on February 10, 2022. The motion is ready for disposition.

BACKGROUND[5]

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. From 2004 to 2014, Gilead and the government entered into four MTAs (and issued several amendments to those agreements during that time span) that stipulated that Gilead would provide the CDC "with significant quantities of Gilead compounds free of charge." First Am. Compl. ¶¶ 6, 45; *see also* First Am. Compl., Exs. 4-7, ECF Nos. 34-4 to 34-7. In exchange, the government agreed to "promptly notify" Gilead of "any Inventions" derived from work performed under the agreements. First Am. Compl., Ex. 4 at 3. "Inventions" were defined in each MTA as "any inventions, discoveries and ideas that are made, conceived or reduced to practice." First Am. Compl., Ex. 4 at 3. Per the agreements, the CDC was "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." First Am. Compl., Ex. 27 at 2, ECF No. 34-27.

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[2] *See* Hr'g Tr. 6:14 to 7:5 (Feb. 10, 2022).

The date will be omitted from further citations to the hearing transcript.

[3] The parties reportedly used the same numbering system for discovery in both courts. Hr'g Tr. 24:21-23.

[4] The parties previously agreed that "[d]eposition testimony given in the Delaware action shall be deemed given in this action as well." Joint Status Report of March 17, 2021 at 26, ECF No. 24. The reverse is also true; any response the government makes to discovery in this action will be applicable in the District of Delaware. Hr'g Tr. 6:22 to 7:2.

[5] 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.

Additionally, Gilead and CDC entered into two CTAs in 2004. First Am. Compl. ¶¶ 50, 57. The first CTA was amended in 2007, and the second was amended three times between 2006-2012. First Am. Compl. ¶¶ 54, 60. The CTAs 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.

In February 2006, the CDC first took steps to patent inventions "related to purported inventions that 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. It was not until years later that the Patent and Trademark Office issued several patents.[6] Having previously received approval from the Food and Drug Administration on July 16, 2012 for the use of the drug Truvada for HIV-1 pre-exposure prophylaxis and begun doing so, s*ee* First Am. Compl. ¶ 15, the government notified Gilead on March 11, 2016—some years later—that Truvada "may be covered" by a patent "recently obtained" by the CDC. First Am. Compl., Ex. 26 at 1, ECF No. 34-26. Gilead countered that the government had breached their agreements 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. Since that time, the court has held that it possessed jurisdiction over the case and declined to dismiss the action. *See Gilead Sciences, Inc. v. United States*, 151 Fed. Cl. 742 (2020); *Gilead Sciences, Inc. v. United States,* 155 Fed. Cl. 336 (2021). Coordinated discovery has proceeded simultaneously in both this case and the related case before the district court in Delaware. During the course of discovery, the parties took over 100 hours of deposition testimony, *see* Def.'s Opp'n at 2, in which Gilead received conflicting testimony from various government employees about how or who tracked the government's obligations under the agreements. Pl.'s Mot. at 8-9.[7]

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[6] Those patents are Nos. 9,044,509 (issued June 2, 2015); 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.

[7] The director of the CDC's Technology Transfer office testified that she did not determine whether the CDC had obligations under MTAs. Pl.'s Mot., Ex. 8 at 70:20 to 71:4, ECF No. 51-8. In contrast, an employee of the National Institutes of Health stated that she "presume[d]" that obligations associated with MTAs were tracked by the CDC's Technology Transfer Office. *Id.*, Ex. 9 at 87:17 to 88:4, ECF No. 51-9. Further employees within the CDC provided conflicting testimony regarding who bore the responsibility of ensuring compliance with the CDC's obligations. *Compare id.*, Ex. 10 at 96:14 to 97:23, ECF No. 51-10 ("Q: Did you ever have to notify any party to a material transfer agreement based on the discovery described in a material transfer agreement? A. No. . . . Q: Would this type of notification have fallen on Lisa [Blake-DiSpigna]'s plate? Would Lisa have been responsible for something like that? A. Yes."), *with id.*, Ex. 11 at 41:11-20, ECF No. 51-11 ("Q: So, if Ms. Ghosh had suggested that it was your office's responsibility to notify Gilead, would you agree with that? A: No. . . . Q: Why not? A: Because our role was administrative services. And our job was simply to put

On October 21, 2021, Gilead served the government with a Rule 30(b)(6) notice. Particular to this motion, Topic 130 of that notice sought testimony regarding:

> The policies, procedures, and persons involved in tracking the [g]overnment's obligations under material transfer agreements, clinical trial agreements, or Cooperative Research and Development Agreements [("CRADAs")] that CDC and [Public Health Service ("PHS")] enter into, including but not limited to procedures or guidance related to the persons responsible for providing disclosures or notice under any such agreements, what such disclosure or notice typically includes, and the timing of such disclosure or notice.

Pl.'s Mot., Ex. 2 at 2, ECF No. 51-2. The parties conferred about Topic 130 on November 8, 2021 before the government served formal responses to the Rule 30(b)(6) notice. Pl.'s Mot at. 3; Def.'s Opp'n at 3-4. At that time, the government raised its concern that Topic 130 was overly broad. Pl.'s Mot. at 3; Def.'s Opp'n at 4. Gilead avers that it clarified that the topic sought "testimony only with respect to the policies and procedures governing agreements involving CDC and PHS and that it was willing to further limit the scope of the topic to CDC's policies and procedures related to its obligations in MTAs and CTAs." Pl.'s Mot. at 3. Thereafter, Gilead did not serve an amended version of Topic 130, and the government objected to the topic as overly broad in its responses served on November 18, 2021. Def.'s Opp'n at 4.

The parties conferred again on December 21, 2021. Pl.'s Mot. at 4; Def.'s Opp'n. at 4. At that time, Gilead offered to limit the scope of the topic "to specific groups at CDC or to a specific time period." Pl.'s Mot. at 5. The government responded that those limitations would not rectify the burden on the government since Topic 130—in the government's view—seeks testimony "concerning every MTA, CTA, or CRADA that unnamed groups at CDC entered into." Def.'s Opp'n at 5. The government offered that it would be willing to provide a witness to testify regarding the specific agreements at issue in the case due to the "unique obligations" created in individual MTAs and CTAs. *Id.*[8] Gilead rejected that compromise, maintaining that Topic 130 "seeks testimony on general policies related to the types of agreements at issue in this case, and not testimony on each and every government collaboration." Pl.'s Mot. 4-5. The parties did not reach an agreement concerning the scope of Topic 130, and the government did not designate a witness to testify to it.

Gilead filed its motion to compel on January 10, 2022. Fact discovery in the case closed on January 21, 2022. *See* Order of April 6, 2021, ECF No. 26. In its motion, Gilead argues that the topic is relevant and not overly broad as it seeks information about the government's monitoring practices generally and that a witness is necessary to address the issue because other government witnesses have given inconsistent answers. *See generally* Pl.'s Mot. The

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together the agreement and get it executed. And we did our part. And that was the responsibility.").

[8] The government contends that a restriction in time is necessary in part because there was a change in structure of the offices responsible for the agreements. Def.'s Opp'n at 7. Prior to 2013, the Office of Technology Transfer essentially handled prosecuting patents while the Office of Administrative Services drafted and negotiated the types of agreements at issue here. Hr'g Tr. 19:24 to 20:18. In 2013, those offices merged. Hr'g Tr. 20:18-23.

government counters that the wording of Topic 130 encompasses every policy and agreement entered into by CDC and PHS and is therefore overly broad. Def.'s Opp'n at 6. Further, the government contends that any inconsistency in testimony is a result of Gilead asking broad questions to the wrong witnesses. *Id.* at 11. Subsequent to the filing of Gilead's motion and the government's opposition brief, the government served a supplemental interrogatory response on January 28, 2022, which stated in part that "CDC and PHS as agencies do not (and did not) track 'the [g]overnment's obligations under [MTAs, CTAs, or CRADAs] that CDC and PHS enter into,' including the MTAs and CTAs at issue in this litigation." Pl.'s Reply, Ex. 1 at 15, ECF No. 58-1.

In its opposition and at the hearing, the government argued that Topic 130 should be limited to the CDC, a specific time period, and to the agreements at issue in this case. *See* Def.'s Opp'n at 8-10; Hr'g Tr. 19:6-23; 22:19 to 23:5. At the hearing, Gilead suggested limiting discovery under the topic to "policies from the CDC and the PHS for these types of agreements, MTAs and CTAs." Hr'g Tr. 26:14-24.

STANDARDS FOR DECISION

"Questions of the scope and conduct of discovery are, of course, committed to the discretion of the trial court." *Florsheim Shoe Co. v. United States*, 744 F.2d 787, 797 (Fed. Cir. 1984). "Accordingly, resolution of a motion to compel discovery is committed to that discretion." *3rd Eye Surveillance, LLC v. United States*, 143 Fed. Cl. 103, 109 (2019) (citing *Heat & Control, Inc. v. Hester Indus., Inc*., 785 F.2d 1017, 1022 (Fed. Cir. 1986)). When deciding motions to compel, the "court must balance potentially conflicting goals," *Petro-Hunt, L.L.C. v. United States*, 114 Fed. Cl. 143, 144 (2013), with the understanding that "[m]utual knowledge of all the relevant facts gathered by both parties is essential to proper litigation," *Hickman v. Taylor*, 329 U.S. 495, 507 (1947).

ANALYSIS

Rule 30(b)(6) requires that a party serving a notice under this rule "must describe with reasonable particularity the matters for examination." In turn, the named organization "must then designate one or more . . . persons who consent to testify on its behalf." *Id.* Rule 30(b)(6) is subject to the limitations of Rule 26(b)(2), and the court must limit the scope of a Rule 30(b)(6) topic to the extent it is unreasonably cumulative or is unduly burdensome. *See* RCFC 26(b)(2)(C)(1)-(3). Therefore, "Rule 30(b)(6) call[s] on the court[] to ensure that both sides are adhering to the rule's objective of fair access to corporate information and, at the same time, to guard against overreaching by the party seeking discovery and failure of the [organizational] party to satisfy its obligations." 8A Richard L. Marcus, Federal Practice & Procedure § 2103 (3d ed. 2021) (discussing Fed. R. Civ. P. 30); *see Ierardi v. Lorillard, Inc.*, Civ. A. No. 90-7049, 1991 WL 66799, at *2 (E.D. Pa. Apr. 15, 1991) ("The purpose of Rule 30(b)(6) is to ensure that corporations supply relevant information to opposing counsel relating to corporate practices, policies, procedures and actions.") (discussing Fed. R. Civ. P. 30(b)(6)).[9]

[9] RCFC 30(b)(6) mirrors Fed. R. Cir. P. 30(b)(6), and the rules should be interpreted *in pari materia*.

The government does not contest the relevancy of Gilead's inquiry generally but does contend that Gilead has failed to meet its obligation under Rule 30(b)(6) to describe the inquiry with particularity. *See* Def.'s Opp'n at 12. Ultimately, the party seeking discovery bears the burden of showing it has defined its deposition notice with particularity. *See* 8A Richard L. Marcus, Federal Practice & Procedure § 2103 (3d ed. 2021) (discussing Fed. R. Civ. P. 30). Both parties have offered potential limitations for the topic. The government would limit the topic according to time, agency, and the specific agreements in this case, Def.'s Opp'n 7-8, while Gilead would limit the topic to CDC and PHS policies regarding MTAs and CTAs generally. Hr'g Tr. 26:14-24. The parties are correct to offer limitations to the inquiry because it is overly broad as written in that it seeks information about all of the CDC's and PHS's MTAs, CTAs, and CRADAs without a time limitation. While Gilead contends that it seeks information related only to "general policies and procedures that [CDC and PHS] follow to track their obligations under the specific types of agreements," Pl.'s Reply at 3, the language of the notice does not necessarily reflect that focus.

Pursuant to Rule 26(b)(2)(C), the court will limit Topic 130 of Gilead's Rule 30(b)(6) notice by time, agency, and type of agreement. The court will address the parties' suggested limitations in turn, beginning with whether the topic should be limited to the CDC alone or should also include PHS. The government argues that PHS is irrelevant to the claim because "all the agreements in this case were between Gilead and the CDC." Def.'s Opp'n at 8. In response, Gilead argues that the MTAs at issue are titled "Public Health Service Material Transfer Agreement," Pl.'s Reply at 3 n.2 (citing First Am. Compl., Ex. 4 at 1), and those agreements create obligations for PHS because it agreed to "give serious and reasonable consideration to [p]rovider's request for a non-exclusive or exclusive license on commercially reasonable terms under PHS's intellectual property rights in or to any [i]nventions." *Id.* (citing First Am. Compl., Ex. 4 at ¶ 8).

Eight of the eleven agencies of the Department of Health and Human Services make up PHS. In effect, PHS is a sprawling entity whose policies and procedures encompass agencies and agreements that are unrelated to this case. Further while Gilead is correct that the MTAs state obligations for "PHS," each MTA also states that the National Institutes of Health, the Food and Drug Administration, and the CDC are collectively referred to as PHS and the "recipient" under each agreement is listed solely as CDC. First Am. Compl., Ex. 4 at 1; Ex. 5 at 1, ECF No. 34-5; Ex. 6 at 1, ECF No. 34-6; Ex. 7. at 1, ECF No. 34-7. Gilead does contend that CDC, as a sub-agency of PHS, may be subject to general PHS policies that would not be considered CDC policies. Hr'g Tr. 25:21 to 26:13. In light of the breadth of PHS, the lack of other PHS agencies' involvement, and the predominance of CDC's role in this case, the court will limit the scope of Topic 130 to agreements concerning the CDC specifically and any general policies that PHS has implemented that pertain to the CDC. Policies specific to other agencies within PHS and their MTAs and CTAs will be beyond the scope of the now limited topic.

The government next advocates that the topic should be limited to the specific MTAs and CTAs at issue in this case. Def.'s Opp'n at 7; Hr'g Tr. 22:23 to 23:5. While Gilead's original request encompassed all MTAs, CTAs, and CRADAs, it has since expressed a willingness to limit its request to MTAs and CTAs as categories. Hr'g Tr. 26:20-24. It maintains, however, that Topic 130 must extend to all MTAs and CTAs, not just the ones at issue here, to accomplish its goal of determining what CDC's general policies and procedures are in regard to tracking its obligations under these types of agreements. Pl.'s Mot. at 7. The government maintains that a

non-specific discussion of MTAs and CTAs is not possible due to each agreements' unique terms. Def.'s Opp'n at 7; Hr'g Tr. 29:24 to 30:8.

As an initial matter, in light of the distinct nature of CRADAs and Gilead's own willingness to limit its request in that regard, CRADAs are removed from the scope of Topic 130. The court, however, will not limit the topic to the specific MTAs and CTAs involved in this case. The purpose of Rule 30(b)(6) is in part to give parties the opportunity to obtain information about the general policies and procedures of its opponent. *See* 8A Richard L. Marcus, Federal Practice & Procedure § 2103 (3d ed. 2021) (discussing Fed. R. Civ. P. 30). Limiting Gilead's discovery to only the six agreements at issue here would deprive them of the relevant knowledge of whether CDC (and PHS as a whole) have general policies that were not followed in this case. While the government stated in its supplemental interrogatory response that CDC and PHS "do not (and did not) track 'the government's obligations'" under these types of agreements, it still must designate a witness to testify whether that failure was proper under applicable policies, and whether the failure had a reasonable basis in law and fact. Pl.'s Reply, Ex. 1 at 15. In that same vein, where the government contends that it was the role of the principal investigators to track the obligations under CTAs, *see* Hr'g Tr. 17:23 to 18:24; 21:16 to 22:2, it again must produce a witness to testify to the CDC's procedures in that regard.

The court, however, will limit the scope of Topic 130 to MTAs and CTAs entered into by CDC between the relevant time of 2004 and 2014 when the agreements and amendments here were made. While this time period does encompass the years before the technology transfer office and the office of administrative services were merged, *see supra* n.8, Rule 30(b)(6) contemplates that "one or more" individuals may be designated to address the issues raised. *See* RCF 30(b)(6).

Topic 130 should now be read as:

> The policies, procedures, and persons involved in tracking the government's obligations under *material transfer agreements and clinical trial agreements* that *the CDC* entered into *between 2004 and 2014*.[10]

These limitations bring the topic within the confines of Rule 30(b)(6) as explicated by this court in *Ehren-Haus Indus., Inc. v. United States*, 150 Fed. Cl. 513 (2020), by limiting it to policies at issue during the relevant time of the contracts at issue.

CONCLUSION

For the reasons set forth above, the government's motion to compel is GRANTED IN PART AND DENIED IN PART. Fact discovery is reopened for this purpose until April 5, 2022,

[10] The government argues that the entire notice was made impermissible by Gilead's use of the language "including, but not limited to . . ." pursuant to *Reed v. Bennett*, 193 F.R.D. 689, 692 (D. Kan. 2000). Rather than strike the entire notice, the court has stricken the impermissible language consistent with a ruling by the District Court of the District of Columbia. *See Tri-State Hosp. Supply Corp. v. United States*, 226 F.R.D. 118, 125 (D. D.C. 2005) (striking "but not limited to" language from a Rule 30(b)(6) notice).

and the government is instructed to designate a witness or witnesses to respond to the modified Topic 130 by March 18, 2022.

It is so **ORDERED**.

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