IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE UNITED STATES OF AMERICA,	)	
	)	
Plaintiff/Counterclaim Defendant,	)	
	)	
v.	)	
	)	
GILEAD SCIENCES, INC.,	)	C.A. No. 19-2103 (MN)
	)	
Defendant/Counterclaim Plaintiff,	)	
	)	
and GILEAD SCIENCES IRELAND UC,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

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March 22, 2024
Wilmington, Delaware

NOREIKA, U.S. DISTRICT JUDGE:

The Court presided over a six-day jury trial from May 2, 2023 to May 9, 2023. (*See* D.I. 450 ¶ 2; *see also* D.I. 476, 477, 478, 479, 480 & 481 ("Tr.")). At the end of the trial, the jury returned a verdict in favor of Defendants Gilead Sciences, Inc. ("GSI") and Gilead Sciences Ireland UC ("GSIUC") (together, "Defendants" or "Gilead") and against Plaintiff the United States ("Plaintiff" or "the United States" or "the government"), finding that there was no direct infringement of the Asserted Claims of three patents owned by the United States, and that all Asserted Claims were invalid on the bases of anticipation and obviousness, and in the case of one asserted claim, also for lack of enablement. Presently before the Court is Plaintiff's renewed motion for judgment as a matter of law or, in the alternative, motion for a new trial (D.I. 487). For the reasons set forth below, the Court will GRANT-IN-PART and DENY-IN-PART Plaintiff's motions.

I. BACKGROUND

This case concerns U.S. Patent Nos. 9,579,333 ("the '333 Patent"), 9,937,191 ("the '191 Patent") and 10,335,423 ("the '423 Patent") (collectively, "the Patents-in-Suit"), all owned by the United States. The Patents-in-Suit relate to two-drug regimens, known as pre-exposure prophylaxis (PrEP), which effectively prevent new HIV infections. Plaintiff filed this action on November 6, 2019, asserting that Defendants induce infringement of claim 13 of the '333 Patent, claim 18 of the '191 Patent, and claim 18 of the '423 Patent (collectively, "the Asserted Claims")[1] by the manufacture, importation, marketing, distribution, labeling, offering for sale, and/or sale of Gilead's Truvada® and Descovy® products when used for PrEP. (*See* D.I. 433 ¶ 1).

[1] Other claims were dropped prior to trial. (*Compare* D.I. 441, *with* D.I. 433). In addition, prior to trial, the Court determined that another claim asserted by Plaintiff, claim 13 of U.S. Patent No. 9,044,509 ("the '509 Patent"), was invalid for improper dependency. (D.I. 450 ¶ 14).

From May 2, 2023 to May 9, 2023, the Court presided over a jury trial. (*See* D.I. 450 ¶ 2; *see also* D.I. 476, 477, 478, 479, 480 & 481). At the end, the jury found that the United States had not proven by a preponderance of the evidence that one or more patients or physicians, either separately or jointly, directly infringed any of the Asserted Claims by using Truvada® for PrEP or Descovy® for PrEP. (D.I. 468 at 2-3; D.I. 469 at 2-3). Because direct infringement is a necessary predicate of induced infringement, the jury did not reach the questions concerning whether either Gilead entity, GSI or GSIUC, had induced infringement with respect to either drug. (*Id.*). The jury further found that Defendants had proven by clear and convincing evidence that all Asserted Claims are invalid as anticipated and obvious, and in addition, that claim 18 of the '423 patent is invalid because it is not enabled. (*Id.* at 4).

On May 15, 2023, the Court entered judgment on the jury verdict under Rule 58(b) of the Federal Rules of Civil Procedure. (D.I. 471). On June 12, 2023, Plaintiff renewed its motion for judgment as a matter of law and included an alternative request for a new trial in that motion. (D.I. 487). Briefing on those motions is complete. (D.I. 489 & 490).

I. LEGAL STANDARDS

A. Judgment as a Matter of Law

Judgment as a matter of law may be entered against a non-moving party if the Court "finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on [an] issue." Fed. R. Civ. P. 50(a)(1). Judgment as a matter of law is appropriate "only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993) (citing *Wittekamp v. Gulf & W. Inc.*, 991 F.2d 1137, 1141 (3d Cir. 1993)). Entry of judgment as a matter of law is a

remedy to be invoked "sparingly." *CGB Occupational Therapy, Inc. v. RHA Health Servs. Inc.*, 357 F.3d 375, 383 (3d Cir. 2004).

Following a jury trial, a renewed motion for judgment as a matter of law under Rule 50(b) may be granted only if the movant demonstrates "that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) (alteration in original) (quoting *Perkin–Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984)). Substantial evidence is such relevant evidence that a reasonable mind might accept as adequate to support the finding under review. *See Enplas Display Device Corp. v. Seoul Semiconductor Co.*, 909 F.3d 398, 407 (Fed. Cir. 2018). In determining whether substantial evidence supports the jury verdict, the Court may not make credibility determinations, weigh the evidence, or substitute its own conclusions for those of the jury where the record evidence supports multiple inferences. *See Lightning Lube*, 4 F.3d at 1166. Moreover, in the Third Circuit, when the movant bears the burden of proof on an issue, judgment as a matter of law is appropriate only if "there is insufficient evidence for permitting any different finding." *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1177 (3d Cir. 1976) (citations omitted); *see also* 9 Wigmore on Evidence § 2495 at 306 (3d ed. 1940).

B. Motion for a New Trial

A new trial may be granted to all or any of the parties and on all or part of the issues in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States. Fed. R. Civ. P. 59(a). Common reasons for granting a new trial are: (1) the jury's verdict is against the clear weight of the evidence and a new trial is necessary to prevent a miscarriage of justice; (2) there exists newly

discovered evidence that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the Court unfairly influenced the verdict; or (4) the jury's verdict was facially inconsistent. *See Ateliers de la Haute-Garonne v. Broetje Automation-USA Inc.*, 85 F. Supp. 3d 768, 775 (D. Del. 2015).

Whether to grant a new trial is a question committed to the Court's discretion. *See Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36 (1980). Unlike the standard for judgment as a matter of law, the Court need not view the evidence in the light most favorable to the verdict winner when ruling on a motion for a new trial. *See Ateliers*, 85 F. Supp. 3d at 775. "Nevertheless, new trials because the verdict is against the weight of the evidence are proper only when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks [the] conscience." *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1353 (3d Cir. 1991).

II. DISCUSSION

In its motion for judgment as a matter of law or, in the alternative, motion for a new trial, Plaintiff argues that the Court should upset the jury's findings as to both direct infringement and invalidity. Alternatively, Plaintiff requests a new trial on two grounds, both concerning evidentiary rulings made by the Court pretrial. The Court addresses these issues largely in turn.

A. Plaintiff's Motion for Judgment as a Matter of Law

Plaintiff takes issue with the jury's findings on patent infringement and validity.[2] Concerning direct infringement, Plaintiff argues that it provided unrebutted evidence that at least

[2] At trial and in their post-trial briefing (apart from the question of enablement of claim 18 of the '423 Patent), the parties focused on claim 13 of the '333 Patent as representative or did not differentiate between the asserted claims of the Patents-in Suit. As no party disputes that claims 18 of the '191 and '423 Patents rise and fall with claim 13 of the '333 Patent (*see*, *e.g.*, Tr. 947:17-24), the Court proceeds similarly here.

one patient or physician infringed the Asserted Claims. Regarding invalidity, Plaintiff argues that Defendants failed to meet their burden to prove that the Asserted Claims were anticipated, obvious, and in the case of claim 18 of the '423 Patent, not enabled.

1. Plaintiff's Evidentiary Support for Direct Infringement

The United States relies on testimony from its expert witness on infringement, Dr. Robert Murphy. As relevant here, Dr. Murphy's testimony focused on his personal experience as a physician, including counseling patients and prescribing Truvada® or Descovy® for PrEP, and on his analysis of Risk Evaluation and Mitigation Strategy (REMS) surveys conducted by Gilead, pursuant to FDA request. (*See, e.g.*, Tr. 553:15-554:5, 556:20-557:13, 561:14-562:13, 575:4-587:15). Patent infringement is a question of fact, "reviewed for substantial evidence when tried to a jury." *ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1311 (Fed. Cir. 2007). A factual finding is supported by substantial evidence if a reasonable jury could have found in favor of the prevailing party in light of the evidence presented at trial. *See Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1357–58 (Fed. Cir. 1999).

a. Dr. Murphy's Personal Experience

The Asserted Claims each include five steps: (1) the preamble, (2) the "selecting" step, (3) the "administering" step, (4) the "thereby" step; and (5) the "wherein" step. (*See* Tr. 567:1-7). Dr. Murphy provided unrebutted evidence of direct infringement based on his personal experience prescribing PrEP and counseling PrEP patients. He testified that he has counseled "many hundreds" of patients on using PrEP and written "dozens" of PrEP prescriptions (Tr. 553:19-554:5) and that PrEP patents and/or physicians practice each step of the Asserted Claims when they follow the Truvada® or Descovy® for PrEP insert instructions. (Tr. 562:3-5, 567:1–590:22).

First, patients using Truvada® or Descovy® for PrEP are periodically tested to confirm they remain HIV negative while receiving the drugs, which confirms that "establishment" of a "self-replicating infection" has been inhibited, as required by the preamble. (Tr. 572:22–574:23; Tr. 578:7–14 (Truvada®); Tr. 600:13–18, 604:2–9 (Descovy®)). Second, the "selecting" step is met where the patient is confirmed as being HIV-negative before beginning PrEP. (Tr. 578:15–579:13 (Truvada®); Tr. 600:13–18, 604:10–23 (Descovy®)). Third, by taking a daily tablet of Truvada® or Descovy®, the "administrating" step of the Asserted Claims is met because the patient is taking a "pharmaceutically effective amount" of the claimed two-drug combination. (Tr. 580:15–581:19 (Truvada®); Tr. 605:14–606:18 (Descovy®)). Fourth, the "thereby" step requires, according to the Court's construction, for the patient to remain "negative for the immunodeficiency virus [e.g., HIV]" while being administered Truvada® or Descovy® for PrEP. (Tr. 583:2–4). The respective inserts both instruct that patients be HIV tested every three months, and patients actually are tested to confirm they remain HIV negative, which infringes the "thereby" step. (Tr. 583:5–22 (Truvada®); Tr. 606:19–607:17 (Descovy®)).

The "wherein" step requires administering the drug combination prior to a potential exposure to HIV, which the Court construed to mean "prior to engaging in activity that could result in an exposure" to HIV. (D.I. 186 at 13). According to Dr. Murphy, his patients did not follow the safe sex practices outlined in the Truvada® and Descovy® inserts, even though he counseled "every one of them" on such practices. (Tr. 590:6–15). Thus, PrEP patients, including his own, were at "high risk" for HIV infection and subject to potential exposures to HIV, as set forth in the Asserted Claims. (*See* Tr. 615:13–616:1, *see also* Tr. 642:6–19 (asserting that "less than one percent" of his patients were not potentially exposed)). For these reasons, Dr. Murphy and his PrEP patients directly infringe the "wherein" step in accordance with the insert instructions

designating PrEP for "high risk" patients and the Court's claim construction. (Tr. 590:16–22; Tr. 583:3–587:4 (Truvada®); Tr. 607:18–609:15, 611:7–25 (Descovy®)).

In response, Gilead focuses on induced, not direct, infringement. Gilead relies on testimony that physicians and patients who follow the instructions on the Truvada® and Descovy® inserts do not infringe because they are not exposed to HIV, by virtue of abiding by the recommended safe sex practices included on the inserts. Although Dr. Murphy acknowledged that patients who strictly follow the safe sex practices in the PrEP labels do not infringe, (Tr. 642:3-11; *see also* D.I. 489 at 19), he noted that based on his own experience, such patients are hypothetical, because "almost none" practice safe sex in reality. (Tr. 590:6-15, 643:2-17). Dr. Charles Flexner, Gilead's expert, confirmed that PrEP patients do not always adhere to safe sex practices, such as correct and consistent condom use. (Tr. 1020:25-1021:7; *see also* D.I. 460 at 3). The evidence may suggest that administration to some patients does not infringe. But that does not undermine the uncontradicted evidence presented that administration to some patients does infringe.

b. Gilead's REMS Survey Data

In addition to his personal experience, Dr. Murphy testified about Gilead's REMS data. The REMS surveys were periodically submitted "assessments" designed to evaluate if "there was compliance" with the label's instructions for safe and effective PrEP usage.[3] (Tr. 458:13-22). Plaintiff argues that Gilead's REMS data demonstrates infringement of all of the Asserted Claims.

[3] The FDA required that Gilead conduct this survey when it applied to for a PrEP designation for Truvada®. (*See* Tr. 455:9-456:6). Although REMS surveys were conducted solely on the use of Truvada for PrEP®, Government witnesses testified that Truvada® data was applicable to the testing rates and behavior of Descovy® for PrEP patients because it involved the "same patient group" or "pool" and the "same clinician group" or "pool." (Tr. 601:17–21, 610:8–14.).

(D.I. 487 at 8). Gilead argues that the jury was entitled to disregard the REMS survey data because of when the surveys were conducted in relation to when the patents were issued and because the surveys presented aggregated data. The Court agrees.

As previously stated, in evaluating a motion for judgment as a matter of law, the Court must view the evidence in the light most favorable to the nonmovant and give it the advantage of every fair and reasonable inference. *Lightning Lube*, 4 F.3d at 1166. Here, Gilead contested that the REMS surveys were evidence of infringement based on the fact that most of the REMS surveys occurred before the date that the earliest asserted patent issued. (D.I. 489 at 20; Tr. 1000:16-20, 1001:8-1003:12, 1012:13-18). Additionally, Gilead's expert, Dr. Flexner, testified that the REMS survey data relied on by the Government fails to show potential exposure to HIV and thus does not include all claim limitations. (*See* Tr. 1000:22-1001:3; D.I. 489 at 22). The jury was entitled to evaluate and believe either or both of these arguments.

c. JMOL Must Be Granted as to Direct Infringement

Because Plaintiff had the burden of proof on the issue of direct infringement, judgment as a matter of law is appropriate only if "there is insufficient evidence for permitting any different finding." *Fireman's Fund Ins. Co.*, 540 F.2d at 1177 (citations omitted). Here, Plaintiff has satisfied that standard in part. Although the Court is not convinced that Plaintiff's reliance on the contested REMS surveys merits relief, Dr. Murphy's essentially unrebutted testimony as to his personal experience does. There is insufficient evidence to support the jury's finding of no direct infringement, and the Court will grant judgment as a matter of law on this issue.

2. Induced Infringement

Under 35 U.S.C. § 271(b), "whoever actively induces infringement of a patent shall be liable as an infringer." Liability for inducing infringement requires "that the alleged infringer's

actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006) (en banc) (citing *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 554 (Fed. Cir. 1990)). Inducing infringement thus necessitates "actual intent to cause the acts which constitute the infringement." *Hewlett–Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990). Further, "[t]he requirement that the alleged infringer knew or should have known his actions would induce actual infringement necessarily includes the requirement that he or she knew of the patent." *DSU Med. Corp.*, 471 F.3d at 1304. Intent can be proven by either direct or circumstantial evidence. *See Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986).

Because the jury determined that there was no direct infringement, it did not reach the questions concerning whether Gilead induced infringement. Gilead urges that even if the Court were to conclude that the Government is entitled to JMOL of direct infringement, a new trial is not warranted, but instead, the Court should grant JMOL of no induced infringement in favor of Gilead. (D.I. 489 at 23). The Court agrees up to a point; a new trial is not warranted at this juncture, because as described below, the Court will not upset the jury's findings as to invalidity. It will not, however, go further and enter JMOL of no induced infringement for Gilead.

3. Invalidity

Defendants argued that the Asserted Claims are invalid as anticipated, obvious, and in the case of claim 18 of the '423 Patent, not enabled. Specifically, Defendants argued that the Asserted Claims were anticipated by prior public knowledge, relying on three sources: (1) Dr. Robert Grant, (2) Dr. Marcus Conant, and (3) Dr. John Kaldor. Defendants also argued that the Asserted Claims were obvious based on three combinations of references: (1) Tsai 1995 (JTX-12) and the August

2004 Truvada® Label (JTX-10), (2) the 2004 California PEP Guidelines (JTX-11) and the August 2004 Truvada® Label (JTX-10) or (3) all three references together. Lastly, Defendants argued that claim 18 of the '423 Patent was not enabled because a skilled artisan would be unable to practice the claim's full scope without undue experimentation. The jury agreed that the claims are anticipated, obvious, and in the case of claim 18 of the '423 Patent, not enabled. (*See* D.I. 468 at 4; D.I. 469 at 4). The Court finds that substantial evidence supports the jury's verdict on each of the three theories of invalidity.

a. Anticipation

A claimed invention is anticipated when it "was known to or used by others in this country before the date of the patentee's invention." *UCB, Inc. v. Watson Lab'ys Inc.*, 927 F.3d 1272, 1289 (Fed. Cir. 2019) (citation and quotation marks omitted). "A patent is invalid for anticipation under 35 U.S.C. § 102 if a single prior art reference discloses each and every limitation of the claimed invention." *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1351 (Fed. Cir. 2016). A prior art reference demonstrating prior knowledge or use "must have been available to the public." *Woodland Tr. v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998). "[D]issemination and public accessibility are the keys to the legal determination whether a prior art reference was published," as is statutorily required. *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989) (internal quotation mark and citation omitted). "Anticipation is a factual question, and a jury verdict regarding anticipation is reviewed after trial for substantial evidence." *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1343 (Fed. Cir. 2003). Gilead argues that the Asserted Claims were anticipated by prior public knowledge in 2004 and 2005 for at least three reasons: (1) Dr. Robert Grant proposed a robust clinical trial of Truvada® for PrEP, expected that Truvada® would work effectively, and told many colleagues of his planned study; (2) Dr. Marcus

Conant knew that Truvada® could prevent HIV infection and prescribed it to three of his patients for PrEP; and (3) Dr. John Kaldor approached Gilead to propose using Truvada® for PrEP in a human trial.

i. Dr. Robert Grant

Gilead argues that the jury was entitled to find that Dr. Grant knew of the claimed invention (using Truvada® for PrEP) by at least August 2004, before the earliest alleged invention date (February 3, 2006),[4] and that he communicated that idea to others without restriction. The Government contends that the documents Gilead relies on, a concept sheet (JTX62) and draft protocol (JTX64) to study the use of Truvada® for PrEP, fail to disclose the "thereby" step recited by the claims and were not public, and thus cannot support a finding of anticipation.

Regarding whether these documents were public, the Government focuses on the fact that every page of the documents was marked "confidential" and that the cover page of the protocol included a note that it was "intended only to focus discussions of protocol development among interested parties." (JTX64 at 64.001). The jury, however, heard substantial evidence that the information was not in fact confidential. For example, Dr. Grant testified that he intended his concept sheet to be sent to others, albeit "a very limited audience" (Tr. 407:6-15), and that he sent the document to Gilead, (Tr. 411:16-412:21; *see also* DTX-182 at 1). In addition, Dr. Grant "talked over the idea of adding a [T]ruvada arm" to the clinical trial he was conducting, with Dr. Mary Fanning, who was a project officer at the NIH at the time and later, the NIH's associate director of clinical research, "who seemed to be very enthusiastic about the idea." (DTX-182 at 1; *see also* Tr. 412:14-413:19). Dr. Grant also shared his draft protocol with "three people at

[4] Viewing the evidence most favorably to Gilead, *see Lightning Lube*, 4 F.3d at 1166, the earliest date of invention is February 3, 2006, which is the filing date of the provisional application for the '509 Patent.

Gilead" (Tr. 421:13-422:4) and discussed using Truvada® for PrEP with the Gates Foundation to secure more funding (DTX-155 at 2).

The jury also heard from other witnesses who confirmed public knowledge of Truvada® for PrEP before the invention date. Dr. Fanning testified that Dr. Ward Cates and Family Health International knew that Dr. Grant wanted to give Truvada® for PrEP to humans by March 2005 because "Bob Grant would talk to everybody." (Tr. 890:10-20). Dr. Page, Dr. Grant's co-investigator on the Peru PrEP trial, recounted many conversations in 2004 in which she and Dr. Grant discussed Truvada® for PrEP. (Tr. 901:12-903:19, 913:14-915:14, 921:1-922:2). She confirmed that by late 2004, Truvada® for PrEP was not a secret. (Tr. 923:2-5). Similarly, Dr. Thomas Coates, co-director of the HIV Prevention Trials Network, testified that "Truvada for PrEP was being discussed" as soon as the FDA approved Truvada® for HIV treatment in August 2004, and that the use of Truvada® for PrEP was "a common topic of discussion" within this group's "entire network of scientists." (Tr. 927:11-928:15). Dr. Coates also recalled discussing Truvada® for PrEP with NIH and CDC personnel in 2004. (Tr. 929:7-930:14). Dr. Grant and his team had discussed adding Truvada® to PrEP trials with Dr. Coates as well as Dr. Cates and Dr. Kenneth Mayer by January 12, 2005, all of whom were "interested in [adding] a Truvada arm for their prevention studies." (DTX-155 at 2; *see* Tr. 913:14-915:8). The jury heard and evaluated the competing evidence and was free to decide that Dr. Grant's knowledge was public despite the "confidential" marking on the concept sheet and protocol. The Court will not reweigh that evidence.

Similarly, the Government's contention that the documents do not disclose the "thereby" step of the Asserted Claims fails. The jury heard testimony that Dr. Grant was prepared "to enroll 2,700 humans in [his] proposed study" of Truvada® for PrEP (Tr. 410:2-5). Dr. Page confirmed

the research team's confidence in Truvada® for PrEP, testifying that she had a "very high expectation" that it would work because "[t]here was a good body of literature to support" that it would and because it was known that "two drugs were better than one." (Tr. 916:10-15). The jury was entitled to find that this testimony in combination with the documents shows that Dr. Grant's and others' prior knowledge met all claim limitations, including the "thereby" step.

ii. Dr. Marcus Conant and Dr. John Kaldor

Having already determined that the jury's anticipation verdict is supported by substantial evidence, the Court will only briefly touch on the alternative grounds for support put forth by Gilead. First, Gilead argues that the jury's anticipation verdict is reinforced by Dr. Conant's prescriptions to at least three patients who used Truvada® for PrEP before the invention date. The Government does not dispute that the jury could have found Dr. Conant credible, but instead argues a lack of corroboration for his testimony. Whether testimony is sufficiently corroborated is a question of fact. *TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1302 (Fed. Cir. 2016). There are no hard and fast rules as to what constitutes sufficient corroboration, and each case must be decided on its own facts. The law has "repeatedly rejected an element-wise attack on corroboration" by not requiring that every claim limitation be included in each piece of corroborating evidence or "that every detail of the testimony be independently and conclusively supported." *Id.* at 1301-02 (citations omitted); (*see also* D.I. 450 ¶ 12).

Here, the jury saw contemporaneous evidence corroborating Dr. Conant's account, including articles from 2006 quoting Dr. Conant as having prescribed Truvada® for PrEP to three of his patients, a practice that he testified he began right after Truvada® was approved in 2004. (*See* DTX-509 at 2; DTX-510 at 2; Tr. 793:22-796:11). The Government introduced other articles quoting Dr. Conant as prescribing tenofovir or Viread® for PrEP to many patients (*see* DTX-126;

PTX-213), which Dr. Conant testified that he did until the FDA approved Truvada®, at which point he switched to the "better combination of drugs," namely Truvada®. (Tr. 790:23-792:2). The jury also heard specific details about Dr. Conant's patient, Nick, whom Dr. Conant prescribed Truvada® for PrEP, not PEP, which he confirmed while testifying. (Tr. 800:17-803:5). Although it may be that there were a few inconsistencies within Dr. Conant's testimony and between it and the documentary evidence Gilead presented, the Court finds that the jury could have reasonably concluded that Dr. Conant's testimony was sufficiently corroborated in order to support its finding of anticipation.

As to prior public knowledge of Dr. Kaldor, Dr. Flexner testified that Dr. Kaldor knew of Truvada® for PrEP and wanted to use it in a study in 2005. (Tr. 975:3-12, 991:20-992:9). He further testified that Dr. Kaldor approached Gilead in the United States asking for Truvada® for use in a human trial he was proposing. (*Id.*). The Government did not cross-examine Dr. Flexner on this testimony, nor did it object to the jury instruction on Dr. Kaldor. (*See* D.I. 464 at 20).

The Court finds that each of these sources of prior public knowledge and use provides substantial evidence of anticipation supporting the jury's verdict.

b. Obviousness

Turning now to obviousness, Plaintiff maintains that Gilead has not proven that the Asserted Claims are obvious. Although obviousness is ultimately a question of law, it is based on underlying factual findings. *See Game & Tech. Co. v. Activision Blizzard Inc.*, 926 F.3d 1370, 1379 (Fed. Cir. 2019). "What a reference teaches and whether a person of ordinary skill in the art would have been motivated to combine the teachings of separate references are questions of fact." *Pregis Corp. v. Kappos*, 700 F.3d 1348, 1353 (Fed. Cir. 2012). "Where, as here, the jury made no explicit factual findings regarding obviousness, [the Court] must determine whether the implicit

findings necessary to support the verdict are supported by substantial evidence." *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1294 (Fed. Cir. 2009) (citing *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1310 (Fed. Cir. 2000)). Specifically, a jury's "verdict of obviousness must be supported by facts of (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) any objective indicia such as commercial success or long-felt need." *Id*.

Defendant offered three combinations of references to show that the Asserted Claims were obvious to a person of ordinary skill in the art. Having found that the jury's verdict of invalidity based on anticipation is supported by multiple grounds, the Court addresses just one ground of obviousness here and finds that substantial evidence supports the jury's verdict.

i. Tsai 1995, the August 2004 Truvada Label, and CA PEP Guidelines

Dr. Flexner testified that Tsai 1995, the August 2004 Truvada® Label, and the CA PEP Guidelines, when considered in combination, taught each step of the Asserted Claims. (Tr. 987:6-17). According to Dr. Flexner, both Tsai 1995 and CA PEP teach: (1) the preamble (Tr. 978:20-979:1, 984:6-9), (2) the "selecting" step (Tr. 979:2-8, 984:9-12), (3) half (in the case of Tsai) or all (in the case of CA PEP) of the "administering" step (Tr. 979:9-14, 984:12-20), and (4) the "thereby" step (Tr. 979:15-980:1, 984:21-25). Dr. Flexner further testified that Tsai teaches (5) the "wherein" step (Tr. 980:2-13). The 2004 Truvada® Label, in combination with Tsai and CA PEP, also teaches the "administering" step. (Tr. 981:5-9, 985:6-11).

The focus of the Government's argument is that none of the references teach the "thereby step." According to the Government, Tsai does not teach the "thereby" step because it refers only to the inhibition of a self-replicating infection in *monkeys*, not in humans, as required by the Court's construction of this step. The jury however, heard testimony that both Tsai 1995 and CA

PEP taught the "thereby" step and could properly rely on such testimony. Dr. Flexner testified that because "Tsai was presenting this monkey model as a model for human infection with HIV," the steps Tsai teaches, including the "thereby" step, are applicable to humans. (Tr. 980:14-981:2). He further noted that "[t]here are some things that we can ethically do in monkeys, that we cannot ethically do in humans," specifically including "conduct[ing] experiments where we challenge humans with HIV." (Tr. 980:18-21). Further, several witnesses confirmed the significance of Tsai's disclosure that tenofovir provided complete protection from HIV infection. (Tr. 796:20-797:8 (Dr. Conant), Tr. 955:14-956:21 (Dr. Flexner), Tr. 1088:4-1089:17 (Dr. Johnson); *see also* Tr. 733:5-734:1 (Mr. Alton), Tr. 870:2-871:2 (Dr. Dieffenbach), Tr. 201:15-203:19 (Dr. Folks), Tr. 419:3-420:1 (Dr. Grant), Tr. 295:9-296:17 (Dr. Heneine)).

The Government also argues that Tsai does not disclose the "administering" step because only one drug was used in the study, not the two required by the claim language. The jury heard testimony however, that in combination, Tsai 1995 and the 2004 Truvada® Label, teach administration of both emtricitabine and tenofovir. (Tr. 981:3-14). In addition, a named inventor and Government witness, Dr. Walid Heneine, acknowledged that Tsai 1995 taught that tenofovir could be combined with another compound to prevent HIV. (Tr. 298:24-299:18). Gilead's expert, Dr. Flexner, further testified that a physician or clinician would have been highly motivated to combine Tsai with the "safety, efficacy, tolerability, and the favorable resistance profile" of tenofovir and emtricitabine in an oral combination, as taught by the 2004 Truvada® Label. (Tr. 981:3-982:7).

Regarding the "wherein" step, neither CA PEP nor the 2004 Truvada® Label describe administration "prior to exposure." Gilead acknowledges this and argues, based on Dr. Flexner's testimony, that the efficacy of Truvada®, as explained by the 2004 Truvada® Label, combined

with CA PEP would provide a person of ordinary skill in the art with "all the teaching necessary" to administer the drug combination for prevention, prior to a potential exposure. (Tr. 985:1-15). Indeed, the jury heard that there "are plenty of other examples in infectious diseases of using an anti-infective drug that is known to treat an infectious disease if given before the disease occurs, to prevent that same infection." (Tr. 952:2-954:6). Dr. Lynn Paxton explained that PrEP "ma[de] sense," and was a "logical extension from PEP," and that doctors "had been doing postexposure prophylaxis for HIV for many years." (Tr. 892:24-894:17). Other witnesses agreed that efficacy for PEP showed efficacy for PrEP. (*See, e.g.*, Tr. 416:25-418:16 (Grant agreeing with a statement he wrote in 2004 that "evidence supporting the efficacy of prophylaxis with and [sic] antiretroviral and decreasing HIV conversion derives primarily from the experience with post-exposure prophylaxis"), Tr. 879:19-881:15 (Smith stating that "if you can . . . stop [HIV infection] after exposure, then you should be able to stop it before exposure.")). Moreover, Tsai teaches this step because "15 of the 25 animals in the Tsai 1995 experiment received Tenofovir four hours before exposure to the immunodeficiency retrovirus." (Tr. 980:2-13).

The jury also heard testimony that motivation to combine existed for the combination of Tsai and the 2004 Truvada Label, CA PEP Guidelines and the 2004 Truvada® Label, and all three references together. Dr. Flexner testified that:

> for people who wanted to prevent this infection in individuals at risk, the only tool we had in our tool box at that time was a drug or a drug combination. And knowing what was known then in August 2004 about the efficacy of Tenofovir in animal models, and the availability of an effective, safe, well tolerated once a day oral drug combination, in this case, Truvada, I think a person of skill in the art would have seen that as the best tool we had to prevent HIV in humans.

(Tr. 981:22-982:7 (further testifying that Truvada was an "obvious tool")). Dr. Flexner also testified that the CA PEP Guidelines recommended the use of Truvada® for HIV prevention in

humans in the PEP setting, and that Truvada® was known to be safe, effective, tolerable, and convenient for patients in the treatment context. (Tr. 985:16-986:2). Finally, Dr. Flexner testified that a skilled artisan "would have had motivation to put [all three references] together." (Tr. 987:6-17). The jury also heard testimony that a person of ordinary skill in the art would have had a reasonable expectation of success based on these combinations of references. (Tr. 982:12-983:3, 986:3-16; *see also* Tr. 953:11-954:6 & 881:7-15 (Doctors knew of "plenty of other examples" of using treatment drugs to prevent infection, and that PrEP should work just like PEP)).

Based on the combination of the three references discussed above and relatedly, the motivation to combine, the jury reasonably could have found that Defendants met their burden to prove invalidity due to obviousness by clear and convincing evidence. Thus, the verdict as to obviousness will remain undisturbed.

ii. Secondary Considerations

The United States devotes little space in its briefing to address secondary considerations, relying on its argument that the prior art references do not contain all elements of the Asserted Claims, and they therefore do not establish a *prima facie* case of obviousness. (D.I. 490 at 13). Because the Court finds that the jury's verdict as to obviousness was supported by substantial evidence, it must consider secondary considerations, or objective indicia of nonobviousness, before reaching an obviousness determination, as a "check against hindsight bias." *See In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litig.*, 676 F.3d 1063, 1078-79 (Fed. Cir. 2012). It addresses those here.

The jury was entitled to credit Gilead's expert (Dr. Flexner) over the Government's (Dr. Grant) in finding that secondary considerations do not overcome the obviousness of the Asserted Claims. Beginning with unexpected superior results, Dr. Flexner explained that the

closest prior art included Tsai 1995, which showed 100% protection, while the Government's monkey study using Truvada® showed only 50% (or, according to the Government, 66.6%) efficacy. (Tr. 987:23-988:20, 1312:19-1313:22).

Dr. Flexner also clarified that the iPrEx study showed only a 44% efficacy rate at preventing HIV infection. (Tr. 1314:24-1315:14). Contrary to Dr. Grant's claim of "an abundance of skepticism" about PrEP (Tr. 1230:2-1231:13), Dr. Flexner testified that skepticism in the field was not about efficacy, but about whether people would take it properly or would engage in more risky behavior (Tr. 1315:15-22, 1319:8-1320:2, 990:14-991:8; *see also* Tr. 768:1-769:4 & 475:8-25 (testimony from Mr. Alton and Dr. Birnkrant discussing Gilead's concerns that Truvada® for PrEP would encourage disinhibition or improper use)). In addition, doctors, including Dr. Grant, published articles in 2005 encouraging the use of PrEP, providing evidence that it worked as expected. (*See, e.g.*, Tr. 1315:23-1319:7; DTX-246 (article by Dr. Grant and 17 others); DTX-247 (article by Dr. Coates)).

Similarly, the jury could have attributed the commercial success of Truvada® and Descovy® for PrEP to factors described by Dr. Flexner, such as the products' excellent safety, efficacy, and tolerability, or advertising (Tr. 1321:14-1322:20) and rejected Dr. Grant's assertion that Gilead's profits show the invention's novelty (Tr. 1232:11-24). Likewise, the jury could have credited Dr. Flexner's testimony that any alleged copying was of "ideas that were already out there before the government even initiated its experiments with monkeys." (Tr. 1320:17-1321:3). The jury was free to conclude that the monkey study built on information known in publications like Tsai 1995, the 2004 Truvada® Label, and CA PEP, among others. Finally, the jury could have found that any long-felt need for prevention was not met by the claimed invention, but by others, including Dr. Grant, who proposed studying Truvada® for PrEP in 2004, and Dr. Conant, who

was already prescribing it to his patients. (Tr. 991:9-19). As Dr. Flexner recounted, the contemporaneous invention of the use of Truvada® for PrEP by Dr. Grant, Dr. Conant, and Dr. Kaldor confirms the claims' obviousness. (Tr. 991:20-992:9); *see Regents of the Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1295 (Fed. Cir. 2018) ("Simultaneous invention may serve as evidence of obviousness when considered in light of all of the circumstances."). For these reasons, the jury's obviousness verdict is amply supported and reflects factual determinations within the province of the jury.

c. Enablement

The jury found that claim 18 of the '423 Patent was not enabled. A patent is enabled when its specification describes the claimed invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use the invention." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 612 (2023) (quoting 35 U.S.C. § 112(a)). To satisfy section 112 of the Patent Act, the specification must enable a person of ordinary skill in the art to make and use the claimed invention. 35 U.S.C. § 112(a); *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 690 (Fed. Cir. 2001). A patent need not "describe with particularity how to make and use every single embodiment within a claimed class." *Amgen*, 598 U.S. at 610–11. Rather, "a specification may call for a reasonable amount of experimentation to make and use a patented invention." *Id.* at 612. To establish a lack of enablement, "a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation.'" *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014) (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)).

Plaintiff argues that claim 18 of the '423 Patent is enabled and that the jury's finding otherwise is unreasonable. In support, it characterizes Dr. Flexner's testimony on enablement as

"conclusory" and lacking in evidentiary support. (D.I. 487 at 28-29). To the contrary, Dr. Flexner testified that the specification did not enable a skilled artisan to carry out the claimed PrEP method using all "tenofovir prodrugs" because that term applies to a "family of chemicals," which would include "thousands or tens of thousands of possible prodrug candidates." (Tr. 994:19-995:3). In addition, he addressed the eight *Wands* factors and discussed why each factor supports a finding that claim 18 is not enabled. (Tr. 995:4-998:5; *see also* DDX-3.33 (Dr. Flexner's demonstrative slides)); *In re Wands*, 858 F.2d at 736-37. He described the claim's scope as "incredibly broad" due to its recitation of "tenofovir prodrugs," and that "an enormous amount of experimentation" would be required to determine which tenofovir prodrugs would work in the claimed method. (Tr. 995:15-24, 997:19-22). He also testified that the '423 Patent provides "essentially no guidance or direction" on how to make that determination, and only one working example. (Tr. 995:25-996:15). As to the nature of the invention, Dr. Flexner noted that the claim involved a "process for inhibiting a life-threatening infection." (Tr. 996:16-20). He also testified that the state of the prior art, the relative skill in the art, and the predictability of the art supported finding non-enablement. (Tr. 996:21-997:18). Notably, the Government did not cross-examine Dr. Flexner about enablement at all.

In addition, the Government's expert, Dr. Darren Thakker, acknowledged that different tenofovir prodrugs have different biological properties and toxicity, and that a skilled artisan would need to do experiments to test whether a compound would work as a tenofovir prodrug. (Tr. 1183:12-22). Dr. Thakker also admitted that he had not calculated how many compounds might work as tenofovir prodrugs (Tr. 1184:16-1185:22 ("It could be 10, 20, or it could be more.")). He agreed that the '423 Patent provides only a single working example of a tenofovir prodrug (TDF), and that the patent fails to discuss which categories of tenofovir prodrugs might

be effective for the claimed method or why. (Tr. 1185:23-1186:8). Dr. Thakker also conceded that when he formed his enablement opinions, he was unaware that the CDC scientists performed more experiments in 2016 to determine whether TAF (a tenofovir prodrug) and FTC would work for PrEP – the combination in Descovy® that the Government now asserts claim 18 covers. (Tr. 1190:2-1195:13); *cf. Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1375 (Fed. Cir. 2017) (finding that post-priority-date evidence of potentially undue experimentation was relevant to determining enablement).

To the extent Dr. Thakker's opinions on enablement conflicted with Dr. Flexner's, the jury was entitled to credit Dr. Flexner. *See, e.g.*, *Smith v. Garlock Equip. Co.*, 658 F. App'x 1017, 1027 (Fed. Cir. 2016) (explaining that a "battle of the experts" requires "the fact finder [to] weigh the merits of competing expert testimony"). Thus, the Government has not shown entitlement to JMOL on the issue of enablement of claim 18 of the '423 Patent.

B. Plaintiff's Request in the Alternative for a New Trial

Plaintiff requests a new trial based on this Court's rulings on certain evidence, specifically relating to the exclusion of *Inter Partes Review* (IPR) petitions and the limited admission of the parties' Material Transfer Agreements (MTAs).[5] The parties briefed these issues in their motions *in limine* and argued them at the pretrial conference. (*See* D.I. 434, Exs. 9P.1 & 9D.1; D.I. 447 at 52:5-58:6 & 64:18-65:15). The Court excluded the IPR non-institution proceedings, finding that the minimal relevance of that evidence would be far outweighed by the risk of confusing and prejudicing the jury. (D.I. 447 at 65:11-15). Regarding the MTAs, the Court found that they were relevant to Gilead's noninfringement defenses, specifically whether they had knowledge of

[5] The Court's ruling limited the evidence Defendants could introduce regarding the MTAs to the extent that it related to their argument that they did not have knowledge of infringement. The Court also permitted Plaintiff to raise objections at trial.

infringement, and permitted their admission for that limited purpose. (*Id.* at 57:20-58:6; *see also* D.I. 450 at 3 n.5). Plaintiff argues that the Court erred in both rulings. The Court addresses these arguments below.

1. Exclusion of IPR Petitions

Before trial, Defendants moved to exclude evidence of related agency invalidity proceedings, including the PTAB's IPR non-institution decisions for the asserted patents and the EPO's opposition to a foreign counterpart of the asserted patents. (D.I. 434, Ex. 9D.1 at 1). Defendants argued that admitting such evidence would confuse the jury, have minimal probative value, result in trial delay, and overall, be unfairly prejudicial. (*Id.* at 1-3). The Court granted Defendants' motion, finding that "the minimal relevance of the evidence . . . is far outweighed by the risk of confusing and prejudicing the jury."[6] (D.I. 447 at 65:12-15). Plaintiff now contends that the jury verdict goes against the weight of the evidence and in addition, that Gilead "repeatedly made misleading and confusing statements that left the jury with the incorrect impression that the use of Truvada for PEP, and PEP guidelines, specifically, were never considered by the Patent Office in evaluating the nonobviousness of the asserted claims."[7] (D.I. 487 at 25).

In support of its contention that the jury verdict is against the weight of the evidence, in addition to arguing that the prior art does not render obvious the "thereby" step, Plaintiff argues

[6] IPR institution is a specialized agency determination that does not provide "the benefit of a full adversarial proceeding," because it is based "on a record that [is] less than complete." *ART+COM Innovationpool GmbH v. Google Inc.*, C.A. No. 14-217-TBD, 2016 WL 11531119, at *2 (D. Del. May 16, 2016). Thus, Rule 403 "strongly favors exclusion" because a non-institution "is not a final decision on validity, is based on different legal standards, and has no estoppel effect." *Andover Healthcare, Inc. v. 3M Co.*, C.A. No. 13-843-LPS, 2016 WL 6404111, at *2 (D. Del. Oct. 27, 2016).

[7] Plaintiff moves in the alternative on this ground, seeking judgment as a matter of law on the jury's obviousness verdict.

that because Gilead itself was not interested in pursuing PrEP during the relevant timeframe, 2004-2006, the jury verdict rests on a contradiction. In other words, because Gilead – "one of the major HIV research companies during the relevant timeframe" – did not pursue Truvada® for PrEP, no person of skill in the art would have pursued Truvada® for PrEP. (*See id.*). The Court does not find this argument compelling. As Gilead points out, it is a company. As such, it has concerns that may be different than those of a person of skill in the art, and not confined to skepticism that Truvada® for PrEP would work. Those concerns included that people would not take the drug as instructed (*e.g.*, skip doses) or that it would encourage disinhibition. (*See* Tr. 747:8-748:14 (Mr. Alton discussing Gilead's concern that Truvada® for PrEP would encourage disinhibition), Tr. 768:1-769:4 (Mr. Alton discussing Gilead's concern that patients would take the drugs "episodically"), Tr. 475:8-25 (Dr. Birnkrant admitting that Gilead did not pursue indication in part because it was concerned about encouraging disinhibition), Tr. 1319:8-1320:2 (Dr. Flexner explaining that Gilead's hesitation to pursue a PrEP indication was unrelated to efficacy)).

Plaintiff also argues that Gilead misled the jury to believe that PEP guidelines were never considered by the Patent Office in evaluating the nonobviousness of the Asserted Claims. (D.I. 487 at 25). Plaintiff further complains that due to the Court's pretrial ruling, it was unable to cross-examine Dr. Flexner on the guidelines presented before the PTO and those relied on by Gilead at trial, which the Government contends are materially similar. (*Id.* at 26).

Gilead emphasizes that its statements and those of its witnesses concerned the patent examiner not the Office. Thus, Gilead argues that it did not improperly open the door to the IPR proceedings and further that the Government forfeited its argument by failing to seek reconsideration of the *in limine* ruling at trial. (D.I. 489 at 27-28). In reply, Plaintiff argues that it was not required to reraise its objection at trial because the Court granted Defendants' motion *in*

limine. (D.I. 490 at 15 (citing *Walden v. Georgia-Pacific Corp.*, 126 F.3d 506, 519 (3rd Cir. 1997))). The Court agrees to the extent that the Government's objection would be the same as it was prior to trial. To the extent that the objection is based on a change of circumstance, such as in response to evidence or testimony elicited by Defendants during trial, the Government should have sought reconsideration of the Court's *in limine* ruling.[8] Ultimately, because the Court does not find that Gilead mislead or confused the jury to such an extent as to justify a new trial, that the Government never reraised its objection is of little matter.

2. Admission of MTAs

Ahead of trial, Plaintiff moved *in limine* to exclude evidence, testimony, and argument regarding the MTAs, as well as other agreements.[9] Plaintiff argued that allowing such evidence would be highly prejudicial and had no probative value. (D.I. 434, Ex. 9P.1 at 1-3). The Court denied Plaintiff's motion in part, finding that such evidence was relevant to "questions with respect to inducement," D.I. 447 at 57, which includes both knowledge of infringement and intent to induce. Now, Plaintiff reiterates its earlier argument. Although Plaintiff construes it broadly, stating that "the Court denied the Government's motion to preclude Gilead from offering arguments and testimony about breach of contract issues," the brunt of its argument is that

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8 *See, e.g.*, 2 Michael H. Graham, Handbook of Federal Evidence § 103:8 (9th ed. 2022) ("If the relevant facts and circumstances change materially after the advance ruling has been made, those facts and circumstances cannot be relied upon on appeal unless they have been brought to the attention of the trial court by way of a renewed, and timely, objection, offer of proof, or motion to strike.").

9 By way of background, between 2004 and 2008, Gilead and the CDC executed several MTAs, pursuant to which Gilead provided the CDC with FTC, tenofovir, and tenofovir disoproxil fumarate (TDF), a tenofovir prodrug. Under the terms of the MTAs, CDC was to "promptly disclose to [Gilead] all results, data, and other information or materials derived from" any materials and confidential information provided by Gilead, as well as to "promptly notify [Gilead] of any Inventions." (D.I. 1 ¶¶ 122–23).

discussion of the notice provision in the MTAs confused the jury, specifically regarding the issue of whether Defendants had actual knowledge of the patents. Plaintiff further contends that by allowing Gilead to argue that the United States failed to promptly notify Gilead, per the MTAs, the Court in effect permitted Gilead to indicate that Plaintiff had behaved unethically and unfairly, which accordingly, was highly prejudicial. (D.I. 487 at 30). In response, Gilead argues that the Court's pretrial ruling was correct and that its introduction of evidence of and testimony about the MTAs and related argument was proper. (D.I. 480 at 29).

Gilead also points out that Plaintiff failed to raise any objections to the admission of the now-complained-of evidence, testimony, or argument at trial. Plaintiff argues in reply that it did not need to reraise its objections because the Court limited the issues to be revisited in its Order After Pretrial Conference, D.I. 450. In that Order, the Court clarified that "Defendants may introduce evidence related to the material transfer agreements at trial to the extent that it relates to their argument that they did not have knowledge of infringement," but "may not introduce the evidence to argue their unenforceability defenses before the jury." (D.I. 450 at 3 n.5). Prior to the issuance of this order, during the pretrial conference, the Court told Plaintiff that it could raise objections related to the MTAs during the trial. (D.I. 447 at 58 ("[I]f there is an objection that [the Court] need[s] to deal with in a particular context in realtime, you can raise that at the trial."); *see also id.* at 57-58 ("[W]hen we're in the middle of trial . . . if you have an objection [to the MTAs], you can make the objection.")). The government forfeited any argument that Gilead strayed beyond the permissible use of the MTAs by failing to object at trial.

Plaintiff references a discussion the Court had with the parties outside the presence of the jury as indicative of the Court's "concern for juror confusion based on Gilead's presentation of MTA issues." (D.I. 487 at 30 (citing Tr. 536:25–544:23)). That much is true – the Court did press

the parties, particularly Gilead, on the relevance of the notice provision of the MTAs. In fact, at that time, Plaintiff objected to an exhibit proffered by Gilead, which resulted in a discussion of how the issue of notice was being presented to the jury and the related risk of confusing the jury, and the Court sustained the objection. (Tr. 534:18-541:18).

Plaintiff also argues that Gilead elicited the MTA evidence and testimony improperly, "permeat[ing] the record with irrelevant, misleading, and confusing allegations about breach of contract". (D.I. 487 at 30 (citing examples without explanation, none of which it raised in its motion *in limine* nor objected to at trial)). Gilead maintains that it introduced the MTAs at trial for the purposes of providing direct evidence of its intent to protect itself from infringement liability and of its justified, good-faith belief that selling its products in fact did not infringe any government patents.[10] (*See, e.g.*, Tr. 849:7-12 (Dr. Rooney testifying that Gilead believed its actions did not induce infringement because it "trusted" that "the CDC would adhere to its obligations to promptly notify Gilead of any inventions" relating to the MTAs)). In addition, Gilead argues that the MTAs were relevant to other issues, including why Dr. Conant did not have specific patient records that would further corroborate his testimony, the credibility of government witnesses like Dr. Heneine, and damages (*i.e.*, to show how Gilead's situation was unique from other licensees). (Tr. 289:25-290:14, 674:2-681:15, 697:7-699:19, 792:8-793:5). Plaintiff does not contest the propriety of these other uses. In fact, following cross-examination, the United States questioned one of its witnesses, Dr. Heneine, regarding notice, specifically whether he felt like he had given notice to Gilead through the competing interest section of an article he co-authored. (Tr. 349:12-350:2; 379:6-13). Plaintiff was able to address issues of notice with their

[10] *See Roche Diags. Corp. v. Meso Scale Diags.*, 30 F.4th 1109, 1118-19 (Fed. Cir. 2022). (holding a good-faith belief in freedom to operate defeats inducement liability, even where that belief is based on erroneous interpretation of an agreement).

witnesses and was not unfairly prejudiced. And the Court does not find that the admission of evidence and testimony and related argument regarding the MTAs justifies a new trial.

The Court has already found that substantial evidence supports the jury's verdict on invalidity. For the same reasons, the Court concludes that the jury's verdict was not against the weight of the evidence, even without viewing the evidence most favorably to Defendants. That is, Plaintiff has failed to show that "a miscarriage of justice would result if the verdict were to stand," that the verdict "cries out to be overturned" or that the verdict "shocks [the] conscience." *Williamson*, 926 F.2d at 1352-53.

3. Conditional Ruling on a New Trial Under Rule 50(c)(1)

Rule 50(c)(1) provides that, "[i]f the court grants a renewed motion for judgment as a matter of law, it must also conditionally rule on any motion for a new trial by determining whether a new trial should be granted if the judgment is later vacated or reversed." Fed. R. Civ. P. 50(c)(1). Should the Federal Circuit later reverse or vacate the grant of judgment as a matter of law on direct infringement, there would be no need for a new trial as the Federal Circuit would, in essence, be upholding a finding of no infringement. Similarly, if the Federal Circuit should later reverse as to all grounds of invalidity but not this Court's grant of judgment as a matter of law on direct infringement, this Court believes that a new trial on the issue of induced infringement is warranted.

III. CONCLUSION

For the foregoing reasons, Defendants' renewed motion for judgment as a matter of law or, in the alternative, a new trial (D.I. 487) is GRANTED-IN-PART and DENIED-IN-PART. An appropriate Order will follow.