

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH IRELAND LIMITED;
BAUSCH HEALTH US, LLC; and
BAUSCH HEALTH AMERICAS INC.,

Plaintiffs,

v.

PADAGIS ISRAEL PHARMACEUTICALS
LIMITED; PADAGIS US LLC; and
PADAGIS LLC,

Defendants.

Civil Action No. 22-4248 (MCA) (AME)

JOINT PROPOSED DISCOVERY PLAN

Pursuant to Federal Rules of Civil Procedure 16 and 26(f) and Local Civil Rule 26.1(b), Plaintiffs Bausch Health Ireland Limited (“Bausch Ireland”), Bausch Health US, LLC (“Bausch US”), and Bausch Health Americas Inc. (“Bausch Americas”) (collectively, “Bausch” or “Plaintiffs”) and Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, “Padagis” or “Defendants”) have conferred and submit the following Joint Proposed Discovery Plan.

1. **Set forth the name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.**

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2. **Set forth a brief description of the case, including the causes of action and defenses asserted.**

This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and 21 U.S.C. § 355(j) (“the Hatch-Waxman Act”), filed by Bausch in response to Padagis’s filing of Abbreviated New Drug Application (“ANDA”) No. 215393 (“Padagis’s ANDA”) with the United States Food and Drug Administration (“FDA”).

Defendants are seeking approval from the FDA to commercially market a generic version (“Padagis’s ANDA Product”) of Bausch’s Arazlo® (tazarotene 0.045%) product prior to the expiration of U.S. Patent No. 11,311,482 (the “’482 patent”). The ’482 patent is assigned to Bausch Health Ireland Limited and currently expires on May 11, 2038.

This litigation was commenced following Bausch’s receipt of a notice letter dated May 12, 2022, in which Padagis stated that its ANDA contains a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the Padagis ANDA Product before the expiration of the ’482 patent, which is listed in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as “the Orange Book”) for Bausch’s Arazlo® product. The ’482 patent relates to, among other things, methods of treating acne vulgaris using topical pharmaceutical compositions containing 0.045% tazarotene.

In this litigation, Bausch asserts, *inter alia*, that the submission of Padagis’s ANDA infringes one or more valid claims of the ’482 patent. Padagis denies infringement of the ’482 patent and contends that the claims of the ’482 patent are invalid. There is no 30-month stay applicable to this litigation. ECF No. 32-1 at ¶¶ 1-4.

3. **Have settlement discussions taken place? Yes _____ No x**

(a) What was plaintiff’s last demand?

(1) Monetary demand: \$ N/A

(2) Non-monetary demand: N/A

(b) What was defendant’s last offer?

(1) Monetary offer: \$ N/A

(2) Non-monetary offer: N/A

4. **The parties [have x have not _____] met pursuant to Fed. R. Civ. P. 26(f).**

5. **The parties [have x have not] exchanged the information required by Fed. R. Civ. P. 26(a)(1). If not, state the reason therefor.**

The parties served their initial disclosures on the date set forth in Exhibit 1.

6. **Explain any problems in connection with completing the disclosures required by Fed R. Civ. P. 26(a)(1).**

As noted above, the parties have served their initial disclosures on the date set forth in Exhibit 1.

7. **The parties [have x have not] conducted discovery other than the above disclosures. If so, describe.**

Pursuant to the requirements of Local Patent Rule 3.6(a), Defendants have produced a copy of their ANDA as it existed on August 26, 2022. Otherwise, no discovery has occurred in this litigation.

8. **Proposed joint discovery plan:**

- (a) **Discovery is needed on the following subjects:**

The anticipated discovery needs of the parties at this time are stated without limiting the scope of information sought by the parties in discovery and without waiver of any party's right to object to any particular discovery request.

Plaintiffs and Defendants anticipate discovery relating to the claims and defenses in the parties' pleadings, including infringement/non-infringement and validity/invalidity of the '482 patent, as well as various related issues, claims, and affirmative defenses. For example, Plaintiffs expect to take discovery on Defendants' ANDA No. 215393 and correspondence with the FDA; research and development related to the topical 0.045% tazarotene lotion product described in ANDA No. 215393; and Defendants' contentions. Defendants expect to take discovery, for example, on Plaintiffs' research and development relating to the '482 patent and Arazlo®; Plaintiffs IND and NDA and correspondence with the FDA; and Plaintiffs' contentions.

- (b) **Discovery [should should not x] be conducted in phases or be limited to particular issues. Explain.**

The parties agree that discovery should not be conducted in phases, other than that fact discovery should conclude before expert discovery. The parties propose that discovery should proceed according to the schedule set forth in Exhibit 1.

- (c) **Proposed schedule:**

- (1) Fed. R. Civ. P. 26 Disclosures See Exhibit 1 .
- (2) E-Discovery conference pursuant to L. Civ. R. 26.1(d) November 22, 2022 .

- (3) Service of initial written discovery See Exhibit 1.
- (4) Maximum of 25 interrogatories by each side to each other side.
- (5) Maximum of 10 depositions to be taken by each side, including depositions of third parties deposed pursuant to subpoena.

Depositions taken pursuant to Fed. R. Civ. P. 30(b)(6) shall be counted as a single deposition, regardless of the number of witnesses designated to testify.

With respect to fact witnesses who are (i) designated by a party to provide testimony pursuant to Fed. R. Civ. P. 30(b)(6), or (ii) employees or former employees of a party that such party intends to call as a witness at trial, the parties will work together to have the depositions of those witnesses occur in the United States. The depositions will proceed according to the Federal Rules of Civil Procedure and applicable Local Civil Rules and practices. In the event that the depositions are to occur remotely, the parties will confer in good faith to determine mutually-agreeable remote deposition arrangements.

The parties agree to a 7-hour limit per witness unless that witness requires a translator, in which case the time limit will be extended to 14 hours.

- (6) Motions to amend or to add parties to be filed by See Exhibit 1.
- (7) Factual discovery to be completed by See Exhibit 1.
- (8) Plaintiff's expert report due on See Exhibit 1.
- (9) Defendant's expert report due on See Exhibit 1.
- (10) Expert depositions to be completed by See Exhibit 1.
- (11) Dispositive motions to be served within See Exhibit 1 days of completion of discovery.

(d) Set forth any special discovery mechanism or procedure requested.

The parties agree that a Discovery Confidentiality Order ("DCO") will be required in this action. The parties propose that the DCO be submitted according to the schedule set forth in Exhibit 1.

- (e) **A pretrial conference may take place on:** See Exhibit 1.
 - (f) **Trial date:** See Exhibit 1 (Jury Trial; x Non-Jury Trial).
9. **Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problems with out-of-state witnesses or documents, etc)?** Yes No x. If so, please explain.

10. **Do you anticipate any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced?**
Yes _____ No **x**.

If so, how will electronic discovery or data be disclosed or produced? Describe any agreements reached by the parties regarding same, including costs of discovery, production, related software, licensing agreements, etc.

11. **Do you anticipate entry of a Discovery Confidentiality Order? See L.Civ.R. 5.3(b) and Appendix S.**

The parties agree that a Discovery Confidentiality Order (“DCO”) will be required in this action. The parties propose that the DCO be submitted according to the schedule set forth in Exhibit 1.

12. **Do you anticipate any discovery problem(s) not listed above? Describe.**
Yes _____ No **x**.

13. **State whether this case is appropriate for voluntary arbitration (pursuant to Local Civil Rule 201.1 or otherwise) or mediation (pursuant to Local Civil Rule 301.1 or otherwise). If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition or dispositive motions, etc.).**

The parties do not believe that this case is appropriate for voluntary arbitration or mediation at this time. The parties are open to revisiting the appropriateness of voluntary arbitration or mediation after the close of discovery.

14. **Is this case appropriate for bifurcation? Yes _____ No **x****

15. **An interim status/settlement conference (with clients in attendance), should be held in _____.**

The parties do not believe scheduling of a status/settlement conference is necessary at this early stage of the litigation. The parties are open to revisiting the appropriateness of holding a status/settlement conference after the close of discovery.

16. **We [do _____ do not **x**] consent to the trial being conducted by a Magistrate Judge.**

17. **Identify any other issues to address at the Rule 16 Scheduling Conference.**

The parties do not foresee any other issues for discussion during the Rule 16 Scheduling Conference.

Respectfully submitted,

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EXHIBIT 1 – SCHEDULE

No.	Event	Date
1.	Service of Rule 26(a) Initial Disclosures	October 28, 2022
2.	Plaintiffs' Disclosure of Asserted Claims (L. Pat. R. 3.6(b))	November 15, 2022
3.	Submission of Proposed Discovery Confidentiality Order	November 18, 2022
4.	Defendants' Invalidity Contentions and attendant document production (L. Pat. R. 3.6(c)-(d))	December 22, 2022
5.	Defendants' Non-Infringement Contentions and attendant document production (L. Pat. R. 3.6(e)-(f))	December 22, 2022
6.	Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions and attendant document production (L. Pat. R. 3.6(g)-(h))	February 15, 2023
7.	Plaintiffs' Responses to Invalidity Contentions (L. Pat. R. 3.6(i))	February 15, 2023
8.	Exchange of Proposed Terms for Claim Construction (L. Pat. R. 4.1(a))	February 22, 2023
9.	Exchange of Preliminary Claim Construction and Extrinsic Evidence (L. Pat. R. 4.2(a)-(b))	March 6, 2023
10.	Identification of all intrinsic and extrinsic evidence that each party intends to rely on to oppose the other party's claim construction (L. Pat. R. 4.2(c))	March 17, 2023
11.	Submission of Joint Claim Construction and Prehearing Statement (L. Pat. R. 4.3)	March 24, 2023
12.	Deadline for Substantial Completion of Document Production	April 21, 2023
13.	Exchange of Opening Markman Briefs (L. Pat. R. 4.5(a))	April 26, 2023
14.	Deadline to seek leave to amend pleadings or to join new parties	May 3, 2023
15.	Completion of non-expert Claim Construction Discovery (L. Pat. R. 4.4)	May 10, 2023
16.	Completion of discovery from an expert who submitted a certification with Opening Markman Brief (L. Pat. R. 4.5(b))	May 17, 2023
17.	Exchange of Responsive Markman Briefs (L. Pat. R. 4.5(c))	June 9, 2023
18.	Submission of proposed schedule to Court for Claim Construction Hearing (L. Pat. R. 4.6)	June 13, 2023
19.	Claim Construction Hearing	Set by Court
20.	Deadline for disclosures related to advice of counsel defense (L. Pat. R. 3.8)	30 days after entry of Claim Construction Order
21.	Fact Discovery Deadline	July 14, 2023
22.	Exchange of opening expert reports	August 16, 2023
23.	Exchange of rebuttal expert reports	September 19, 2023
24.	Exchange of reply expert reports	October 13, 2023
25.	Expert discovery deadline, including depositions	November 10, 2023
26.	Deadline for filing dispositive motions	December 1, 2023
27.	Oppositions to dispositive motions	January 5, 2024
28.	Replies to dispositive motions	January 19, 2024
29.	Deadline for filing <i>Daubert</i> motions and motions-in-limine	TBD

No.	Event	Date
30.	Dispositive motion hearing	Set by Court (~2/2024)
31.	Joint Final Pretrial Order deadline	Set by Court (~2/2024)
32.	Final Pretrial Conference	Set by Court (~2/2024)
33.	Trial	Set by Court (~3/2024)