IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

VIIV HEALTHCARE COMPANY; SHIONOGI & CO., LTD.; and VIIV HEALTHCARE UK (NO. 3) LIMITED,

Plaintiffs/Counter-Defendants,

v.

CIVIL ACTION NO. 1:17CV197 (Judge Keeley)

MYLAN PHARMACEUTICALS, INC.,

Defendant/Counter-Claimant.

UNDER SEAL

MEMORANDUM OPINION AND ORDER
GRANTING DEFENDANT'S MOTION TO STRIKE [DKT. NO. 152],
DENYING PLAINTIFFS' EXPEDITED MOTION FOR AN EXTENSION OF
TIME [DKT. NO. 165], AND MODIFYING CERTAIN SCHEDULING DEADLINES

On December 16, 2019, the defendant, Mylan Pharmaceuticals, Inc. ("Mylan"), moved to strike the Plaintiffs', ViiV Healthcare Company, Shionogi & Co., Ltd., and ViiV Healthcare UK (No. 3) Limited (collectively, "ViiV"), Third Supplemental Contentions regarding claims 1-6 of U.S. Patent No. 9,242,986 ("the '986 Patent") (Dkt. No. 152). After receiving an extension of time, ViiV filed its response in opposition on January 10, 2020 (Dkt Nos. 157-1, 159). On January 21, 2020, ViiV moved to extend its deadline to serve its final infringement contentions (Dkt. No. 165). Because the scheduled deadline to do so was January 24, 2020 (Dkt. No. 147), the Court directed Mylan to respond to ViiV's motion by January 23, 2020 (Dkt. No. 166). Mylan filed its combined reply in

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support of its motion to strike and response opposing ViiV's expedited motion on January 23, 2020 (Dkt. No. 167).

At bottom, both motions turn on whether the Court should (1) permit ViiV to reassert claims of infringement as to claims 1-6 of the '986 Patent, and (2) extend ViiV's deadline to serve its final infringement contentions. Here, the answer to both questions is no.

I. BACKGROUND

On October 17, 2019, after repeated urging by Mylan to provide infringement contentions and threatened court substantive intervention, ViiV informed Mylan that its infringement contentions no longer included claims 1-6 (Dkt. No. 153-2 at 3). Thereafter, however, when ViiV served its Third Supplemental Contentions on November 26, 2019, it attempted to reassert claims of infringement for claims 1-6 (Dkt. No. 153-1). After Mylan moved to strike, ViiV claimed that it was reasserting these claims based on "Mylan's recent admission" that its statement to "the Food and Drug Administration ('FDA')

is "not true" (Dkt. No. 159 at 4, 7-16). It further

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contended that the Court's scheduling order permitted it to supplement its disclosures and, in any event, there was no harm to Mylan. Id. at 6.

In addition to seeking to reassert claims of infringement as to claims 1-6, ViiV also sought a significant extension to disclose its final infringement contentions; as well, it sought to amend the entire case schedule (Dkt. No. 165, 165-1). In support, ViiV cited (1) the same misrepresentation alleged in its opposition brief, and (2) ongoing delays with fact discovery (Dkt. No. 165-1). These arguments are unavailing.

II. DISCUSSION

Α. ViiV Cannot Complain About the Delays or Deficiencies in Fact Discovery

It is ViiV's own dilatory conduct that has led to its dissatisfaction with the state of fact discovery. Although ViiV makes much of the fact that it needs to travel to India to take three depositions, it never served its Rule 30(b)(1) notices until December 9 and 20, 2019 (Dkt. Nos. 167-12, 167-13). It was only after Mylan informed ViiV in December 2019 that these individuals would have to be deposed in India because all lacked U.S. visas

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(Dkt. No. 167-14 at 2) that ViiV proposed taking their depositions in February and March 2020 (Dkt. No. 167-18 at 2).

The same is true of ViiV's complaints regarding Mylan's allegedly deficient document production. In its expedited motion seeking to extend discovery, ViiV noted that it was only on January 10, 2020, that Mylan produced "critical raw data files relating to its product accused of infringement" (Dkt. No. 165-1 at 2). But Mylan was not required to produce the metadata absent a specific agreement or request, which ViiV has neither claimed nor established. See, e.g., Wyeth v. Impax Labs., Inc., 248 F.R.D. 169, 171 (D. Del. 2006) (holding party complied with its discovery obligations when it did not produce metadata because the parties never agreed to disclose documents in a particular format, the parties never argued that accessing metadata was necessary, and requesting party did not demonstrate a particularized need for metadata); Treppel v. Biovail Corp., 233 F.R.D. 363, 374 (S.D.N.Y. 2006) (requiring production in native format where requesting party asked for it and producing party did not object).

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Therefore, because ViiV is challenging the sufficiency of documents that were produced in August 2019 (Dkt. No. 159 at 23), it has plainly waived its right to complaint when it failed to file a motion to compel the raw data within 30 days following Mylan's allegedly deficient production. L.R. Civ. P. 26.04(B). Thus, ViiV cannot now complain that Mylan only recently produced this metadata by agreement.

B. ViiV Did Not Diligently Review Mylan's March 2019 Document Production

It appears that ViiV did not diligently review Mylan's March 2019 document production. ViiV claims that it is entitled to reassert its previously abandoned infringement claims as to claims

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1-6 because it discovered supporting data in Mylan's August 2019 document production (Dkt. No. 159 at 2). But Mylan produced all of the documents that ostensibly support ViiV's reasserted claims in March 2019, not August 2019. To be sure, ViiV's reasserted claims cite, for example, documents numbered MYL-DTG00034224-438, MYL-DTG00032455-464, and MYL-DTG00032516-535 (Dkt. No. 167-5 at 5-6), all of which were disclosed in March 2019 (Dkt. No. 105 (certificate of service for documents numbered MYL-DTG00032050 through MYL-DTG00036589)). ViiV also cites document number MYL-DTG00043427-640 (Dkt. No. 167-5 at 5), but this was an inadvertent production of a document originally produced as document number MYL-DTG00033969-4182, which also was produced in March 2019 (Dkt. Nos. 105, 167 at 9 n.5). In other words, ViiV's reasserted claims of infringement are based on documents that were long in its possession before it abandoned these claims in October 2019.

Although the Scheduling Order may permit ViiV to supplement contentions before submitting its final infringement its contentions, it does not permit ViiV to reassert claims that have been affirmatively dropped or abandoned by agreement. Especially

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where, as here, ViiV made a strategic decision to drop its infringement claims as to claims 1-6 after being repeatedly pressured by Mylan to provide substantive infringement contentions or face court intervention (Dkt. No. 153-2 at 3). Moreover, a demonstrated lack of diligence in fact discovery, resulting in unfair prejudice to the defendant, is sufficient to strike supplemental infringement contentions. See Nokia Corp. v. HTC Corp., No. 12-550-LPS (D. Del. Dec. 17, 2013), Dkt. No. 162 at 12:16-13:18. Allowing ViiV to supplement its infringement contentions here not only would prejudice Mylan, but also reward ViiV's dilatory conduct and jeopardize the case schedule.

Mylan Did Not Misrepresent or Falsify Facts to the FDA

Third, ViiV's allegations about misrepresentations made by Mylan to the FDA are without merit. To defend its attempt to reassert infringement claims as to claims 1-6, ViiV insists that Mylan has misrepresented information regarding its ANDA product to the FDA (Dkt. No. 159 at 7-16). Specifically, it insists that, although Mylan represented to the FDA

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Id. at 14 (internal citation omitted). "To get to the bottom
of Mylan's positions, [ViiV] asked Mylan whether it would stipulate
to exactly what [it] had told [the] FDA
<u>Id.</u> at 15 (citations omitted).
(Dkt. No. 167 at
5 (emphasis omitted) (citing 167-2)). Mylan never made a blanket
statement to the FDA that
Id. Thus, by presenting
<u>ia.</u> inas, by presenting
Mylan with its proposed stipulation, ViiV effectively asked Mylan

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to concede that its ANDA product infringes

Moreover, ViiV's proposed stipulation regarding the single PXRD peak ignores elementary patent law, which requires more than single-peak analysis to establish infringement. See, e.g., Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1566 (Fed. Cir. 1997) ("It is elementary patent law that all limitations are material. The single-peak analysis was thus insufficient because, as the district court correctly noted, in order to prove infringement Glaxo was required to establish the presence of each limitation of the asserted claims."); see also Merck Sharp & Dohme Corp. v. Amneal Pharm. LLC, 881 F.3d 1376, 1386 (Fed. Cir. 2018) (finding "no clear error in the district court's fact-finding that three peaks were required and that Amneal's ANDA product will not infringe").

The Court Will Not Compel the Production of the Requested D. Discovery

In its combined response and reply brief, Mylan contends that the testing ViiV referenced in its response brief is discoverable

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and, therefore, asks the Court to compel its production (Dkt. No. 167 at 14-15). Although Mylan requested this discovery by email (Dkt. Nos. 167-15), it has not yet served a formal discovery request; therefore, nothing is ripe for adjudication, and in light of the Court's rulings here, may even be moot. Accordingly, the Court denies Mylan's request to compel this discovery.

III. CONCLUSION

Because the Court finds no good cause for ViiV to reassert claims of infringement as to claims 1-6 or for an extension of time to serve its final infringement contentions, it GRANTS Mylan's motion to strike (Dkt. No. 152), and DENIES ViiV's expedited motion for an extension (Dkt. No. 165). However, because ViiV's January 24, 2020 deadline to serve its final infringement contentions has passed, the Court EXTENDS the following dates and deadlines:

- ViiV to serve its final infringement contentions on or before Monday, February 3, 2020;
- ViiV to finally supplement the identification of all accused products on or before Monday, February 3, 2020;

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- Mylan to serve its final invalidity contentions on or before Friday, February 14, 2020;
- Mylan to finally supplement the identification of all invalidity references on or before Friday, February 14, 2020;
- Parties to serve opening expert reports on issues for which parties have the burden of proof on or before Friday, March 13, 2020;
- Parties to serve rebuttal expert reports, including ViiV's disclosure of objective indicia of obviousness, on or before Friday, April 10, 2020; and
- Parties to serve reply expert reports, including Mylan's responsive disclosure to ViiV's disclosure of objective indicia of non-obviousness, on or before Friday, May 1, 2020.

No other dates or deadlines are affected by this Order. It is so **ORDERED**.

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The Clerk is directed to transmit copies of this Order to counsel of record.

DATED: January 28, 2020

/s/ Irene M. Keeley IRENE M. KEELEY UNITED STATES DISTRICT JUDGE