IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND, NORTHERN DIVISION

*

CLASSEN IMMUNOTHERAPIES, INC.

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Plaintiff,

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v. CIVIL NO.: WDQ-04-2607

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BIOGEN IDEC, *et al.*,

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Defendants.

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MEMORANDUM OPINION

Classen Immunotherapies, Inc. ("Classen") sued Biogen Idec ("Biogen") and GlaxoSmithKline ("GSK") (collectively the "defendants") for patent infringement. Pending are the defendants' motions to stay, to compel, and for leave to serve supplemental invalidity contentions. For the following reasons the motion to stay will be denied. The motions to compel and for leave to serve supplemental invalidity contentions will be granted.

I. Background[1]

Classen Immunotherapies owns three patents[2] for methods for choosing immunization schedules for infants. ECF No. 202 ¶¶ 23-

[1] The factual background is drawn from the Third Amended Complaint.

[2] Patents number 6,420,139 ("the '139 patent"), 6,638,739 ("the '739 patent"), and 7,008,790 ("the '790 patent") (collectively, "the patents in suit").

31. Each patent protects a method of choosing an immunization schedule for infants which minimizes the likelihood of developing chronic immune-mediated disorders[3] or common infectious diseases. *Id.* Biogen and GSK manufacture, license, market, and sell vaccines. *Id.* ¶ 6. On August 10, 2004, Classen sued Biogen, GSK, and others,[4] claiming that their studies and informational pamphlets infringed Classen's patents. ECF No. 1.

On August 31, 2011, the Federal Circuit held that the '139 and '739 patents are eligible for patent protection. *Classen Immunotherapies, Inc. v. Biogen Idec*, 659 F.3d 1057, 1066 (Fed. Cir. 2011), *cert. denied* No. 11-1078, 2013 WL 141405 (Jan. 14, 2013). On June 20, 2012, Classen filed a third amended complaint against GSK and Biogen, adding infringement of the '790 patent.[5] ECF No. 202.

On August 9, 2012, the defendants moved to compel Classen to comply with Local Rule 804.1.a and to limit the number of claims asserted. ECF No. 215. On August 28, 2012, Classen opposed the motion, ECF No. 216, and on September 14, 2012, the defendants replied, ECF No. 222.

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[3] Chronic immune-mediated disorders include auto-immune diseases, such as diabetes. *See* ECF No. 219-3 ('790 patent) col.10 l.9-10.

[4] Biogen and GSK are the only remaining defendants.

[5] The '790 patent was issued on March 7, 2006.

On September 10, 2012, the parties submitted their joint claim construction statement and opening briefs. ECF Nos. 219-221. On November 13, 2012, they filed their responsive briefs. ECF Nos. 231-232.

On September 12 and 13, 2012, GSK filed requests for *inter partes* reexamination of the patents in suit at the Patent and Trademark Office ("PTO"). ECF Nos. 234-4 at 6, 234-6 at 5, 234-8 at 5. On October 24, November 19, and November 23, the PTO granted the reexamination requests and issued First Office Actions rejecting all the asserted claims.[6] *See* ECF Nos. 234-4 to 234-9.

On October 11, 2012, the defendants moved for leave to serve supplemental invalidity contentions based on their preparation for the *inter partes* reexamination. ECF No. 225. On October 25, 2012, Classen opposed the motion, ECF No. 228, and on November 13, 2012, the defendants replied, ECF No. 230.

On December 5, 2012, the defendants moved for a stay pending the *inter partes* reexamination. ECF No. 234. On December 26, 2012, Classen opposed the motion. ECF No. 235. On January 14, 2013, the defendants replied. ECF No. 236. The same day, the Supreme Court denied a writ of certiorari. *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, No. 11-1078, 2013 WL 141405 (Jan. 14, 2013).

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[6] GSK did not seek review of every claim in the three patents.

II. Analysis

A. Motion to Stay

The defendants seek a stay of this case pending the PTO's *inter partes* reexamination. ECF No. 234. Classen opposes the motion. ECF No. 235. The Court weighs three factors in determining whether to grant a stay pending reexamination "(1) the stage of the proceedings; (2) whether a stay would unduly prejudice the nonmoving party; and (3) whether a stay would simplify issues and the trial of the case." *In re Webvention LLC '294 Patent Litig.*, 868 F. Supp. 2d 500, 504 (D. Md. 2012).

1. Stage of the Proceedings

"In assessing the stage of the proceedings, Courts focus on whether a trial date has been set and the degree to which discovery has been completed." *Akzenta Paneele + Profit GmbH v. Unilin Flooring N.C. LLC*, 464 F. Supp. 2d 481, 484 (D. Md. 2006). Although this case is in its eighth year, the proceedings are at a relatively early stage.[7] In 2012, the suit survived motions to dismiss. Claim construction briefing is now complete, although a hearing date has not been set. Fact discovery has not yet concluded, and expert discovery has not begun.[8] *See* ECF No. 224 (revised scheduling order). No trial

[7] This case was on appeal from 2006 until 2011.

[8] In reply, the defendants also assert that they will need to redepose the inventor and Classen's claim construction expert

date has been set. Nevertheless, significant time and resources have been expended through the extensive motions practice and appeals. Further, the reexamination process is a long one, taking nearly three years in the PTO plus additional time if appealed to the Federal Circuit.[9] If a stay were entered and the patents survived the full reexamination and appeals process, this case would enter its second decade. Accordingly, this factor weighs against a stay.

2. Prejudice to Classen

The second factor is prejudice to Classen, the non-moving party. Within this analysis of prejudice is a consideration of the tactical advantages of the parties. *See Cellectis S.A. v. Precision Biosciences, Inc.*, No. 5:08-CV-00119-H, 2010 WL 3430854, at *4 (E.D.N.C. Aug. 31, 2010).

The defendants assert that Classen is a non-practicing entity and thus will not be prejudiced by a delay. ECF No. 234-1 at 6-7. Classen responds that its patent is a "time sensitive asset which has a fixed expiration date" and thus it would be prejudiced. ECF No. 235 at 4. Classen does not dispute that it is a non-practicing entity.

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and submit additional claim construction briefing because Classen has taken contradictory positions between the reexamination and this litigation. ECF No. 236 at 8-9.

[9] *See Belden Techs., Inc. v. Superior Essex Commc'ns LP*, Civ. No. 08-63-SLR, 2010 WL 3522327, at *3 (D. Del. Sept. 2, 2010); ECF No. 234-10

Despite Classen's assertion, "delay is inherent in the reexamination process and does not constitute, by itself, undue prejudice." *Cellectis*, 2010 WL 3430854, at *4 (internal quotation marks omitted). Further, the risk of harm is reduced when the plaintiff is a non-practicing entity. *See In re Webvention*, 868 F. Supp. 2d at 505. The defendants contend that accrued interest can compensate Classen for the delay. ECF No. 234-1 at 7. Classen has not disputed this. *See Gioello Enters. Ltd. v. Mattel, Inc.*, No. C.A. 99-375 GMS, 2001 WL 125340, at *2 ("[M]oney damages is an adequate remedy for any delay in redress" where the plaintiff "is not selling or actively licensing goods or services.").

However, the defendants' actions indicate their propensity to prolong the litigation in this case. Rather than seek reexamination at the beginning of this case, the defendants attempted to avoid liability for any potential infringement through the safe-harbor provision of 35 U.S.C. § 271(e)(1). *See* ECF Nos. 15, 16, 20. GSK did not seek reexamination until after the Federal Circuit rejected the safe-harbor argument, and this Court denied GSK's motions to dismiss and for reconsideration. *See* ECF Nos. 195, 214. The defendants appear to be attempting to employ every procedural advantage and delay possible in this

litigation to Classen's detriment. This factor weighs against a stay.[10]

3. Narrowing of the Issues

The defendants assert that a stay would simplify the issues, particularly because 228 claims are at issue. ECF No. 234-1 at 8. Classen contends that the decisions of this Court and the Federal Circuit have already narrowed the issues, and proceeding with claim construction on 16 disputed terms will not waste resources because the terms are recited throughout the patents. ECF No. 235 at 3.

According to PTO data, 89% of *inter partes* reexaminations end in cancellation or changes to claims; 42% end in cancellation or disclaimer of all claims. ECF No. 234-10. Although the First Office Action is still early in the reexamination process, all the contested claims in the three patents were rejected on numerous grounds. *See* ECF Nos. 234-5, 234-7, 234-9. Further, the Federal Circuit expressed doubt about the validity of the patents based on prior publications.[11] *Classen*, 659 F.3d at 1062. If the PTO proceeds on its current course, the issues

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[10] *See Mike's Train House, Inc. v. Broadway Ltd. Imps., LLC*, Civil No. JKB-09-2657, 2011 WL 836673, at *4 (D. Md. Mar. 3, 2011).

[11] The parties' arguments about the possibility of certiorari to the Supreme Court are now moot. *See GlaxoSmithKline v. Classen Immunotherapies, Inc.*, No. 11-1078, 2013 WL 141405 (Jan. 14, 2013) (denying cert.).

for trial will be fully narrowed: there will be none left. Such findings of invalidity by the PTO, after a ruling in favor of Classen in this Court would be a significant waste of time and resources. *See Akzenta*, 464 F. Supp. 2d at 486.

Although this Court and the Federal Circuit have narrowed the issues, the previous appellate delays have prompted Classen to broaden the issues by adding another patent to its complaint. *See* ECF No. 172-1. Narrowing the issues somewhat favors a stay.

On balance, however, the stage of this litigation and the potential harm to Classen by further delay do not favor a stay. Accordingly, the defendants' motion will be denied.

B. Motion to Compel and Reduce Number of Claims

The defendants ask the Court to compel Classen to comply with Local Rule 804.1.a and to reduce the number of claims asserted. ECF No. 215. Classen contends that it has complied with Local Rule 804.1.a, and it should not have to reduce the number of claims asserted until after claim construction. ECF No. 216.

1. Reducing the Number of Claims

The defendants assert that Classen must reduce the number of claims to a more manageable number.[12] Classen agrees that it

[12] In their motion, the defendants request a total of 30 claims, ECF No. 215 at 8, but in their reply they request five claims per patent--a total of 15 claims. ECF No. 222 at 9.

will need to reduce the number of claims, but requests that it do so after the close of fact discovery. ECF No. 216.

There are 16 disputed terms, all present in the independent claims, for claim construction.[13] *See* ECF No. 220 at 11-49. Claim construction briefing has concluded. Consequently, the parties have either mitigated or struggled through the large number of claims. Resolving the disputed terms through claim construction will enable Classen to more ably choose the claims on which it wishes to proceed. Accordingly, Classen will be ordered to reduce the number of claims to 30 within 15 days of the claim construction ruling.[14]

2. Local Rule 804.1.a

The defendants assert that Classen's disclosure of its Infringement Contentions do not comply with Local Rule 804.1.a.i-iv, ix. ECF No. 215. Classen contends that it has complied with the Local Rule, and the defendants are on notice of its theory of infringement. ECF No. 216 at 3. Local Rule 804.1.a requires disclosure of Infringement Contentions including:

> i. Each claim of each patent in suit that is allegedly infringed by each allegedly infringing party . . .;

[13] There are also three remaining issues in the agreed constructions. *See* ECF No. 220 at 2.

[14] This is the deadline for amending the Infringement Contentions. *See* ECF No. 224.

ii. Separately for each allegedly infringed claim, each accused apparatus, product, device, process, method, act or other instrumentality ("Accused Instrumentality") of each allegedly infringing party of which the party is aware. This identification shall be as specific as possible. . . .;

iii. A chart identifying specifically where each limitation of each asserted claim is found within each Accused Instrumentality, including for each limitation that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that performs the claimed function;

iv. For each claim which is alleged to have been indirectly infringed, an identification of any direct infringement and a description of the acts of the alleged indirect infringer that contribute to or are inducing that direct infringement. Insofar as alleged direct infringement is based on joint acts of multiple parties, the role of each such party in the direct infringement must be described; . . .

ix. If a party claiming patent infringement alleges willful infringement, the basis for such allegation.

Local Rule 804.1.a. Local Rule 804.6 permits amendment of Contentions "upon written consent of all parties or, for good cause shown, upon leave of the Court." The Court's scheduling order gives a "[d]eadline for amending final infringement contentions based upon claim construction decision" 15 days after the claim construction ruling. ECF No. 224 at 2.

Classen contends that it has fulfilled its obligations by giving the defendants notice about the infringement, and the scheduling order contemplates that it will amend the Infringement Contentions. ECF No. 216 at 3. The defendants assert that the deadline for amendment allows "Classen to amend . . . after a claim construction ruling to account for a construction that differs from what Classen understood a term to mean, not to correct contentions that were defective when served." ECF No. 222 at 3.

Although there does not appear to be any decision in this district interpreting Local Rule 804.6 in the context of a scheduling order, the defendants' interpretation is the better one. The scheduling order provides a final deadline, based on the claim construction ruling. *See* ECF No. 224. At any time before the deadline, Classen may amend with consent or good cause. Local Rule 804.6. The claim construction ruling may provide good cause for amendment because of the clarification made by the ruling. The basic substance of the Infringement

Contentions and the Accused Instrumentalities, however, will not be changed, particularly for any constructions in Classen's favor. Similarly, the ruling will not remedy any defects in the initial Infringement Contentions. Accordingly, the Infringement Contentions are not "preliminary" or amenable to the considerable amendment that Classen appears to contemplate.

Although not a separately stated requirement, Local Rule 804.1.a requires the Infringement Contentions to explicitly refer to each defendant and its infringement. *See, e.g.*, Local Rule 804.1.a.ii, iv. The Infringement Contentions are framed in terms of the "defendants." *See generally* ECF Nos. 215-3 to 215-6.

Further, Classen has combined numerous claims on its charts. *See, e.g.*, ECF No. 215-5 at 11 (combining claims 136-144, 145-154, 155-164, and 165-168 of the '790 patent). Classen claims that these are dependent claims and it is "no need for any more detailed description" because "the context and basis for infringement has already been established" in the independent claims. *See* ECF No. 216. Although this Infringement Contention may apprise the defendants of the alleged infringement, it does not comply with Local Rule 804.1.a.ii, which requires identification of the Accused Instrumentality "[s]eparately for each allegedly infringed claim." Similarly, Local Rule 804.1.a.iii requires the chart to

"identify[] specifically where each limitation of each asserted claim is found within each Accused Instrumentality"; the combination of the claims fails to do so.

Accordingly, Classen has not complied with Local Rule 804.1.a. As claim construction briefing has been completed, and Classen will need to reduce the number of claims, service of Infringement Contentions on all 228 claims would be a waste of Classen's resources and of little use to the defendants. Accordingly, Classen will be ordered to serve compliant Infringement Contentions on 30 claims within 15 days of the claim construction ruling.

C. Motion to Amend the Invalidity Contentions

The defendants seek leave to amend their Invalidity Contentions based on prior art of which they became aware during the *inter partes* reexamination process. ECF No. 225. Classen contends that the defendants will be estopped from relying on that prior art if the reexamination does not invalidate the patents-in-suit. ECF No. 228 at 2.

Under 35 U.S.C. § 315(c), a third-party requester for an *inter partes* reexamination is estopped from later asserting in a civil action "the invalidity of any claim finally determined to be valid and patentable on any ground which the third-party requester raised or could have raised during the *inter partes*

reexamination proceeding." 35 U.S.C. § 315(c) (2006).[15] Consequently, GSK will be estopped from asserting invalidity by prior art if the patents survive reexamination. GSK acknowledges the potential estoppel and agrees that Classen's right under § 315(c) will not be affected by the supplementation of the Invalidity Contentions. ECF No. 230 at 3. Any estoppel will likely arise years in the future, at the conclusion of the reexamination process, and the likelihood of wasting resources here is small. Accordingly, the motion will be granted.

III. Conclusion

For the reasons stated above, the motion to stay will be denied. The motions to compel and for leave to serve additional invalidity contentions will be granted.

2/22/13
Date

William D. Quarles, Jr.
United States District Judge

[15] Section 315 has been amended, effective September 16, 2012. *See* Leahy-Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284, 300-01, 304. GSK filed the requests for *inter partes* reexamination shortly before the amendment took effect. *See* ECF Nos. 234-4, 234-6, 234-8.