20-1407, -1417

United States Court of Appeals for the Federal Circuit

TAKEDA PHARMACEUTICALS U.S.A., INC.,
Plaintiff - Appellant,

v.

MYLAN PHARMACEUTICALS INC.,
Defendant - Appellee.

Appeals from the United States District Court for the District of Delaware
in Case No. 1:19-cv-02216-RGA, Judge Richard G. Andrews

CORRECTED REPLY BRIEF FOR PLAINTIFF-APPELLANT

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March 18, 2020

FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Takeda Pharmaceuticals U.S.A., Inc. **v.** Mylan Pharmaceuticals Inc.

Case No. 2020-1407, -1417

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ■ (appellant) ☐ (respondent) ☐ (appellee) ☐ (amicus) ☐ (name of party)

Takeda Pharmaceuticals U.S.A., Inc.

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Takeda Pharmaceuticals U.S.A., Inc.	None	Takeda Pharmaceutical Company Limited; Takeda Pharmaceutical International AG

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

Francis DiGiovanni, Faegre Drinker Biddle & Reath LLP
Thatcher Rahmeier, Faegre Drinker Biddle & Reath LLP

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Rev. 10/17

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharm. Inc., No. 1:19-cv-02216-RGA (D. Del.)
Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Labs. Ltd. et al., No. 20-325-RGA (D. Del.)
Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Labs. Ltd. et al., No. 20-1545 (Fed. Cir.)

3/18/2020
Date

/s/ Edgar H. Haug
Signature of counsel

Please Note: All questions must be answered

Edgar H. Haug
Printed name of counsel

cc: _____

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INTRODUCTION

Mylan Pharmaceuticals Inc.'s ("Mylan") Opposition ("Opp." or "Opposition Brief") (ECF No.[1] 47) to Takeda Pharmaceuticals U.S.A., Inc.'s ("Takeda") Opening Appeal Brief ("Op. Br.") (ECF No. 35) only confirms that the district court abused its discretion in denying a preliminary injunction. *First*, Mylan does not deny that the summary-judgment decision in *Takeda Pharm., U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-cv-1268-RGA (D. Del. Oct. 3, 2014) (the "*West-Ward* Litigation") adjudicated noninfringement with respect to only three of the eight patents asserted in that litigation. *Second*, Mylan acknowledges that all claims, counterclaims, and defenses for the remaining five asserted patents were dismissed with prejudice, including the defenses and counterclaims of Hikma Pharmaceuticals LLC and West-Ward Pharmaceutical Corporation (collectively "Hikma") with respect to noninfringement, invalidity, and unenforceability. Accordingly, Mylan does not dispute that for these five patents, which were asserted in the *West-Ward* Litigation, there was no "holding" on the issues of noninfringement, invalidity, or unenforceability, as

[1] "ECF" refers to documents from this Court's docket.

required by Section 1.2(d). *Third*, Mylan does not provide any rationale as to why the parties, in the context of a Hatch-Waxman settlement, would have intended Mylan's license to be triggered where only a subset of the asserted patents were adjudicated as not infringed, invalid, or unenforceable, when such decision would not change the status quo in the colchicine market. To the contrary, the purpose of the License Agreement is to provide Mylan a date certain on which it can enter the market with its generic colchicine product, which can be accelerated upon the occurrence of certain events that have a material effect on the colchicine market.

Accordingly, because Mylan's license was not triggered by the *West-Ward* Litigation, Mylan has breached the License Agreement and willfully infringed the Patents-in-Suit. The district court erred in finding otherwise. Takeda is likely to succeed in this appeal.

Mylan also does not deny that Section 1.10 of the License Agreement expressly provides that a breach of the agreement entitles Takeda "to immediate injunctive relief to prevent Mylan from marketing the Mylan ANDA Product in breach of Paragraphs 1.2 and 1.4 of this License Agreement." This provision is dispositive of the

remaining factors to consider in deciding whether to grant a preliminary injunction. Separately, as discussed below, the balance of hardships strongly favors Takeda because a preliminary injunction would maintain the status quo in the colchicine market. Moreover, the public interest favors enforcement of valid patent rights.

Because all of the factors tip decidedly in Takeda's favor, the district court abused its discretion in denying Takeda's motion for a preliminary injunction.

ARGUMENT

I. Takeda Is Likely to Succeed Because Mylan's Proposed Interpretation of Section 1.2(d) Is Contrary to the Plain Meaning of the License Agreement and Ignores the Context Under Which the License Agreement Was Entered

A. The Unambiguous Language of Section 1.2(d) Supports Takeda's Interpretation That the *West-Ward* Litigation Was Not a Triggering Event Under Section 1.2(d)

The *West-Ward* Litigation was not a triggering event as required by Section 1.2(d). Mylan reads Section 1.2(d) of the License Agreement to be triggered even if a Final Court Decision does not adjudicate **all** claims of the Licensed Patents asserted in the *West-Ward* Litigation. Mylan's interpretation of Section 1.2(d) of the License Agreement is

simply incorrect. Mylan's interpretation requires that Section 1.2(d) be read as applying to only to those Licensed Patents that were "***both***" asserted and adjudicated. Opp. at 23 (emphasis in original). In fact, Mylan argues throughout its Opposition Brief that Section 1.2(d) be rewritten to include "***both***" asserted and adjudicated when Section 1.2(d) only includes "were asserted and adjudicated." *See* Opp. at 11, 18, 20, 21, 23, 24, 25. By inserting the word "***both***" in Section 1.2(d), Mylan is trying to rewrite that section as applying only to patents that were asserted at the time of adjudication.

Additionally, Mylan's interpretation also ignores that Section 1.2(d) refers to "**all** unexpired claims." Appx88(§ 1.2(d)). Under Mylan's flawed interpretation, "[i]f a patent was not both asserted and adjudicated, it is irrelevant for the purposes of Section 1.2(d)." Opp. at 23 (emphasis omitted). In other words, Mylan simply chooses to ignore the five other patents that were asserted in the *West-Ward* Litigation and removed from the case without any holding of noninfringement, invalidity, and unenforceability as required by Section 1.2(d). Because there was no "holding" whatsoever with respect to five asserted patents, and certainly no holding that any of those five patents were (i) not

infringed, or (ii) any combination of not infringed and invalid or unenforceable as required by Section 1.2(d), the *West-Ward* Litigation cannot trigger Section 1.2(d).

Unable to refute that its interpretation of Section 1.2(d) renders the term "asserted" superfluous, Mylan accuses Takeda of "ignor[ing] that the plain language of Section 1.2(d) requires the unexpired patent claims be asserted 'against a Third Party' in order for the provision to apply." Opp. at 23-24 (emphasis omitted). Mylan is incorrect.

Mylan relies on its misguided example that Section 1.2(d) would not apply to a declaratory-judgment action because a patent is "not 'asserted… against a Third Party' as required by Section 1.2(d)." Opp. at 24. Not so. Section 1.2(d) *does* apply in instances of declaratory-judgment actions as the patents are "asserted," provided Takeda denies the allegations of noninfringement, invalidity, or unenforceability. Ironically, under Mylan's interpretation of Section 1.2(d), (i) a declaratory-judgment action that finds *all* of the Licensed Patents to be not infringed *would not* trigger Section 1.2(d), whereas (ii) an infringement action that finds *only some* of the asserted patents to be not infringed—with no finding one way or the other with respect to the

remaining asserted patents—*would* trigger Section 1.2(d). To state Mylan's interpretation is to refute it.

Mylan also attempts to rewrite the License Agreement by proclaiming that the five patents from the *West-Ward* Litigation "were neither 'asserted' nor 'adjudicated' for the purposes of Section 1.2(d)" Opp. at 22. However, even Mylan admitted in its Opposition Brief that "Takeda had asserted eight patents against Hikma in the *West-Ward* Litigation." Opp. at 8. Mylan's attempt to rewrite cannot overcome the fact that the five patents were "asserted" in the *West-Ward* Litigation, and removed from the case without any holding of noninfringement, invalidity, or unenforceability as required by Section 1.2(d).[2] The mere fact that these five patents were dismissed prior to the end of the litigation does not negate that these patents "were asserted" and were a subset of the Licensed Patents. Mylan's argument to the contrary hinges on its belief that in order to be "asserted," all claims of a patent

[2] Contrary to Mylan's statements through out its opposition brief, both parties in the *West-Ward* Litigation ***jointly agreed*** to a stipulated dismissal of the five patents, as well as Hikma's defenses and counterclaims. It was not, as Mylan contends on pages 8, 18, 40, and 54 of its opposition brief, the result of any voluntarily action brought by Takeda. *See* Fed. R. Civ. P. 41(a)(1)(A)(i) (providing that a unilateral, voluntary dismissal is not available after the filing of an answer or summary-judgment motion); *see also* Op. Br. at 31-32.

must be pressed against a third party through the end of the litigation. Had the parties intended for that to be the case, Section 1.2(d) would have been drafted to say so explicitly. The erroneous nature of Mylan's interpretation is further confirmed by the fact that it permits Section 1.2(d) to be triggered even when "***all***" of the asserted claims are not "adjudicated."

In contrast to Mylan's atextual interpretation of Section 1.2(d), Takeda's interpretation gives meaning to "asserted" and "adjudicated." The term "asserted" defines the claims that need to be considered, and the term "adjudicated" makes clear that those claims that were "asserted" need to be adjudicated. As Mylan admits, the claims of five of the patents that were "asserted" in the *West-Ward* Litigation were never adjudicated. Appx2901; Appx2905. As such, because not "all" of the claims of the Licensed Patents that were "asserted" were "adjudicated," and there was no corresponding holding of noninfringement, invalidity, or unenforceability, Section 1.2(d) was not triggered.

B. This Court Should Ignore Mylan's Attempt to Distort the Record and Takeda's Position

Mylan's misguided attempt to redirect this Court's attention to a purported waiver by Takeda is of no avail. According to Mylan, Takeda has "repeatedly admitted these withdrawn patents were not 'adjudicated' under Section 1.2(d)" such that Takeda's "admission is dispositive because it necessarily leads to the conclusion that the only three Licensed Patents that were both asserted and adjudicated in the *West-Ward* Litigation were held to be 'not infringed' in a 'Final Court Decision.'" Opp. at 20. Mylan then argues that because of Takeda's purported waiver, Hikma's arguments for its Motion for Leave to File an Amici Brief should be rejected by this Court. Opp. at 53. To the contrary, Takeda has not waived any such argument.

Takeda has consistently argued to the district court—as well as to this Court—that only three of the eight patents in the *West-Ward* Litigation were "adjudicated" as not infringed, invalid or unenforceable, and that the remaining five patents were not "adjudicated" as not infringed, invalid or unenforceable, as required by Section 1.2(d) of the License Agreement. *See* Appx3419-3420; ECF No. 6 at 13; ECF No. 26-1 at 1, 5; ECF No. 35 at 9, 17, 24. Section 1.2(d) is triggered **only** if

there is a decision of noninfringement, invalidity, or unenforceability concerning "all unexpired claims of the Licensed Patents." Appx88(§ 1.2(d)). With respect to the remaining five patents, there was no adjudication of noninfringement, invalidity, or unenforceability as would be required to trigger Section 1.2(d). Even if this Court were to conclude that the remaining five patents were "adjudicated" in some way[3], there is still no adjudication with a holding of noninfringement, invalidity, or unenforceability as required by Section 1.2(d). Thus, there was no trigger of Mylan's license.

Rather, those five patents were subject to a voluntary dismissal with prejudice stipulated by the parties. As Takeda argued to the district court and made clear in this Court, "[a] voluntary dismissal with prejudice constitutes an adjudication solely for claim preclusion and not issue preclusion and '[does] not decide any specific issue at all.'" Op. Br. at 18 (quoting *Levi Strauss & Co. v. Abercrombie & Fitch*

[3] In claiming that Takeda waived the argument that the stipulated dismissal constituted some type of adjudication (Opp. at 20, 53-58), Mylan ignores that Takeda repeatedly pointed out that regardless of whether the dismissal constituted an adjudication, it was in no event an adjudication of noninfringement, invalidity, or unenforceability as would be required to trigger Section 1.2(d). *See* Op. Br. at 18,19, 24.

Trading Co., 719 F.3d 1367, 1372-73 (Fed. Cir. 2013)) (emphasis added); *see* Appx3420.

Accordingly, because the issues of infringement, invalidity, and unenforceability were not determined one way or the other for the five asserted Licensed Patents, there was no "adjudicat[ion] against a Third Party" holding that all of the claims "are either (i) not infringed; or (ii) any combination of not infringed and invalid or unenforceable." Takeda's interpretation makes sense because when the stipulation was entered, Takeda and Hikma had simply agreed to remove these patents from the case without the court making a finding as to infringement, validity, or enforceability. *See also* ECF No. 18-2 at 5 ("The Stipulation and Order to Dismiss purposefully did not include any finding that the five DDI patents were infringed/not infringed, valid/invalid, or enforceable/unenforceable, as Takeda and Hikma had not reached any agreement on those terms.").

C. Takeda's Interpretation Is Consistent with the Parties' Objective Intent, Whereas Mylan's Interpretation Is Not

Under Delaware law it is unequivocal that "[w]hen interpreting a contract, the role of [the] court is to effectuate the parties' intent."

Lorillard Tobacco Co. v. Am. Legacy Found., 903 A.2d 728, 739 (Del. 2006). Indeed, when interpreting a contract, courts "will give priority to the parties' intentions as reflected in the four corners of the agreement[.]" *GMG Capital Inv., LLC v. Athenian Venture Partners I, L.P.*, 36 A.3d 776, 779 (Del. 2012). As Takeda explained in detail (ECF No. 6 at 11-16; ECF No. 26-1 at 2-7; ECF No. 35 at 15-19), the four corners of the License Agreement make clear that where a court's findings of noninfringement, invalidity, or unenforceability are limited to only a subset of asserted patents, Section 1.2(d) will not be triggered.

In response, Mylan wrongly characterizes Takeda as "suggesti[ng] that the parties intended for Section 1.2(d) to be limited to litigation involving 'Generic Equivalents'[] to Colcrys® and thus to exclude the *West-Ward* Litigation, which related to the colchicine product Mitigare® and its authorized generic." Opp. at 27. To the contrary, Takeda merely pointed out that at the time the parties negotiated and entered into the License Agreement, Mitigare®—the product at issue in the *West-Ward* Litigation—had already been on the market. *See* Op. Br. at 19-21. Accordingly, it makes no sense to conclude that the parties intended the *West-Ward* Litigation to trigger Mylan's license when such

a decision would have no effect on the colchicine market. A logical absurdity in Mylan's position, which Mylan never addressed or attempted to explain in its Opposition Brief.

Moreover, Takeda has never said that the *West-Ward* Litigation is categorically barred as a Section 1.2(d) trigger as Mylan incorrectly contends. *See* Opp. at Sec. D. Rather, Takeda has consistently maintained that the outcome of the *West-Ward* Litigation does not trigger Section 1.2(d) because it failed to satisfy Section 1.2(d)'s requirements. Under Takeda's interpretation, the *West-Ward* Litigation would have triggered Mylan's license had there been a Final Court Decision holding all eight asserted patents to be not infringed, invalid, or unenforceable, even though the product in the *West-Ward* Litigation was not a Generic Equivalent.

Mylan also mischaracterizes Takeda's position as being that Section 1.2(d) applies only if the status quo changes based upon the entry into the market of a generic Colcrys® product. Opp. at 30-34. That is not Takeda's position. *See* Op. Br. at Sec. II(A)(3). Rather, given the License Agreement's license accelerators' (*see, e.g.*, Appx88(§ 1.2(b)); Appx89(§ 1.2(f))) clear focus on allowing Mylan to launch upon

the occurrence of certain limited events regarding generic Colcrys® products, it makes sense to interpret Section 1.2(d) narrowly, instead of giving Section 1.2(d) the expansive interpretation that Mylan is advocating.

Mylan also wrongly denies that the License Agreement's Most Favored Nation ("MFN") provision (Appx91-92(§ 1.5)) acknowledges that certain "Earlier Filers" were permitted earlier entry dates than Mylan. Opp. at 34-35. Section 1.5 unambiguously provides that the terms in Mylan's License Agreement shall be "equivalent to or better than the terms being offered to any Third Party (other than Generic Entry Dates offered to [certain Earlier Filers])[.]" Appx91-92(§ 1.5). That proviso would be unnecessary if Mylan were being offered the same entry date as those Earlier Filers. Accordingly, the MFN provision objectively shows the parties' overarching intent that Mylan would launch ***after*** the Earlier Filers, and certainly not ***before*** the Earlier Filers as Mylan seeks to do.

D. Mylan's Proposed Interpretation Would Lead to Absurd Results

Mylan still points to no reason why Takeda would have agreed to the exceedingly broad interpretation of Section 1.2(d) that the district

court adopted. *See* Op. Br. at 29-30. Instead, Mylan attempts to dispute that absurd results that would flow from Mylan's interpretation. Opp. at 36-41. Mylan's arguments do not withstand scrutiny.

1. The Plain Language of the Hatch-Waxman Act Confirms the Absurd Results that Would Result from Mylan's Overly Broad Interpretation of Section 1.2(d)

Mylan wrongly denies that Takeda's interpretation—i.e., that Section 1.2(d) is triggered only when there has been an adjudication of noninfringement, invalidity, or unenforceability with respect to ***all*** of the patents that were asserted in the litigation—is most sensible given that the 30-month stay is lifted only by a judgment that applies to all claims. Opp. at 36-39.[4] Mylan's argument is belied by the plain language of the Hatch-Waxman Act, which provides (in relevant part) that a 30-month stay can be terminated before the 30-month period runs only if there is a "***substantive determination*** that there is no

[4] Mylan is also incorrect to suggest that the 30-month stay is applicable only to generic products. *See* Opp. at 36,37. Contrary to Mylan's suggestion, the 30-month stay—and early termination thereof based upon a district court's substantive determination of noninfringement or invalidity—applies also to 505(b)(2) brand products. 21 U.S.C. § 355(c)(3)(C)(i).

cause of action for patent infringement." 21 U.S.C. § 355(j)(5)(B)(iii)(I) (emphasis added).

Mylan does not—and cannot—dispute that under this plain language, five of the eight patents that were asserted in the *West-Ward* Litigation were not subject to a "substantive determination that there is no cause of action for patent infringement" and therefore were not "adjudicated" to be invalid, unenforceable, or not infringed. *See* Appx88(§ 1.2(d)). Rather, Mylan points to 21 C.F.R. § 314.107(b)(3)(viii) ("Rule 107(b)(3)(viii)"), which provides for the 30-month stay being lifted if a court enters a dismissal, "with or without prejudice, without a finding of infringement[.]" 21 C.F.R. § 314.107(b)(3)(viii). There are at least two problems with Mylan's argument.

First, Rule 107(b)(3)(viii) is "effective December 5, 2016" and applies only "to any new [ANDA] submission . . . received by FDA on or after [December 5, 2016]." 81 Fed. Reg. 69580 at 69632 (Oct. 6, 2016). Mylan's ANDA was filed in September 2016—well before the effective date of Rule 107(b)(3)(viii). Appx2089(¶ 46). Accordingly, Rule 107(b)(3)(viii) is inapplicable to Mylan's ANDA.

Second, Rule 107(b)(3)(viii) is invalid because it is flatly inconsistent with the statute, which provides for the early termination of a 30-month stay only if there is a "substantive determination that there is no cause of action for patent infringement[.]" 21 U.S.C. § 355(j)(5)(B)(iii)(I). Indeed, during the notice-and-comment period, one comment correctly pointed out that Rule 107(b)(3)(viii) "should be withdrawn because the statute does not specify that an order of dismissal without a finding of infringement will terminate a 30-month stay." 81 Fed. Reg. at 69627, comment 58. In response, the FDA made no attempt to square Rule 107(b)(3)(viii) with the plain language of the statute. *Id.* The statute makes clear that there must be a "substantive determination that there is no cause of action for patent infringement" in order to terminate a 30-month stay. 21 U.S.C. § 355(j)(5)(B)(iii)(I). In sharp contrast, Rule 107(b)(3)(viii) purports to permit a 30-month stay to terminate even absent such a substantive determination. Therefore, because Rule 107(b)(3)(viii) conflicts with the statute, it is invalid. *See Teva Pharm. U.S.A., Inc. v. Sebelius*, 595 F.3d 1303, 1315-18 (D.C. Cir. 2010) (invalidating an FDA regulation that was inconsistent with the plain language of 21 U.S.C. § 355(j)); *see also*

Facebook, Inc. v. Windy City Innovations, LLC, ---F.3d---, No. 2018-1400, slip op. at 23-24 (Fed. Cir. Mar. 18, 2020) (invalidating the USPTO's interpretation of the IPR statute where the USPTO's interpretation conflicted with the statute's plain language); *Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351, 1361 (Fed. Cir. 2019) (invalidating USPTO regulations that were inconsistent with the patent statute).

As Mylan recognizes, "Takeda had asserted eight patents against Hikma." Opp. at 8. The mere fact that these five patents were removed from the case by way of a stipulated dismissal—including the dismissal of Hikma's defenses and counterclaims of noninfringement, invalidity, and unenforceability—does not render such patents "***un***asserted" as Mylan suggests. Opp. at 21. Rather, those five patents were never subject to any type of determination (substantive or otherwise) that Takeda's allegations of patent infringement lacked merit. Accordingly, as per § 355(j)(5)(B)(iii)(I), a stipulation of dismissal—in the absence of a substantive determination of noninfringement, invalidity, or unenforceability—would not terminate Mylan's 30-month stay. The accelerator provisions of Section 1.2 were intended to operate only in the event of a material change to the status quo in the colchicine

market. It is therefore entirely sensible to interpret Section 1.2(d) to be triggered only by an event that mirrors the type of occurrence that would lift a 30-month stay.

Although Mylan stresses that the 30-month stay is not explicitly mentioned in the License Agreement (Opp. at 37), Mylan ignores that the Hatch-Waxman Act is referenced repeatedly in the License Agreement. Appx74; Appx90(§ 1.2(g)); Appx92(§§ 1.5 and 1.7); Appx103. It therefore makes sense to interpret the License Agreement against the backdrop of the Hatch-Waxman Act. *See Chi. Bridge & Iron Co. N.V. v. Westinghouse Elec. Co. LLC*, 166 A.3d 912, 913-14 (Del. 2017) ("In giving sensible life to a real-world contract, courts must read the specific provisions of the contract in light of the entire contract.").

Mylan's attempts to distinguish Takeda's cited case law (Opp. at 38-39) are unavailing. In *Endo Pharm.*, a court found that a dismissal for lack of standing did not terminate a 30-month stay because the dismissal did not substantively determine any issue of infringement or validity, as provided for in the Hatch-Waxman Act. *Endo Pharm. Inc. v. Mylan Techs. Inc.*, No. 11-220-GMS, 2013 WL 936452, at *5 (D. Del. Mar. 11, 2013) (Appx3940-3941) (discussing 21 U.S.C.

§ 355(j)(5)(B)(iii)). Similarly, the stipulation in the *West-Ward* Litigation failed to address—one way or the other—the issues of infringement, invalidity, or unenforceability, as evidenced by the fact that Hikma expressly dismissed with prejudice its defenses and counterclaims of noninfringement, invalidity, and unenforceability. Moreover, Mylan wrongly dismisses as "irrelevant" (Opp. at 39 n.11) the decision in *Sanofi-Aventis v. FDA*, 725 F. Supp. 2d 92 (D.D.C. 2010). Far from "irrelevant," the *Sanofi-Aventis* decision establishes that a 30-month stay is terminated only if *the district court* makes a substantive determination of the merits of the patent-infringement allegations. 725 F. Supp. 2d at 98-99. Because the district court in the *West-Ward* Litigation made no such determination with respect to five of the eight asserted patents, a judgment of the type issued in the *West-Ward* Litigation would not have terminated any 30-month stay.

Finally, Mylan's attempt to distinguish the 2015 FDA decision cited by Takeda (Opp. at 39 (citing ECF No. 26-2)) is unavailing. In that decision, the FDA concluded that a dismissal for lack of personal jurisdiction "[did] not . . . constitute the type of substantive decisions described in [the Hatch-Waxman Act][.]" ECF No. 26-2 at 7. Similarly

here, a stipulation of dismissal of all claims, defenses, and counterclaims—including dismissal with prejudice of all allegations of noninfringement, invalidity, and unenforceability—cannot trigger the end of any 30-month stay.

2. Mylan's Challenge to the "amended label hypothetical" Is Similarly Incorrect

Mylan erroneously discounts the fact that under Mylan's overly broad interpretation of Section 1.2(d), a third party could trigger Mylan's license simply by: (i) seeking FDA approval for a dosing regimen identical to that of Colcrys® and then being sued by Takeda for infringement of all of the Patents-in-Suit; (ii) amending its label to carve out certain indications, resulting in Takeda having to drop certain patents from the suit; and (iii) obtaining a judgment of noninfringement with respect to the remaining patents. In response, Mylan claims that this is irrelevant because "Section 1.2(d) is triggered based upon a change relating to Licensed Patents—not a change in the colchicine market." Opp. at 40. But Section 1.2(d) is premised on the assumption that a change related to the Licensed Patents *is also* a change, or potential change, in the colchicine market. If a party obtains a judgment of noninfringement, invalidity, or unenforceability on all

patents that it is accused of infringing, that generally allows that party (and potential other similarly situated generic filers) to obtain final FDA approval to launch and sell its product, free and clear of any patent issues. Mylan's interpretation of Section 1.2(d), in sharp contrast, would permit Mylan to enter the market early based upon a judgment that does nothing to alter the status of the colchicine market and does not potentially open the door for other generic products to come to market. Such an interpretation does not square with the parties' intent and should be rejected.

Mylan errs in stating that "nothing in [Takeda's] scenario requires Takeda to voluntarily withdraw Licensed Patents." Opp. at 40. This is simply untrue. Some of the Patents-in-Suit are directed to methods of treating gout with colchicine, whereas others are directed to methods of treating familial Mediterranean fever ("FMF") with colchicine. Moreover, some of the Patents-in-Suit are directed to very specific dosing regimens for the treatment of gout and/or FMF. If an ANDA filer originally sought FDA approval to market a drug for the treatment of two indications but subsequently withdrew one indication, the patentee could be required to seek dismissal of the patent-infringement

claims regarding the withdrawn indication—absent evidence that the ANDA filer was still encouraging the use of its product in connection with the withdrawn indication. Similarly, if an ANDA filer amended its label to exclude a certain dosing regimen, the patentee could have an obligation to seek dismissal of the patent-infringement claims with respect to any patents that are directed to that regimen—absent evidence that the ANDA filer was still encouraging the use of that particular dosing regimen.[5] Accordingly, Mylan is incorrect to suggest that a patentee never has an obligation to drop patents from a case.

E. Contrary to Mylan's Arguments, Takeda's Interpretation of Section 1.2(d) Would Not Render that Section Meaningless

Mylan's defense of the district court's conclusion that Takeda's interpretation of Section 1.2(d) would render that section "meaningless"

[5] Contrary to Mylan's suggestion (Opp. at 41), a dosing regimen that is materially different from the Colcrys® label would likely be non-approvable by the FDA. *See, e.g.*, 21 C.F.R. § 314.127(a)(2) (providing that the FDA will refuse to approve an ANDA if "[i]nformation submitted with the ANDA is insufficient to show that each of the proposed conditions of use has been previously approved for the listed drug referred to in the ANDA"); 21 C.F.R. § 314.127(a)(7) (providing that an ANDA will not be approved if "[i]nformation submitted in the ANDA is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the ANDA").

only underscores the fallacy of the district court's finding. Opp. at 41-45.

Mylan denies that a defendant would insist upon a judgment of noninfringement as part of a settlement, and points to several cases in which no such judgment was entered. Opp. at 42-43. This, however, ignores that Mylan itself has insisted on such a judgment before. *See Flamel Ireland, Ltd. v. Mylan Pharm. Inc.*, No. 1:15-cv-00178 (IMK), D.I. 85 (N.D.W.V. Dec. 6, 2016) (Appx4116-4118); *VIIV Healthcare Co. v. Mylan Inc.*, No. 12-1065-RGA, D.I. 37 (D. Del. Dec. 18, 2012) (Appx4119-4121). Moreover, the point is that a generic applicant ***may*** insist on a judgement of noninfringement, not that a generic applicant will ***always*** insist on a judgement of noninfringement. Given the plain language of the Hatch-Waxman Act, it makes complete sense that a generic applicant (aside from the first filer) would require a judgment of noninfringement on *all* asserted patents, to trigger the forfeiture provisions in the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (providing for a forfeiture of the first filer's 180-day exclusivity period after a certain time subsequent to a judgment of noninfringement or invalidity).

Additionally, Mylan mischaracterizes Takeda's position as "contend[ing] that it is not routine for parties to drop asserted claims throughout the course of a patent litigation." Opp. at 44 (citing Op. Br. at 31). Takeda has never disputed that parties sometimes drop claims during a patent litigation. However, in the context of Hatch-Waxman litigation, defendants frequently insist on a judgment of noninfringement—rather than a simple stipulated dismissal—for the reasons explained above.[6] And in any event, the district court's ruling effectively treats dropped patents as akin to a holding of noninfringement. But this would cause precisely the result the district court sought to discourage by forcing patentees to fully litigate all patents to conclusion during the course of a litigation, for fear of triggering another filer's ability to launch its product.

Finally, Mylan denies that the district court "was relying on an assessment of [Mylan's] subjective intent." Opp. at 45. But the district court expressly based its decision—at least in part—on its view that

[6] Although Mylan claims that patentees can unilaterally drop a subset of patents from the case under Rule 41 prior to an answer being filed (Opp. at 42), Mylan's argument is misguided. It is unusual for patents to be dropped from a case at the pleading stage, which is usually before any discovery has occurred.

Mylan would not have subjectively agreed to Takeda's interpretation of Section 1.2(d). Appx20-21. As explained above, an objectively reasonable third party having read the entire License Agreement would conclude that the Agreement unambiguously dictates Takeda's interpretation. Indeed, any such person reading the License Agreement would understand that the parties negotiated for Mylan to be able to enter the market on a date certain, as provided in Section 1.2(a). Under the accelerator provisions of Section 1.2, Mylan could market earlier under several narrow extraordinary circumstances, where it might be considered unfair for Mylan to have to wait for the date certain. The accelerator provisions were never intended to be mere alternatives to the agreed date. Rather, they were included to address significant changes in the market dynamics that might render it inequitable for Mylan to have to wait for the date certain. Takeda's interpretation is consistent with these principles, whereas Mylan's is not. The district court erred in concluding otherwise.

II. Takeda Will Suffer Irreparable Harm Absent a Preliminary Injunction

Section 1.10 of the License Agreement provides that Takeda "shall be entitled to immediate injunctive relief to prevent Mylan from

marketing the Mylan ANDA Product in breach of Paragraphs 1.2 and 1.4 of this License Agreement." Appx 94. At the preliminary-injunction hearing, Mylan acknowledged this, and expressly stated that "[Mylan is] not running away from what the contract says. [Mylan] want[s] to make that clear. We stand by it[.]" Appx3889-3890. Nevertheless, Mylan now denies that Takeda would suffer irreparable harm. Because Section 1.10 is clear and unambiguous, this Court should reject Mylan's attempt to contradict the License Agreement and its own admissions.

Mylan mischaracterizes the district court as holding that "Takeda failed to demonstrate irreparable harm." Opp. at 45. To the contrary, the district court simply concluded that "[w]ithout consideration of Section 1.10 [of the License Agreement], I do not find that Takeda has shown it will suffer irreparable harm absent a preliminary injunction." Appx21. The district court reached this conclusion only because it found that it was "unlikely that Mylan breached the Agreement." *Id.* The district court in no way discounted the irreparable harm that Takeda would suffer if Mylan breached the License Agreement. *See id.* Nor could it, given the unequivocal nature of Section 1.10.

Mylan further contends that Takeda's "practice of granting licenses under the Licensed Patents demonstrates that . . . any associated harm can be addressed with monetary damages." Opp. at 48. This argument is misplaced. Indeed, this Court has upheld the grant of a preliminary injunction against a generic pharmaceutical company—including a finding of irreparable harm—even when a brand pharmaceutical company had already licensed the patents to two other generic competitors. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008). Moreover, in vacating the denial of a permanent injunction, this Court recently clarified that "[i]rreparable harm, not adequately compensable at law, may exist even if there is evidence that, for example, the patent owner is 'willing[ ] to license its patent' . . . ." *Texas Advanced Optoelectronic Sols., Inc. v. Renesas Elecs. Am., Inc.*, 895 F.3d 1304, 1331 (Fed. Cir. 2018) (quoting *eBay Inc. v. MercExchange, L.L.C.,* 547 U.S. 388, 393 (2006)); *see also Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1329 (Fed. Cir. 2008) (affirming the grant of a permanent injunction even where patent owner had granted licenses to other entities, because "[a]dding a new [direct] competitor to

the market may create an irreparable harm that the prior licenses did not").

III. The Remaining Preliminary-Injunction Factors Weigh in Takeda's Favor

Section 1.8 and Section 1.10 of the License Agreement bar Mylan's arguments (Opp. at 49-52) that the balance of hardships and the public interest favor Mylan. Because Mylan agreed that a breach of the License Agreement would constitute "infringe[ment of] one or more of the claims of [Takeda's] Patents" and "entitle [Takeda] to immediate injunctive relief," Mylan cannot now argue against the issuance of an injunction in the event of a breach by Mylan. Appx93-94.

As discussed previously, the balance of hardships favors maintaining the status quo. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1362 (Fed. Cir. 2008) (affirming the grant of a preliminary injunction where such an injunction would maintain the status quo).

Moreover, it is well-established that there is a strong public interest in enforcing valid patent rights. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006). There is also an important public interest in enforcing private settlement agreements. *See Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 350 (Fed. Cir. 1988*); see also*

TP Group-CI, Inc. v. Vetecnik, No. 16-623-RGA, 2016 WL 5864030, at *3 (D. Del. Oct. 6, 2016) (Appx3953).

For all these reasons, the balance of hardships and public interest favor Takeda.

CONCLUSION

For at least the reasons expressed above and in Takeda's opening brief, this Court should reverse the district court's denial of a preliminary injunction, and remand with instructions that a preliminary injunction be issued.

Respectfully submitted,

Takeda Pharmaceuticals U.S.A., Inc.

Dated: March 18, 2020

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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