IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS, U.S.A., INC., Plaintiff; v. WEST-WARD PHARMACEUTICAL CORPORATION, HIKMA AMERICAS INC., and HIKMA PHARMACEUTICALS PLC, Defendants.	Civil Action No. 14-1268-RGA-SRF

MEMORANDUM OPINION

Mary W. Bourke and Daniel M. Attaway, WOMBLE BOND DICKINSON (US) LLP, Wilmington, DE; Jeffrey I. Weinberger, Ted G. Dane, Heather E. Takahashi, Elizabeth L. Laughton (argued), and Hannah L. Dubina, MUNGER, TOLLES & OLSON LLP, Los Angeles, CA; Celia R. Choy, MUNGER, TOLLES & OLSON LLP, Washington, DC; Peter A. Detre, MUNGER, TOLLES & OLSON LLP, San Francisco, CA, attorneys for Plaintiff.

Dominick T. Gattuso, HEYMAN ENERIO GATTUSO & HIRZEL LLP, Wilmington, DE; Charles B. Klein (argued) & Ilan Wurman, WINSTON & STRAWN LLP, Washington, DC, attorneys for Defendant.

December 12, 2018

ANDREWS, U.S. DISTRICT JUDGE:

Currently pending before the Court is Defendants West-Ward Pharmaceutical, Hikma Americas, and Hikma Pharmaceuticals' Motion for Summary Judgment. (D.I. 347). The Parties have fully briefed the issues. (D.I. 349; D.I. 361; D.I. 368). The Court held oral argument on October 16, 2018. (D.I. 410). For the following reasons, Defendants' motion for summary judgment is GRANTED.

I. Background

Plaintiff Takeda Pharmaceuticals manufactures and markets Colcrys, a branded 0.6 mg colchicine tablet used for the treatment of gout prophylaxis and acute gout flares. (D.I. 362, Ex. 4). In 2010, Plaintiff's predecessor became the sole provider of colchicine on the pharmaceutical market, after receiving FDA authorization and the FDA removing all other colchicine products. (D.I. 362 Ex. 1 ¶¶ 32-38). Plaintiff's predecessor also owned several patents directed to a method of treating acute gout flares with colchicine by administering 1.2 mg oral colchicine at the onset of an acute flare, followed by 0.6 mg oral colchicine one hour later ("the Acute Gout Flare Patents"). (D.I. 133 ¶ 30); U.S. Patent No. 7,964,647 cl. 1; U.S. Patent No. 7,981,938 cl. 1; U.S. Patent No. 8,415,395 cl. 1.

Hikma Pharmaceuticals received FDA approval of a paper New Drug Application ("paper NDA") for Mitigare on September 26, 2014. (D.I. 349 at 6-7). Mitigare is a 0.6 mg colchicine capsule indicated solely for the prophylaxis of gout. (D.I. 362, Ex. 5). Shortly thereafter, on October 3, 2014, Plaintiff filed suit against Defendants West-Ward Pharamaceutical, Hikma Americas, and Hikma Pharmaceuticals ("Defendants"). (D.I. 1). After the Federal Circuit affirmed the denial of a preliminary injunction on January 9, 2015, *Takeda Pharm., U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015), Defendants

launched Mitigare and its authorized generic (Mitigare AG). (D.I. 349 at 7). Plaintiff also launched its competing authorized generic of Colcrys (Colcrys AG). (*Id.*).

The Court later dismissed the suit for failure to state a claim on May 18, 2016. (D.I. 122). The Court then granted Plaintiff's Motion to Alter Judgment of Dismissal and for Leave to Amend its Complaint on December 15, 2016 (D.I. 124; D.I. 132) and implemented phased discovery. (D.I. 150).

Plaintiff's Second Amended Complaint alleges Defendants induced infringement of the Acute Gout Flare Patents through post-launch marketing efforts for Mitigare. (D.I. 133). The Complaint asserted two different sets of patents: the Drug-Drug Interaction patents[1] and the Acute Gout Flare Patents. (D.I. 133 ¶ 28). Defendants filed a motion for summary judgment on May 4, 2018. (D.I. 347). After this filing, Plaintiff voluntarily dismissed its infringement claims under the Drug-Drug Interaction patents. (D.I. 376). Thus, only the Acute Gout Flare Patents remain at issue for the purposes of summary judgment.

The parties do not dispute that Defendants (1) negotiated both exclusive and non-exclusive contracts with insurance payers (D.I. 349 at 17), (2) hired InVentiv Health as a pharmaceutical marketing force focused on encouraging prescribers to prescribe Mitigare or Mitigare AG (D.I. 361 at 9), (3) created promotional materials which direct readers to the American College of Rheumatology Guidelines for the treatment of gout (D.I. 133-14, Ex. N at 6 and 8 n.6), and (4) provided samples of Mitigare directly to prescribers. (D.I. 361 at 15). Mitigare's label also includes language that directs patients to consult their physician if they experience an acute gout flare. (D.I. 133, Ex. K). Defendants' exclusive contracts contain either

[1] The Drug-Drug Interaction patents are directed to a method of treating patients by reducing the dose of colchicine when prescribed with certain other medication. (D.I. 133 ¶¶ 27, 29; D.I. 133, Exs. D, F, G, H, J).

a "block" or a "step edit." (D.I. 362, Ex. 13-15). A "block" is where Defendants have agreed to provide a manufacturer rebate to the insurance payer to cover only Mitigare/Mitigare AG and to exclude Colcrys/Colcrys AG from the payer's formulary. (D.I. 410 at 34:14-19). A formulary determines how much of the prescription cost will be the patient's responsibility. A "step edit" is where the insurance payer agrees to require that a patient has tried Mitigare or Mitigare AG and failed before the insurance payer will cover a prescription for Colcrys or Colcrys AG. (D.I. 361 at 10; D.I. 410 at 37:17-23).

Plaintiff alleges that Defendants' post-launch marketing activities have induced infringement of the Acute Gout Flare Patents. (D.I. 133). Defendants now seek summary judgment on the induced infringement claims. (D.I. 347).

II. Legal Standard

A. Summary Judgment

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." Fed. R. Civ. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247–49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

B. Induced Infringement

35 U.S.C. § 271(b) provides, "Whoever actively induces infringement of a patent shall be liable as an infringer." "To prove inducement, the patentee must show direct infringement and that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91 (2011). The plaintiff "must [] prove that the defendants' actions led to direct infringement." *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263,

1274 (Fed. Cir. 2004); *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 313 F. Supp. 3d 582, 591 (D. Del. 2018) ("Without proof of causation, . . . a finding of inducement cannot stand."). Both causation and intent may be shown through circumstantial evidence. *See Sanofi v. Watson Labs, Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017) ("[I]nducement law permits the required factual inferences about intended effects to rest on circumstantial evidence . . . ."); *GlaxoSmithKline*, 313 F. Supp. 3d at 595 n.13 (recognizing that plaintiff may prove causation with circumstantial evidence).

Inducement requires a defendant to take "active steps" to induce a third party to infringe. These active steps can be "as broad as the range of actions by which one in fact causes, or urges, or encourages, or aids another to infringe a patent." *Tegal Corp. v. Tokyo Electron Co.*, 248 F.3d 1376, 1378-79 (Fed. Cir. 2001). However, inducement "requires successful communication between the alleged inducer and the third-party direct infringer." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1331 (Fed. Cir. 2016). If the active step intended to induce infringement is never communicated to the third-party direct infringer, then the active step has not caused infringement and inducement has not occurred. *Id.* at 1330-31. Moreover, "[the] sale of a lawful product by lawful means, with the knowledge that an unaffiliated, third party may infringe, cannot, in and of itself, constitute inducement of infringement." *Takeda Pharm., U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015) (quoting *Dynacore*, 363 F.3d at 1276 n.6).

III. DISCUSSION

Defendants assert that summary judgment should be granted because (1) there is no support for Plaintiff's allegations that Defendants' marketing materials and insurance contracts induced infringement, and (2) there is no evidence of any identified direct infringement tied to

the allegation that a Mitigare sales representative encouraged infringement. (D.I. 349 at 14). Plaintiff responds that evidence in the record gives rise to a genuine issue for trial on the following allegations: (1) Defendants' promotional materials, labeling of Mitigare, and sampling activities evidence Defendants' intent to induce infringement; (2) Defendants induced infringement by negotiating exclusive agreements with payers; and (3) Defendants induced infringement by engaging in off-label promotion. (D.I. 361 at 19-24).

A. Promotional Activities

Plaintiff alleges that Mitigare's labeling, promotional materials, and samples show that Defendants intended to induce infringement. (D.I. 361 at 23-24). The Court disagrees. First, the Federal Circuit has already determined that the Mitigare and Mitigare AG label language directing patients to consult their doctor if they suffer an acute gout flare does not induce infringement. *Takeda*, 785 F.3d at 632-33.

Second, Defendants' promotional materials do not create an inference that Defendants intended to induce infringement. Defendants' promotional materials reference recommendations from the American College of Rheumatology Guidelines ("the Guidelines"). The Guidelines contain directions for both the non-patented method of treating gout prophylaxis with colchicine and the patented method of treating acute gout flares with colchicine. (D.I. 362, Ex. 3). Defendants' promotional materials generally reference the specific sections of the Guidelines related to Mitigare's indicated non-patented use—the treatment of gout prophylaxis. (D.I. 363, Ex. 64 at 3 n.6; D.I. 363, Ex. 65 at 3 n.2 (both referencing only the pages of the Guidelines focused on prophylaxis)). The most favorable reference to Plaintiff is where the Mitigare "Sell Sheet" directs the reader to the Guidelines in general, rather than to a specific section. (D.I. 133-14, Ex. N at 6, 8 n.6). However, the content of the "Sell Sheet" solely refers to Mitigare's use

for gout prophylaxis. (D.I. 133-14, Ex. N). Intent to induce cannot be inferred from a citation to instructions for the product's legitimate use solely because the Guidelines also contain instructions for the patented method. *Takeda Pharm.*, 785 F.3d at 631 ("Merely describing an infringing mode is not the same as recommending, encouraging, or promoting an infringing use or suggesting that an infringing use should be performed.") (internal quotations omitted).

Finally, intent to induce cannot be inferred from Defendants' sampling activities. Plaintiff points to a few statements from physicians consulted in third-party market research as evidence of Defendants' intent to induce infringement through providing samples. (D.I. 361 at 15 (quoting Ex. 50 at 22 ("Physicians mostly want samples of Mitigare . . . so that patients experiencing gout-related pain 'can walk out of the office with something'") and Ex. 50 at 23 ("if you have samples, you can give them to patients right away to help them with acute attack"))). However, these statements support only the inference that Defendants knew that some doctors would provide samples of Mitigare to their patients for an infringing use. Other quotations of physicians were provided in this research which indicated that samples would likely be used for gout prophylaxis. (D.I. 361 Ex. 50 at 22-23). Furthermore, "[i]t is well established that 'mere knowledge of possible infringement by others does not amount to inducement.'" (D.I. 121 at 18 (quoting *Warner-Lambert*, 316 F.3d at 1364)). Defendants' distribution of samples of a product with a substantial non-infringing use is not any different from the lawful sale of that same product. *Cf.* 21 C.F.R. § 203 (regulating pharmaceutical sales in subpart C and the distribution of pharmaceutical samples in Subpart D). The mere knowledge that the third-party recipient may engage in infringing use upon receipt of the product therefore cannot create an inference of intent to induce. Plaintiff has not pointed to any evidence that would allow an inference that Defendants intended to induce infringement.

B. Exclusive Payer Contracts

Plaintiff asserts that Defendants induced infringement by (1) offering insurance payers substantial financial incentives in the forms of rebates to enter exclusive agreements for Mitigare/Mitigare AG with (2) the intention to drive a complete conversion from Colcrys/Colcrys AG to Mitigare/Mitigare AG (3) without regard to the indicated use of prescriptions. (D.I. 361 at 19-21). Plaintiff alleges that a complete conversion of the market from Colcrys/Colcyrs AG to Mitigare/Mitigare AG through the "blocks" and "step edits" included in these contracts would *necessarily* cause infringement of the Acute Gout Flare Patents. (*Id.* at 20). Plaintiff further asserts that Defendants' sales force communicated these exclusive contracts to prescribers "to encourage them to convert to Mitigare." (*Id.* at 13).

In rebuttal, Defendants assert that negotiation of exclusive payer contracts alone cannot support a jury finding of induced infringement. (D.I. 349 at 17). Defendants argue that the insurance contracts "represent lawful sales activities . . . [they are] entitled to undertake to promote sales of [Mitigare/Mitigare AG] for its admittedly substantial non-infringing use." (*Id.*). Additionally, Defendants note that the exclusive contracts were negotiated with insurance payers, not with prescribing doctors or patients who are alleged to have infringed the patents. (D.I. 368 at 6). In Defendants' view, the negotiation of exclusive payer contracts with the knowledge that doctors or patients may infringe due to the contract, cannot in and of itself constitute inducement of infringement.

As the Federal Circuit has repeatedly recognized, the Congressional policy behind authorizing ANDA and paper NDAs was to avoid foreclosing the possibility of marketing a generic drug for a non-patented use. *Takeda*, 785 F.3d at 631 ("[T]he statute was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label

infringing uses."); *see also Caraco Pharm. Labs, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 415 (2012) ("The statutory scheme . . . contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones."); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1360 (Fed. Cir. 2003). Therefore, the mere sale of a drug with the knowledge that a third-party may use it in an infringing manner cannot support inducement where the drug has a substantial non-infringing use. *Dynacore*, 363 F.3d at 1275. The relevant questions are then: (1) is the negotiation of an exclusive contract with insurance payers comparable to a "lawful sale," (2) is there sufficient evidence to support an inference that Defendants intended to induce infringement by negotiating these contracts, and (3) is there sufficient evidence to support an inference that the insurance contracts actually induced doctors to prescribe Mitigare or Mitigare AG for the treatment of Acute Gout Flares.

First, I find it clear that negotiating an exclusive contract with an insurance payer is comparable to a lawful sale of the product. As both Plaintiff and Defendants noted at oral argument, this case is unique because it deals with a BX rated generic being introduced into the market versus an AB rated generic. (D.I. 410 at 13:19; 35:1-7; 42:18-19). AB rated generics benefit from automatic substitution by pharmacies and prescribers without significant marketing efforts. (D.I. 339 at 5, 8-9). In contrast, a BX rated generic must engage in significant marketing efforts to direct prescribers and patients to their product for its non-infringing uses. (*Id.*). Plaintiff has not pointed to any evidence that Defendants, in negotiating these contracts, represented to payers that Mitigare/Mitigare AG was indicated for, or should be used to treat, acute gout flares. In fact, when certain payers resisted an exclusive contract based on concerns about acute gout flare treatment, Defendants proposed "1 of 2" contracts (allowing Colcrys on the formulary) as an alternative to the exclusive contract. (D.I. 362, Ex. 24 at 2).

Second, Plaintiff has not provided sufficient evidence to create a reasonable inference that Defendants intended to induce infringement. Plaintiff contends that Defendants knew that negotiating an exclusive contract would "necessarily" result in infringing behavior, such that intent to induce the infringing behavior can be inferred. (D.I. 361 at 20). Plaintiff points to *Power Integrations* for support that the contract negotiation was "an affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement." 843 F.3d at 1332. However, in *Power Integrations*, the patent at issue was for an infringing product, not an infringing method. *Id.* at 1321. Moreover, the product had no noninfringing use within the United States. *Id.* at 1334. Therefore, competing for any business in the United States induced infringement. *Id.* Here, that is not the case. Defendants' Mitigare has a substantial noninfringing use—gout prophylaxis. Therefore, efforts to encourage the sale of Mitigare cannot be converted into an attempt to induce infringing behavior without more evidence.

Plaintiff's strongest argument is that the contracts containing "step edits" necessarily result in infringing acts. However, Plaintiff has provided no evidence that would allow a jury to reasonably conclude that an exclusive contract would "necessarily" result in infringing behavior. Plaintiff has not provided any evidence that doctors consider insurance information such as "blocks" or "step edits" in determining whether to prescribe a drug or a particular dosage form (i.e., capsules vs. tablets) of a drug. With "step edits," Plaintiff asserts Defendants "incentivized . . . a benefit design whereby . . . a patient must actually use Mitigare before that patient can receive Colcrys." (D.I. 361 at 20). This is inaccurate. Under a "step edit," a patient must only use Mitigare to receive insurance coverage (and a lower price) for Colcrys. A doctor may still prescribe, and a patient may still use, Colcrys even where the insurance payer uses a step edit. Moreover, Plaintiff's theory of inducement argues that the lack of coverage (and therefore the

increased price of Colcrys) will induce doctors and pharmacies alike to convert Colcrys/Colcrys AG prescriptions for acute gout flares to Mitigare/Mitigare AG. However, this is analytically the same as the introduction of a cheaper generic labelled only for non-patented uses onto the market. In that case, the higher price of the branded drug drives conversion to the cheaper generic for both non-patented use and infringing use. This is not sufficient to conclude that infringing conduct will "necessarily" result. *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012).

As with lawful sales of a product with substantial non-infringing use, the knowledge that an exclusive payer contract may result in infringing use cannot support an inference of intent to induce by itself. This result would violate the congressional policy intending to permit the sale and marketing of generic drugs for substantial non-infringing uses. There must be some additional evidence of intent beyond the contracts themselves. *See Dynacore*, 363 F.3d at 1275. Therefore, Plaintiff must identify some evidence other than Defendants' knowledge that the contracts will result in infringing conduct to support an inference that Defendants intended to induce prescribers to write infringing prescriptions. The evidence that manufacturer's offer rebates to steer patients to their drug is not sufficient to draw an inference of intent to induce infringement. (D.I. 362, Ex. 66 at 131:15-135:4). Nor are the "blocks" or "step edits" contained within the contracts. When any company enters any generic into the market, they intend to steer patients to use their product over competing products of other companies. Mitigare/Mitigare AG has a substantial noninfringing use—gout prophylaxis[2]—and Defendants are entitled to market it for that use. The lack of exceptions within the contracts for acute gout flares also do not give rise to an inference of intent. As Defendants correctly note, induced infringement requires

[2] The majority use of colchicine is for prophylaxis. (D.I. 410 at 9:1-3).

evidence of active steps to induce. Intent to induce may not be inferred from the failure to avoid infringing results. Section 271(b) does not require that Defendants actively protect Plaintiff's patents from third-party direct infringement. Inferring intent to induce from a failure to prevent infringing results does indeed "turn[] the legal test on its head." *Takeda*, 785 F.3d at 632 n.4. Plaintiff has provided no evidence other than speculation of Defendants' intent. This cannot support a finding of inducement.

Third, even if there was sufficient evidence to create a genuine issue of Defendants' intent to induce for trial, there is no evidence that the contracts have actually induced infringement. Plaintiff points to (1) Defendants' expert's statement that exclusive contracts are used to "steer" doctors and patients to a certain drug (D.I. 362, Ex. 66 at 131:15-135:4), (2) the "blocks" and "step edits" that the exclusive contracts contain and (3) Mitigare prescriptions written under exclusive contract plans that "specify [Plaintiff's] patented regimen." (D.I. 361 at 20). However, Plaintiff has not provided any evidence that doctors consider insurance information such as "blocks" or "step edits" in determining whether to prescribe a drug or a particular dosage form (i.e. capsules vs. tablets) of a drug. Plaintiff has not demonstrated that the number of infringing Mitigare prescriptions written under exclusive contract plans is significantly higher than those written under non-exclusive contract plans. Nor has Plaintiff pointed to any evidence that a single doctor prescribed Mitigare instead of Colcrys because of an exclusive payer contract, a block, or a step edit. There is no circumstantial evidence in the record to support an inference of causation. Causation cannot be inferred through mere speculation. The evidence does not create a genuine issue of whether the exclusive contracts induce infringement.

C. Off-Label Promotion

Plaintiff asserts that Defendants induced infringement by engaging in off-label promotion. (D.I. 361 at 21-23). Plaintiff has identified a single doctor, Dr. Elmahdi Saeed, who it alleges was induced to write infringing prescriptions by a Mitigare sales representative. (D.I. 361 at 14). Dr. Saeed stated in his deposition that a Mitigare sales representative told him that Mitigare was indicated for and could be used to treat acute gout flares. (D.I. 363, Ex. 45 at 29:22-30:3, 31:7-10). Dr. Saeed also stated that the representative encouraged him to write Mitigare prescriptions for the treatment of acute gout flares. (*Id.* at 70:5-10). While the sales representative disputes this testimony, the Court will, as it must, take Dr. Saeed's statements as true for the purposes of this motion. Dr. Saeed stated that he prescribed Mitigare off-label for acute gout flares about 4-6 times because of the sales representative's statements. (*Id.* at 65:18-25). However, the parties have not discovered any record of a Mitigare prescription written by Dr. Saeed for the treatment of acute gout flares. (D.I. 410 at 22:14-18).

Defendants argue that there are no facts in the record that identify a single instance of direct infringement that can be tied to Dr. Saaed's statements that a Mitigare sales representative encouraged him to write off-label prescriptions, thereby inducing infringement. (D.I. 349 at 19). Plaintiff alleges that it is entitled to a "reasonable inference that pharmacies filled the prescriptions that Dr. Saeed wrote . . . and that his patients took Mitigare according to his instructions—[Plaintiff's] patented method." (D.I. 361 at 22). Defendants respond that Plaintiff "offers only 'a theoretical possibility' that patients who were given the four to six Mitigare prescriptions written by Dr. Saeed actually filled those prescriptions and administered the pills" using the infringing method. (D.I. 368 at 13). Defendants assert that this speculation cannot create a genuine issue of material fact as to whether direct infringement occurred. (*Id.*).

The Court agrees. First, to show direct infringement of the asserted patents, Plaintiff must show that a patient actually used Mitigare or Mitigare AG according to the infringing method. Second, for induced infringement to have occurred, there must be evidence tying a patient's use of the infringing method to the inducing statements made to Dr. Saeed. Here, taking Dr. Saeed's testimony in the light most favorable to Plaintiff, there is nevertheless insufficient evidence for a reasonable jury to return a verdict for Plaintiff. There is no direct testimony by any patient of Dr. Saeed's that they practiced the patented method nor is there direct evidence that a patient of Dr. Saeed filled a prescription written for the infringing method. Further, due to the small number of infringing prescriptions written by Dr. Saeed and the failure to locate a single one in pharmacy records, it is not reasonable to infer that at least one of them was filled by a pharmacy and taken by a patient in the infringing manner. This would require that a patient (1) actually filled the prescription, (2) actually had a gout flare, and (3) actually took the prescribed Mitigare according to the very particular method of treatment. Given the lack of any evidence beyond Dr. Saeed's statements, there is insufficient evidence to infer that at least one of Dr. Saeed's patients used Mitigare/Mitigare AG in an infringing manner due to the statements of the sales representative. (D.I. 349 at 21-22). Thus, a reasonable jury could not return a verdict for Plaintiff. Summary judgment is proper.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion for Summary Judgment is GRANTED. An accompanying order will be entered.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS, U.S.A., INC.,

Plaintiff,

v.

WEST-WARD PHARMACEUTICAL CORPORATION, HIKMA AMERICAS INC., and HIKMA PHARMACEUTICALS PLC,

Defendants.

Civil Action No. 14-1268-RGA-SRF

ORDER

For the reasons set forth in the accompanying opinion, **IT IS HEREBY ORDERED** that Defendants' Motion for Summary Judgment (D.I. 347) is **GRANTED.**

Entered this 12 day of December, 2018.

Richard G. Andrews
United States District Judge