NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ABRAXIS BIOSCIENCE, LLC, *et al*., **Plaintiffs,** **v.** **ACTAVIS, LLC,** **Defendant.**	**Civil Action No. 16-1925 (JMV)** **MEMORANDUM OPINION**

FALK, U.S.M.J.

This is an ANDA patent case. Before the Court is Defendant Actavis's motion for leave to amend its invalidity contentions. Plaintiffs, Abraxis BioScience LLC and Celgene Corporation (together "Celgene"), oppose the motion. No oral argument is necessary. For the reasons stated below, the motion is **GRANTED**.

RELEVANT BACKGROUND

This Hatch-Waxman patent infringement case arises out of Actavis's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Celgene's Abraxane® product, which is used to treat breast, lung, and pancreatic cancer. Celgene contends that Actavis's accused ANDA product would infringe four patents: U.S. Patent

Nos. 8,853,260 ("'260 patent"); 7,820,788 ("'788 patent"); 7,923,536 ("'536 patent"); and 8,138,229 ("'229 patent").

The Complaint was filed on April 6, 2016. The initial scheduling conference was held on August 3, 2016, and an initial scheduling order was entered on August 18, 2016.

On August 9, 2016, Actavis served its invalidity contentions, totaling 177 pages.

On October 21, 2016, Celgene served its responses to Actavis's invalidity contentions, running 544 pages.

On February 9, 2017, Actavis prepared proposed, amended invalidity contentions and sent them to Celgene, requesting their consent to amend. According to Actavis, it determined an amendment was necessary after its review of Celgene's response, and an intervening decision from the United States District Court for the District of Massachusetts (*Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd.*, 210 F. Supp. 3d 278 (D. Mass. 2016)), which allegedly gives rise to an additional defense in this case.[1]

On March 6, 2017, Celgene responded that "it would not oppose Actavis's proposed amendments regarding secondary considerations . . . if Actavis agrees to withdraw the remainder of its proposed amendments." Actavis declined.

On March 17, 2017, the Undersigned held a conference and authorized briefing on the amendment issue (additional discovery disputes were raised during and after that conference and will be addressed separately).

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[1] *Janssen* is currently on appeal in the Federal Circuit. Actavis's counsel here is also counsel to *Janssen* in the Federal Circuit.

On March 29, 2017, Actavis's request to amend, pursuant to Local Patent Rule 3.7, was filed. It describes the proposed amendments as seeking to:

(1) respond to assertions of secondary considerations of nonobviousness raised for the first time after Actavis served its invalidity contentions ("Amendment 1");

(2) provide additional "technical details" about Actavis's existing defenses under 35 U.S.C. §§ 102 (anticipation); 103 (obviousness) and 112 (lack of written description/enablement), in response to Celgene's contentions ("Amendment 2"); and

(3) describe a legal defense of obviousness-type double patenting ("OTDP") against the asserted claims of the '788 patent based on the *Janssen* decision. ("Amendment 3")

(Def.'s March 29 Letter Br. 1-2.)

On April 12, 2017, Celgene filed opposition, claiming that Actavis's proposed amendments are untimely, lack "good cause," and would cause undue prejudice to Celgene.

Fact discovery is scheduled to close on June 29, 2017. However, the parties have submitted two fully-briefed discovery disputes for resolution and are in the process of briefing two more. In total, the Court will have more than 15 discovery-related letters before it, most of them lengthy with hundreds of pages of exhibits. Thus, a further extension of the discovery period will likely be necessary.

LEGAL STANDARD

"The Local Patent Rules exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their case." *King Pharm., Inc. v. Sandoz*, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010). The Patent Rules "are designed to require the parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *Celgene Corp. v. Natco Pharma Ltd.*, 2015 WL 4138982, at *4 (D.N.J. July 9, 2015). Nevertheless, the Patent Rules are not "a straightjacket into which litigants are locked from the moment their contentions are served . . . [a] modest degree of flexibility exists, at least near the outset." *Astrazeneca AB v. Dr. Reddy's Labs, Inc*., 2013 WL 1145359 (D.N.J. Mar. 18, 2013).

Local Patent Rule 3.7 governs requests to amend contentions. The Rule allows for amendments "only by order of the Court upon a timely application and showing of good cause." *Id*. Good cause "considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the motion to amend were granted." *Astrazeneca*, 2013 WL 1145359, at *3.

Rule 3.7 provides a "non-exhaustive" list of examples that may, absent undue prejudice to the adverse party, support a finding of good cause: "(a) a claim construction by the Court different from that proposed by the party seeking amendment; (b) recent discovery of material prior art despite earlier diligent searches; (c) recent discovery of

nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of Infringement contentions; (d) disclosure of an infringement contention by a Hatch-Waxman Act party asserting infringement . . . that requires response by the adverse party because it was not previously presented or reasonably anticipated . . . ." *Id*.

Courts have also considered the following in determining whether good cause exists: reason for the delay; importance of the information to be excluded; the danger of unfair prejudice; and the availability of a continuance and the potential impact of a delay on judicial proceedings. *See, e.g.*, *Int'l Development, LLC v. Simon Nicholas Richmond and Adventive Ideas*, *LLC*, 2010 WL 3946714, at *3 (D.N.J. Oct. 4, 2010).

In sum, amendment will be permitted when there is "(1) a timely application, (2) there is a showing of good cause, and (3) the adverse party does not suffer undue prejudice." *Celgene Corp.*, 2015 WL 4138982, at *4.

DECISION

The Court is satisfied that Actavis has been diligent and shown good cause for all three of its proposed amendments, and that none of the amendments will cause undue prejudice to Celgene.

A. Timeliness and Good Cause

Actavis claims that it became aware of the basis for proposed Amendments 1 (secondary considerations) and 2 (additional "technical details") only after receiving and

reviewing Celgene's contentions in October 2016. With respect to amendment 3 (the "OTDP" defense), Actavis claims that the *Janssen* decision, issued after its contentions were served, needed to be analyzed and considered before it was determined whether there was a good faith basis for the proposed defense.

Celgene contends that Actavis has delayed and failed to show good cause for various reasons. It argues that Actavis should have known the basis for proposed Amendments 1 and 2 at the time the original invalidity contentions were served, and dispute that anything in their responses provide a basis for the amendments proposed. It also contends that Actavis's amendments seek to reintroduce claim construction issues that were discussed during that phase of the case and abandoned. Finally, Celgene contends that *Janssen* did not change any relevant law and provides no basis for Amendment 3.

The Court finds that Actavis acted diligently and that good cause has been shown.

First, with respect to good cause for Amendment 1, Actavis has explained that the only secondary consideration it knew Celgene would raise was "unexpected results," and that Celgene's response raised a number of other secondary considerations that it should be permitted to address. Celgene downplays that, claiming that its common knowledge in patent cases that secondary considerations such as commercial success are "raised routinely" and should have been included in the Actavis's original contentions. But, diligence is not "a draconian requirement of perfection and clairvoyance." *Oy Ajayt Ltd.*

v. Vatech Am., *Inc.*, 2012 WL 1067900 (D.N.J. Mar. 29, 2012). Moreover, it appears that Actavis's amendments do closely track and respond to secondary considerations contained in Celgene's response, *see* Ex. A. 38-49, 138-47, which suggests that there is good cause for Actavis to seek to amend on that basis. It would also appear to be in the parties' and the Court's best interests to have the parties' positions fleshed out in the most complete way possible.

Second, good cause has been shown with respect to Amendment 2. Actavis explains that it is essentially putting more meat on the bone with respect to its existing Section 35 defenses. Actavis concedes that it was aware that Celgene would claim the asserted claims are not obvious, but it didn't know *why* – i.e., the details – until Celgene's response was served. In light of Celgene's now complete articulation of why the subject claims are not obvious, it is reasonable for Actavis to seek to include additional details on their defenses relating to the subject.[2]

Third, with respect to Amendment 3, the parties dispute the facts and impact of the *Janssen* decision. A particular emphasis is placed on allegedly inconsistent arguments about the state of the law made by counsel who represents both Actavis in this case and

[2] Celgene contends that the amendment also seeks to reintroduce issues abandoned during claim construction meet-and-conferring. The Court has no real way of knowing whether that is the case. Thus far, the parties have advised the Court that claim construction is not necessary in this case. (*See* Joint Claim Construction and Prehearing Statement; ECF No. 52.) If this amendment changes that, it is an issue that the Court can address as part of case management.

Janssen in Massachusetts.[3] Of course, *Janssen* is not binding on this Court. Moreover, it appears from the vigor with which the parties dispute the issue and the meaning of *Janssen* decision, that the area of law is at least arguably not settled and currently before the Federal Circuit. This Court would not purport to settle it in the context of whether there is "good cause" for the amendments sought in this case. Reasonable minds can differ on the state of the law, and Actavis sought to amend based on a decision that supports it view and was published after its contentions were served. The Court finds that is sufficient good cause to seek leave to amend.

With respect to timeliness, the Court believes that all three amendments are timely. Any delay is from October 2016, when Celgene's response was served, to February 2017, when consent to the proposed amendments were sought. That is less than four months to review a 544 page response, investigate, prepare and serve amended contentions, all while complying with other deadlines in the scheduling order and in light of the practical delays of the Holiday season. In a case that is still in the early stages, the Court does not believe that Actavis delayed with respect to seeking amendment.

B. Undue Prejudice

In deciding whether Actavis's proposed amendments would prejudice Celgene, the Court considers whether the proposed amendments would: (1) require the opposing party

[3] Actavis's counsel essentially concedes that arguably different positions with respect to the state of the law on obviousness-type double patenting has been taken in the two cases.

to expend significant additional resources; or (2) significantly delay resolution of the dispute. *See, e.g.*, *TFH Publications v. Doskocil Mfg. Co.*, *Inc.*, 705 F. Supp. 2d 361, 366 (D.N.J. 2010).

Celgene claims it will be unduly prejudiced because it will have to spend time and resources to address new defenses and revised contentions, and would have to at a minimum amend its own contentions. It also argues that fact discovery will have to be extended and that an amendment would undermine the disclosure requirements of the Local Patent Rules.

There is no undue prejudice in this case for a number of reasons.

First, discovery is still in the early stages, despite the scheduling order. Fact depositions have not commenced, and document production just started. Opening expert reports are not due until August 31, 2017. There are also at least three additional discovery disputes being briefed, which will not be fully presented to the Court until the end of May. Therefore, an additional extension of fact discovery would likely be needed even if Actavis's motion to amend was denied.

Second, Celgene has not shown that it will be a large or disproportionately burdensome amount of time or money required to respond to the contentions; the fact that some additional work may be required does not constitute undue prejudice. *See, e.g.*, *AS Am., Inc. v. Masco Corp. of Ind.*, 2013 WL 4084237, at *3 (D.N.J. Aug. 13, 2013) ("[a]lthough defendant's amendment may require some additional work on plaintiff's part, the additional work is not significant or vexatious.").

Third, Actavis has stated that it has no objection to Celgene submitting amended responsive contentions.

Fourth, Actavis claims—and Celgene does not effectively challenge—that only minimal factual discovery would be needed, even on the new OTDP defense.

Fifth, there is no pending claim construction motion or dispositive motion that would impacted by the amendments and trial is far away. The amendment will not prolong the case.

Therefore, there is no undue prejudice to Celgene, and the amendment will be allowed.

CONCLUSION

For the reasons stated above, Actavis's motion for leave to amend its invalidity contentions is **GRANTED**.

s/Mark Falk
MARK FALK
United States Magistrate Judge

Dated: May 15, 2017