UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
(973) 776-7700

CHAMBERS OF
JAMES B. CLARK, III
UNITED STATES MAGISTRATE JUDGE

U.S. COURTHOUSE
50 WALNUT ST. ROOM 2060
NEWARK, NJ 07102

May 29, 2025

LETTER ORDER

Re: IBSA Institut Biochimique SA, et al. v. Accord Healthcare, Inc.
Civil Action No. 23-54 (SRC)

Dear Counsel,

Presently pending before the Court is a motion by Defendant Accord Healthcare, Inc. ("Accord" or "Defendant") seeking leave to amend its Invalidity and Non-Infringement Contentions. *See* Dkt. No. 95. Plaintiffs IBSA Institut Biochimique, SA, IBSA Pharma, Inc. and Altergon SA (collectively "IBSA" or "Plaintiffs") oppose Defendant's motion. *See* Dkt. No. 98. For the reasons set forth below, Accord's motion to amend [Dkt. No. 95] is **DENIED**.

IBSA's initial Complaint in this patent infringement action was filed on January 5, 2023 and asserts claims against Accord pursuant to 35 U.S.C. § 271 concerning Accord's submission of an abbreviated new drug application ("ANDA") seeking FDA approval to market a generic version of IBSA's product Tirosint® - SOL, which is used to treat patients with hypothyroidism. *See* Dkt. No. 1, Complaint. IBSA's initial Complaint alleged that Accord's ANDA submission infringed United States Patent Nos. 10,537,538 (the "'538 Patent") and 11,096,913 (the "'913 Patent"). *Id.* IBSA filed an Amended Complaint to add a claim for infringement of United States Patent No. 11,241,382 (the "'382 Patent") on April 19, 2024 following Accord's submission of a Paragraph IV certification against it on February 20, 2024. *See* Dkt. No. 51, Amended Complaint.

A Pretrial Scheduling Order, which set a deadline of June 14, 2023 for the service of Accord's invalidity and non-infringement contentions, was entered in this matter on May 15, 2023. *See* Dkt. No. 23. Following the filing of IBSA's Amended Complaint, the Court entered an Order extending and/or setting certain deadlines as necessitated by the addition of the '382 Patent. *See* Dkt. No. 56. As relevant to the present motion, the Court's May 7, 2024 Order required the service of Accord's invalidity and non-infringement contentions for the '382 Patent by May 20, 2024. *Id.*

The parties filed their opening *Markman* briefs on October 7, 2024, which sought claim construction of seven terms in the '382 Patent only. *See* Dkt. Nos. 71, 72. On October 17, 2024, IBSA filed a letter requesting leave, with Accord's consent, to amend their infringement contentions for the '382 Patent in light of Accord's revised proposed labeling for its ANDA product. *See* Dkt. No. 73. The Court granted Plaintiffs' request on October 18, 2024. *See* Dkt. No. 74. Shortly thereafter, on October 25, 2024, Accord filed a letter raising certain discovery disputes and notifying the Court of its intention to seek leave to amend its invalidity contentions to rely on certain prior art. *See* Dkt. No. 78. In response to Accord's letter, the Court entered an Order directing the parties to meet and confer regarding any outstanding discovery disputes and instructing Accord to file its motion to amend by November 22, 2024. *See* Dkt. No. 79. On November 20, 2024, the Court issued an Opinion and Order addressing claim construction. *See* Dkt. No. 91. Thereafter, the parties requested that Accord's deadline to file its motion to amend be extended to allow for limited document discovery. *See* Dkt. No. 92. The Court granted the parties' request [Dkt. No. 93] and Accord filed its present motion to amend on December 23, 2024 [Dkt. No. 95]. IBSA filed its opposition on January 6, 2025. *See* Dkt. No. 98. Accord did not file a reply.

Local Patent Rule 3.7 governs a party's request to amend contentions previously disclosed. It provides that "[a]mendment of any contentions, disclosures, or other documents required to be filed

or exchanged pursuant to these Local Patent Rules may be made *only* by order of the Court upon a timely application and showing of good cause." L. Pat. R. 3.7. The rule sets forth non-exhaustive examples of circumstances 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 search; (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contention; . . . and (e) consent by the parties in interest to the amendment and a showing that it will not lead to an enlargement of time or impact other scheduled deadlines . . . .

Id.

The party seeking the amendment bears the burden of demonstrating good cause for the amendment. *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006) ("The burden is on the movant to establish diligence rather than on the opposing party to establish a lack of diligence."). Whether to permit an amendment under Local Patent Rule 3.7 rests in this Court's sound discretion. *See, e.g.*, *Celgene Corp. v. Natco Pharma Ltd.*, Civ. No. 10-5197 (SDW), 2015 WL 4138982, at *3 (D.N.J. July 9, 2015).

Courts in this District have articulated various considerations in determining whether good cause for amendment exists under Local Patent Rule 3.7. "The key factor courts look at to determine whether good cause exists to grant an amendment to a contention is the diligence of the moving party." *Horizon Pharma AG v. Watson Lab'ys, Inc.-Fla.*, No. 13-5124, 2015 WL 12850575, at *2 (D.N.J. Feb. 24, 2015). Diligence "requires that a movant proceed both with diligence throughout discovery and in discovering the basis for the proposed amendment, as well as promptly moving to amend when new evidence is revealed in discovery." *Chiesi USA, Inc. v. Aurobindo Pharma USA, Inc.*, No. 19-18756,

2021 WL 6774679, at *5 (D.N.J. Mar. 26, 2021). "The latter requirement is consistent with the mandate of Local Patent Rule 3.7 that the motion be timely." *Id.* at *4. Additionally, courts consider: "(i) the reason for the delay, including whether it was within the reasonable control of the party responsible for it; (ii) the importance of what the court is excluding and the availability of lesser sanctions; (iii) the danger of unfair prejudice; and (iv) the availability of a continuance and the potential impact of a delay on judicial proceedings. *Id.* (citation omitted).

As is stated often in this context:

> 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 cases. The rules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed. Distinguishable from the liberal standard for amending the pleadings, the philosophy behind amending claim charts [and contentions] is decidedly conservative, and designed to prevent the "shifting sands" approach to claim construction. However, Rule 3.7 is not a straitjacket into which litigants are locked from the moment their contentions are served, but instead, a modest degree of flexibility [exists], at least near the outset. Therefore, while preliminary infringement contentions are still preliminary, it is important to recognize that the Local Patent Rules strive to have the parties establish their contentions early on.

King Pharms., Inc. v. Sandoz Inc., Civ. No. 08-5974 (GEB), 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (internal citations and quotation marks omitted).

Accord seeks to amend its invalidity and non-infringement contentions regarding the '382 Patent and its invalidity contentions regarding the '538 Patent and the '913 Patent. As to the '382 Patent, Accord seeks to amend its invalidity contentions to include "a late disclosed Italian-language reference, the TIROSINT® oral solution product label," and its invalidity and non-infringement contentions to include TIROSINT®-SOL, "a late disclosed commercial embodiment of the '382

Patent."[1] Dkt. No. 96 at p. 3-4.

TIROSINT® oral solution is an earlier generation of IBSA's levothyroxine products and a predecessor to the product at issue in this case, TIROSINT® - SOL. Dkt. No. 98 at p. 9. TIROSINT® oral solution contains 96% ethanol, an additive that is expressly excluded from the patents-in-suit, and has been sold in Italy since October 2011. *Id.*

Accord claims that it only became aware of the TIROSINT® oral solution product label when it was produced by IBSA on July 3, 2024. Dkt. No. 96 at p. 4. Following IBSA's production of the TIROSINT® oral solution product label on July 3, 2024, Accord notified IBSA of its intention to amend its invalidity contentions to rely on the label on September 10, 2024. *Id.* The parties subsequently engaged in meet-and-confers regarding Accord's desired amendments, and on October 18, 2024, IBSA informed Accord that it would not consent to Accord's proposed amendments. *Id.* Accord contends that it has been diligent in amending its contentions because "upon learning of this prior art formulation," it "promptly asked IBSA if it would consent to an amendment" and thereafter "was diligent in following-up with IBSA on its proposed amendments." *Id.* at p. 8.

In response, IBSA argues that Accord has not demonstrated good cause for the subject amendment because Accord was not diligent in identifying TIROSINT® oral solution as alleged prior art. Specifically, IBSA notes that TIROSINT® oral solution "has been on the market in Italy for nearly fifteen years" and "is mentioned throughout the prior art references that Accord cited in its First Notice Letter from more than two years ago . . . ." Dkt. No. 98 at p. 9. IBSA further contends that the TIROSINT® oral solution "product label is readily available to the public via a simple Google search, which is precisely how IBSA identified it, with only a moment's worth of effort." *Id.* at p. 10.

[1] The Court notes that while Accord's brief in support of its motion states that it seeks to use TIROSINT® oral solution only against the '382 Patent, Accord's proposed amended contentions for the '538 Patent and the '913 Patent also include new arguments based on TIROSINT® oral solution. *See* Dkt. No. 97-1, Ex. A at 8-9.

The Court agrees with IBSA that Accord has not demonstrated the requisite diligence. Accord argues it has been diligent in amending its contentions because it "promptly asked IBSA if it would consent to an amendment" and was "diligent in following-up with IBSA on its proposed amendments." Dkt. No. 96 at p. 8. However, "a party's diligence in amending its preliminary invalidity contentions upon finding new prior art is only one factor to consider; the Court also must address whether the party was diligent in discovering the basis for the proposed amendment." *Jazz Pharms., Inc. v. Roxane Lab'ys, Inc.*, No. CIV.A. 10-6108 ES, 2013 WL 785067, at *3 (D.N.J. Feb. 28, 2013) (citations omitted).

As to the second requirement, that Accord demonstrate its diligence in discovering the basis for the proposed amendment, Accord states only that "[n]othing in the disclosure of the asserted patents or the prior art cited on the face of the asserted patents suggests that an Italian government website would be a repository of potential prior art" and argues that while the product label in question is indeed publicly available, "every reasonable search must have a stopping point." Dkt. No. 96 at p. 4 (citations omitted). In the absence of any description by Accord of any search it conducted or argument regarding the diligence of any such search, and in light of the appearance of TIROSINT® oral solution in the public record of the prosecution histories of the '913 Patent and the '382 Patent, the prior art references relied on by Accord throughout this litigation, and the public availability of the product label via a simple search, the Court cannot find that Accord has demonstrated the requisite diligence in discovering the basis for the proposed amendment. *See Jazz Pharms., Inc. v. Roxane Lab'ys, Inc.*, No. 2:10-CV-06108 ES-CLW, 2012 WL 3133943, at *7 (D.N.J. July 30, 2012), *aff'd*, No. CIV.A. 10-6108 ES, 2013 WL 785067 (D.N.J. Feb. 28, 2013) (finding that a party seeking to amend to assert recently discovered prior art has an obligation to conduct a public search for all relevant prior art in a diligent manner).

In addition to TIROSINT® oral solution, Accord seeks to amend its invalidity and non-infringement contentions regarding the '382 Patent to include TIROSINT®-SOL, "a late disclosed commercial embodiment of the '382 Patent." Dkt. No. 96 at p. 4. Accord claims that its Interrogatory No. 2, which was served on IBSA on October 20, 2023, requested that IBSA "identify any formulations that were embodiments of the Patents-In-Suit and were publicly sold by IBSA." *Id.* IBSA responded to Accord's Interrogatory No. 2 on November 22, 2023 identifying TIROSINT®-SOL as a commercial embodiment of '538 Patent and the '913 Patent. *Id.* at p. 5. Thereafter, on April 19, 2024, IBSA filed its Amended Complaint which asserted the '382 Patent, and on October 7, 2024, IBSA filed its Opening Markman Brief in which IBSA "asserted for the first time that TIROSINT®-SOL is an embodiment of the claims of the '382 Patent." *Id.* at p. 9.

In response, IBSA argues that Accord's characterization of TIROSINT®-SOL as a "'late disclosed commercial embodiment' of the '382 [P]atent . . . is untenable" because TIROSINT®-SOL "is the very product at issue in this case . . . ." Dkt. No. 98 at p. 12. IBSA notes that the '382 Patent is listed in the Orange Book for TIROSINT®-SOL and "TIROSINT®-SOL is the product that Accord copied and applied for FDA approval to market before IBSA's patents covering it expire, thus inciting this lawsuit." *Id.* Additionally, IBSA contends that it specifically identified the use of TIROSINT®-SOL as an embodiment of the '382 Patent in both its January 16, 2024 letter concerning the revisions to the TIROSINT®-SOL label and corresponding addition of the '382 Patent to the Orange Book and its July 3, 2024 infringement contentions. *Id.* at p. 13.

Accord's arguments regarding its diligence in seeking to amend to rely on TIROSINT®-SOL are similar to those raised by Accord regarding TIROSINT® oral solution. Accord contends that IBSA only "recently disclosed" that TIROSINT®-SOL is an embodiment of the claims of the '382 Patent in its Opening Markman Brief and its supplemental response to Accord's Interrogatory No. 2 and

therefore that any delay is attributable to IBSA. Dkt. No. 96 at p. 9.

The Court finds Accord's assertion that it only became aware of TIROSINT®-SOL's relevance to this litigation upon receipt of IBSA's Opening Markman Brief and its supplemental response to Accord's Interrogatory No. 2 in October and November of 2024 to be implausible. Not only does Accord again fail to set forth any discussion regarding its diligence in discovering the information it now seeks to add, but as noted by IBSA, TIROSINT®-SOL is the very product at issue in this case. If Accord was indeed unaware of TIROSINT®-SOL's significance to this matter, that unawareness appears to have resulted from Accord's lack of diligence and not from IBSA's alleged "untimely" disclosure of "material prior art." Dkt. No. 96 at p. 9.

Having addressed Accord's requests to amend its contentions regarding the '382 Patent, the Court turns to Accord's request to amend its invalidity contentions regarding the '538 Patent and the '913 Patent to "include a late-disclosed document related to a commercial embodiment of the patents-in-suit," the TIROSINT® Capsule. Dkt. No. 96 at p. 6. Accord claims that on September 17, 2024, it requested that IBSA supplement its response to Accord's Interrogatory No. 2 to identify TIROSINT® Capsules as embodiments of the patents-in-suit. *Id.* IBSA purportedly "refused to provide the requested discovery, but instead produced [on October 15, 2024], for the first time, an excerpt of the NDA for TIROSINT® Capsules, to support its contention that it is not an embodiment of the claims." *Id.* at p. 7.

In response, IBSA argues that Accord seeks to amend based on "information that was publicly available and readily accessible to Accord for many years before this case began." Dkt. No. 98 at p. 15. Specifically, IBSA claims that TIROSINT® Capsules have been approved by the FDA and sold in the United States since October 2006 and that the TIROSINT® Capsule label "has been available publicly since then, is included in the '913 and '382 patent file histories, and is cited on the face of the

‘913 and ‘382 patents.” *Id.* IBSA further notes that Accord has been developing its own generic version of a “softgel capsule” and therefore “surely studied and analyzed TIROSINT® [Capsules] to understand the reference product and its composition” and that TIROSINT® Capsules are mentioned throughout prior art that Accord has cited from the outset of this case. *Id.* at p. 15-16. As to Accord’s assertion that the proposed amendments arise from the confidential document produced by IBSA on October 15, 2024, IBSA claims that Accord raised its proposed amendments related to TIROSINT® Capsules on September 10, 2024, more than a month prior to the production of the nonpublic document cited by Accord.

The Court again finds that Accord has failed to demonstrate the requisite diligence in pursuing the amendments it now seeks. While Accord contends that it was not aware of the significance of TIROSINT® Capsules until October 2024 when IBSA produced the non-public NDA document which provided information regarding the inner fill material for TIROSINT® Capsules, Accord raised its proposed TIROSINT® Capsule amendments to IBSA on September 10, 2024, more than a month prior to the production of the confidential document in question, and “the capsules, their ingredients, and the description of their contents as liquid have been public since October 13, 2006.” Dkt. No. 98 at p. 17.

Accord, for each of the foregoing amendments sought, argues that it acted diligently because it promptly sought to amend upon “learning of” the subject prior art formulations. Accord, however, fails to demonstrate that it acted with diligence in discovering the information it now seeks to add. The information Accord seeks to add was either readily available or known to Accord for a significant period of time prior to Accord seeking leave for the presently sought amendments. Accordingly, the Court finds that the Accord failed to act with or demonstrate the requisite diligence.

In addition to the foregoing amendments, Accord also seeks to add a sentence to its

noninfringement contentions for the '382 Patent based upon "the parties' differing proposed constructions of the claim terms and the Court's claim construction [O]rder . . . ." Dkt. No. 96 at p. 12. Accord, rather than attempting to "tie [its] proposed amendments . . . to any ruling by the District Court in its *Markman* opinion that was contrary to [Accord's] proposal or otherwise unexpected," appears to treat the Court's *Markman* Order as a "'free pass' to amend [their] contentions," which does not constitute good cause. *Razor USA*, 2022 WL 44627, at * (citing *Jazz Pharms., Inc. v. Roxane Labs.*, No. 10-6108, 2015 WL 3822210, at *2 (D.N.J. June 19, 2015)). Indeed, even "[t]hough a different claim construction by the Court *may* support a finding of good cause . . . [t]he moving party still has to show that it acted diligently to determine that the amendment was necessary." *Jazz Pharms., Inc.*, 2015 WL 3822210, at*2 (citing *Horizon Pharma AG v. Watson Labs., Inc.—FL,* No. 13–5124, D.E. No. 138 at 14 (D.N.J. Feb. 24, 2015)).

Here, Accord has failed to include any discussion regarding the particulars of the Court's *Markman* ruling or any explanation regarding how that ruling purportedly justifies the proposed amendment. Instead, without any elaboration, Accord simply states that "[t]he [C]ourt's construction of claim terms in an appropriate basis for amending contentions." Dkt. No. 96 at p. 12. In the absence of any explanation as to the justification for its proposed amendment, beyond impermissibly and conclusorily treating the Court's the *Markman* ruling as a "free pass," the Court cannot find that Accord has acted diligently.[2]

Although the Court finds that Accord has not demonstrated the requisite diligence and therefore denies its motion to amend, the Court will address Accord's assertions that the proposed amendments will not delay the case or cause undue prejudice. As to the undue prejudice prong, the

[2] Accord seeks two additional amendments which it discusses in a single paragraph in its supporting brief. *See* Dkt. No. 96 at p. 2. Accord states, without further discussion, that these amendments are based upon "the Court's claim construction of certain terms and the deposition testimony of [] IBSA's inventors." *Id.* In the absence of any argument set forth by Accord in support of these amendments, the Court denies Accord's request.

Federal Circuit has made it clear that the Court only needs to consider undue prejudice if the moving party's application was timely and satisfies the good cause requirement. *O2 Micro*, 467 F.3d at 1368. Courts in this district, however, have addressed this prong where the movant has proffered a reason, albeit unpersuasive, for the untimeliness of the application and/or failure to illustrate good cause. *See King*, 2010 WL 2015258, at *4. This Court must consider whether permitting the proposed amendments would significantly delay the resolution of the dispute. *Id.* at 5. In particular, the Court must look to the present stage of the litigation and the impact of permitting an amendment on the non-moving party's trial strategy. *Id.*

Curiously, Accord contends that its proposed amendments will not cause any delay in this case because "[e]xpert discovery has not yet commenced, there have been no expert depositions, and there no *Markman* hearing date or trial date." Dkt. No. 96 at p. 11. The Court, however, issued its *Markman* Order on November 20, 2024, more than a month before Accord filed the present motion, and this case is certainly no longer in its early stages.

"Regardless of motivation or purpose, it is apparent that [Accord] seeks to inject a significant swath of new issues, arguments, and theories into the case at the eleventh hour without providing a sufficient justification for having failed to do so earlier." *Cambria Co. LLC v. Hirsch Glass Corp.*, No. CV2110092MASJBD, 2023 WL 5939657, at *7 (D.N.J. Sept. 12, 2023) (internal citations omitted). Although the parties disagree as to the potential impact Accord's proposed amendments would have on the expediency of this matter, it is clear that injecting additional issues into this case at the present juncture would delay and complicate proceedings moving forward. Accord could have, with due diligence, included its proposed amendments far earlier in this litigation. Accordingly, Accord's motion to amend is **DENIED**.

IT IS SO ORDERED.

s/ James B. Clark, III
JAMES B. CLARK, III
United States Magistrate Judge