

**NOT FOR PUBLICATION****UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY****MICROSPHERIX LLC,****Plaintiff,**

v.

**MERCK SHARPE & DOHME CORP.,  
*et al.*,****Defendants.****Civil Action No. 17-3984 (CCC)****MEMORANDUM OPINION****FALK, U.S.M.J.**

This is a patent infringement case. Defendants (collectively referred to as “Merck”) market and sell an implantable progestin contraceptive under the trade name Nexplanon®. Plaintiff, Microspherix, contends Nexplanon infringes three patents: U.S. Patent No. 9,636,401; U.S. Patent No. 9,636,402; and U.S. Patent No. 8,821,835. Before the Court is Merck’s motion seeking to amend its invalidity contentions. The application is opposed. No argument is needed. *See* Fed. R. Civ. P. 78(b).

**Background**<sup>1</sup>

The initial complaint was filed on June 5, 2017. On August 7, 2018, the case was stayed pending *inter partes* review instituted against the asserted patents. The IPR proceedings concluded in August 2020, and the stay was lifted by Order entered on August 10, 2020. While the IPR proceedings were ongoing, an additional patent was issued to Microspherix – U.S. Patent No. 10,493,181.<sup>2</sup>

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<sup>1</sup> The parties are aware of the case’s full background. This section is limited to what is necessary to decide the motion. Information is drawn from the parties’ submissions; direct citations are at times omitted.

<sup>2</sup> When the stay was lifted, Defendants joined the newly issued ‘181 patent to this case through a counterclaim seeking a declaratory judgment of non-infringement. In October 2020, the parties filed a stipulation of dismissal as to this count, thereby removing the ‘181 patent from this case.

On August 17, 2020, Merck sent Plaintiff proposed amended invalidity contentions. After a back and forth about whether Plaintiff would consent to the amended contentions, Plaintiff declined to consent on February 19, 2021.

On March 5, 2021, Merck filed the present motion to amend. Its position is that the proposed amended contentions arise from: (1) a prior art search conducted in connection with the '181 patent issued during the pendency of the stay; and/or (2) Microspherix's § 112-related arguments put forth during the IPR proceedings. Merck contends the amendments are minor; discovery is still open; the case is still in the early stages; and that there is no discernable prejudice. Microspherix contends the amendments are untimely, "not important," and prejudicial.

### **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 good cause has been shown for the proposed amendments, and that none of the amendments will cause undue prejudice to Microspherix. As such, the motion is **GRANTED**.

### **i. Timeliness and Good Cause**

Merck claims their amendments are timely and good cause has been shown because: (1) with respect to the new prior art references, they fit within Rule 3.7(b) because they were uncovered by a search firm during the IPR-generated stay; and (2) with respect to the § 112 arguments, are the result of the IPR proceedings and arguments and positions taken therein.

Microspherix disputes what Merck could have previously uncovered with respect to the prior art references and claims that the Section 112 defenses do not really arise out of the IPR proceedings and should have been known earlier. Merck disagrees, noting that it retained a private search firm, both before prior versions of its invalidity contentions and now, and that this retention alone and the resulting discovery provide good cause under the rules. *See e.g., Uniloc USA, Inc. v. Apple, Inc.*, 2020 WL 3128908, at \*2 (N.D. Cal. June 12, 2020); *see also* L. Pat R. 3.7(b). The parties also engage in a back-and-forth about their communications after Merck raised the possibility of amending its contentions following the IPR. While they blame each other, the fact is these communications dragged on for months and delayed bringing the issue to a head.

What the Court is left with is essentially a dispute about which side delayed in pushing the amendment issue – as one side tells it, Merck let it slip for months; the other side contends Microspherix delayed and dragged feet on whether it would consent to a post-IPR amendment. Either way, what can't be disputed, is that Merck raised the issue of amendment very quickly after the IPR proceedings concluded – within a calendar week. Likewise, there is nothing in the record to refute Merck's positions that a patent issued during pendency of the IPR; that a search firm was retained as a result and uncovered additional prior art references while the IPR was ongoing; that a firm's late discovery of prior art can be good cause to amend contentions (*see* 3.7(b)); and that there was a fulsome IPR review that could reasonably be construed to provide a basis for

additional Section 112 positions. As such, the Court concludes that the concept of amending the contentions was raised in a timely fashion and that there is good cause to support the request.

**ii. Undue Prejudice**

In deciding whether Merck’s proposed amendments would prejudice Microspherix, the Court considers whether the amendments would (1) require the opposing party 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). Neither is an issue here.

Despite its age, the case is nowhere near motion practice or a trial. The case was stayed for two years while IPR proceeded. The jointly agreed-to case management schedule was limited to the early stages of the case and did not even contain a discovery end-date. It is not clear that much, if any, discovery has occurred. There are no dispositive motions pending. Claim construction has not occurred. Trial is not imminent. There is no 30-month stay that is involved in this case and no request for emergent or injunctive relief has been made. The only impact of the amendments would be perhaps a revising of certain claim construction submissions and a small amount of discovery. This does not rise to the level of prejudice or a “significant delay” that would materially alter when this case is reached. Moreover, no showing that the amendments would cause a dramatic increase in cost or expense has been shown.

For the reasons stated above, Merck’s motion to amend its invalidity contentions is **GRANTED**.

**SO ORDERED.**

**s/Mark Falk**  
**MARK FALK**  
**United States Magistrate Judge**

**Dated: June 28, 2021**