IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. MYLAN PHARMACEUTICALS, INC., Defendant.	Civil Action No. 19-2216-RGA

MEMORANDUM ORDER

Currently before the Court is Plaintiff Takeda Pharmaceuticals U.S.A., Inc.'s Motion for a Preliminary Injunction to prohibit Defendant Mylan Pharmaceuticals Inc. from launching a generic version of the drug Colcrys. (D.I. 12). The matter has been fully briefed. (D.I. 13, D.I. 91, D.I. 101). I heard oral argument on January 21, 2020. Because Plaintiff has failed to show it is likely to succeed on the merits or that it will suffer irreparable harm, the Motion is DENIED.

I. BACKGROUND

Colcrys, a branded version of the drug colchicine, is approved by the Food and Drug Administration (FDA) to treat and prevent gout flares and familial Mediterranean fever. (D.I. 15, Ex. 2). Takeda has seventeen patents listed for Colcrys in the FDA's "Orange Book." (D.I. 15, Ex. 4). In 2016, Mylan filed an Abbreviated New Drug Application (ANDA) with the FDA, seeking approval of a generic colchicine product. (D.I. 92, Meckstroth Decl., ¶ 6). Based on that filing, Takeda sued Mylan for infringement of its seventeen Colcrys patents. *Takeda*

Pharmaceuticals U.S.A., Inc.v. Mylan Pharmaceuticals Inc., No. 16-cv-987-RGA. The parties settled their lawsuit on November 7, 2017.

As part of that settlement, the parties signed a License Agreement, which allows Mylan to sell a generic colchicine product, but only after a specified date. (D.I. 15, Ex. 1, "Agreement.") Section 1.2 provides several situations, however, in which Mylan can launch its generic product before that date. Section 1.2(d) states that Mylan is entitled to launch a generic at:

> The date that is [a specified time period] after the date of a Final Court Decision (as defined in Exhibit A) holding that all unexpired claims of the Licensed Patents that were asserted and adjudicated against a Third Party are either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable;

(*Id.*). Exhibit A defines a "Final Court Decision" as "the entry by a federal court of a final judgment from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken." (*Id.*). The "Licensed Patents" include the seventeen Colcrys Orange Book patents Takeda had asserted against Mylan. (*Id.*). A "Third Party" is a "Person other than a Party or an Affiliate of a Party." (*Id.*).

According to Mylan, Section 1.2(d) was triggered by my decision in a separate case, *Takeda Pharm., U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-cv-1268-RGA. In that litigation, Takeda asserted eight of its Colcrys patents against West-Ward, but, during summary judgment briefing, it indicated it was "willing" to dismiss five of them (No. 14-cv-1268-RGA, D.I. 361 at 1 n.2), which it did "with prejudice" a few weeks later. (*Id.*, D.I. 376). I granted summary judgment of non-infringement on the remaining three patents. 2018 WL 6521922 (D. Del. Dec. 12, 2018). There was no appeal.

On October 28, 2019, Mylan notified Takeda that it planned to "immediately start selling" a generic colchicine product "pursuant to the Parties' November 7, 2017 license

agreement (Section 1.2(d))." (D.I. 15, Ex. 11). Takeda sued Mylan on December 2, 2019 for patent infringement and breach of contract. (D.I. 2). Takeda filed this Motion for a Preliminary Injunction three days later, seeking to enjoin Mylan and anyone acting on Mylan's behalf from: "(1) commercially manufacturing, using, offering to sell, or selling within the United States its generic version of Takeda's oral single-active-ingredient colchicine brand drug Colcrys® (the 'Mylan ANDA Product'); (2) entering into and/or continuing discussions with current customers and potential customers regarding the availability of the Mylan ANDA Product; and (3) distributing or shipping the Mylan ANDA Product to customers." (D.I. 12). The parties agreed to a stipulation about further sales and distribution of the "Mylan ANDA Product" pending these proceedings. (D.I. 7 at 2).

II. LEGAL STANDARD

"A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). "A preliminary injunction is an extraordinary remedy never awarded as of right." *Id.* at 24.

III. DISCUSSION

Mylan has failed to show it is likely to succeed on the merits. The critical issue here is whether Section 1.2(d) of the License Agreement permits Mylan to launch its generic colchicine product. The provision applies to a "Final Court Decision," which is defined as "a final judgment from which no appeal . . . has been or can be taken." In *West-Ward*, I granted summary judgment

for the defendant, and Takeda did not appeal within 30 days. That decision is therefore a final judgment, from which appeal is no longer possible. Fed. R. Civ. P. 4(a)(1)(A). It is undisputed that my summary judgment decision in *West-Ward* was a "Final Court Decision." It is also undisputed that Mylan has satisfied the provision's waiting period.

Section 1.2(d) applies if the "Final Court Decision" found the patents were "either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable." In *West-Ward,* I granted summary judgment because a reasonable jury could not have found that the defendant had induced infringement of the three Colcrys patents at issue. *West-Ward*, 2018 WL 6521922, at *6. Therefore, for purposes of Section 1.2(d), my *West-Ward* ruling was a "Final Court Decision" holding that those three patents were "not infringed." Takeda does not dispute this conclusion. (*See* D.I. 13 at 11-12).

Takeda argues nevertheless that the *West-Ward* decision did not trigger Section 1.2(d) because I only ruled on the three patents that were still at issue, and not on the other five that Takeda had dismissed with prejudice. (*Id.*). For Section 1.2(d) to apply, a court must find that "all unexpired claims of the Licensed Patents that were asserted and adjudicated against a Third Party are" not infringed or invalid. According to Takeda, only three patents were "adjudicated," while a total of eight were "asserted." (D.I. 13 at 11.). Therefore, Takeda reasons, the summary judgment decision did not cover "all" unexpired claims of the Licensed Patents at issue. (*Id.*)

I do not think this is a correct reading of the Agreement. Section 1.2(d) applies to patent claims that were "asserted *and* adjudicated," not to patent claims that were "asserted *or* adjudicated." In *West-Ward*, claims from eight patents were "asserted," but claims from only three patents were "asserted and adjudicated." Thus, only those three patents matter for purposes

of Section 1.2(d). Of the three patents that were "asserted and adjudicated" in *West-Ward*, "all" of their unexpired claims were found not infringed. That decision thus triggered Section 1.2(d), which "entitle[s]" Mylan to launch a generic version of Colcrys. I conclude therefore that Takeda has not shown it is likely to succeed on the merits of its patent infringement or breach of contract claims.

Takeda argues that this reading of the Agreement conflicts with the intent of the parties. (D.I. 13 at 12-13). According to Takeda, the purpose of Section 1.2(d) was to ensure Mylan could enter the market if there was some change to the status quo that allowed the launch of other generic Colcrys products. (*Id.* at 12). Takeda asserts that Mitigare, the drug in dispute in *West-Ward*, is not a generic version of Colcrys, and therefore the parties did not envision that a judgment involving Mitigare could trigger Section 1.2(d). (*Id.*). Mylan notes that Mitigare, like Colcrys, is a 0.6 mg colchicine product. (D.I. 91 at 13). While it is undisputed that Mitigare is not a generic version of Colcrys, it does not follow that the language of the contract, as understood by an objective, reasonable third party, requires that Section 1.2(d) is limited to litigation over the possible introduction of generic Colcrys products. *See Exelon Generation Acquisitions, LLC v. Deere & Co.*, 176 A.3d 1262, 1267 (Del. 2017) ("[B]ecause Delaware adheres to an objective theory of contracts, the contract's construction should be that which would be understood by an objective, reasonable third party."). Section 1.2(d) makes no mention of generic Colcrys products. By contrast, Sections 1.2(b) and 1.2(f) refer to the sale of a "Generic Equivalent" of Colcrys, and Section 1.2(e) refers to the sale of "Authorized Generic Products" of Colcrys. The parties therefore clearly knew how to condition provisions of the contract on the launch of generic Colcrys products, but they chose not to condition Section 1.2(d) in such a way.

West-Ward is a "Third Party" for purposes of Section 1.2(d). The Agreement defines a "Third Party" as a "Person other than a Party or an Affiliate of a Party," i.e., Takeda or Mylan. Section 1.2(d) is therefore not limited to situations where Takeda has sued claiming that a generic version of Colcrys infringes some or all of the Licensed Patents. The "Third Party" does not have to be another generic drug competitor. Rather, the provision can be triggered by a Takeda lawsuit against any entity other than Mylan or its affiliates.

Takeda's interpretation would make it trivially easy for Takeda to avoid triggering Section 1.2(d). Takeda could assert all seventeen Colcrys patents against a third party, and then simply withdraw one patent (or one claim of one patent) early in litigation. But even aside from the possibility of such gamesmanship, it is routine for asserted claims to be dropped throughout the course of patent litigation. Takeda's reading of the provision would mean, as a practical matter, attempts by Takeda to enforce its Colcrys patents would never risk a loss that could open the door for Mylan. It seems unlikely that Mylan would have bargained for a practically useless provision. *See Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) ("We will not read a contract to render a provision or term meaningless or illusory.").

Takeda's primary argument for irreparable harm depends on its showing that it is likely to succeed on the merits. (D.I. 13 at 14). Specifically, Takeda cites Section 1.10 of the Agreement, which stipulates that a breach of the Agreement would cause irreparable harm. Because it is unlikely that Mylan breached the Agreement, however, this stipulation is unlikely to be effective. Without consideration of Section 1.10, I do not find that Takeda has shown it will suffer irreparable harm absent a preliminary injunction. Money damages would remedy any harm Takeda will suffer as a result of Mylan launching its product. *See Frank's GMC Truck Ctr., Inc. v.*

Gen. Motors Corp., 847 F.2d 100, 102 (3d Cir. 1988) ("The availability of adequate monetary damages belies a claim of irreparable injury."). I do not think calculating Takeda's damages would be any more difficult than in the usual patent case. Claims of price erosion are not compelling when it appears to be undisputed that that even if Mylan does not enter the market now, other generics will soon do so. By the time there would be any trial for damages, there will be plenty of actual data about how the market reacted to generic entry.

Because Takeda has failed to show that it is likely to succeed on the merits or that it will suffer irreparable harm, it is unnecessary to analyze the remaining factors of the preliminary injunction standard. "A movant must demonstrate both a likelihood of success on the merits and the probability of irreparable harm if relief is not granted. We cannot sustain a preliminary injunction where either or both of these prerequisites are absent." *Id.* (cleaned up).

IV. CONCLUSION

For these reasons, Plaintiff's Motion for a Preliminary Injunction is DENIED. For the same reasons that I do not grant the preliminary injunction, I do not grant any stay pending appeal, except that, in order to give Plaintiff an opportunity to seek immediate relief in the Court of Appeals, if it so chooses, Defendant is ORDERED to maintain the status quo until end of the day January 31, 2020.

IT IS SO ORDERED this 27 day of January, 2020.

United States District Judge