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August 31, 2023

**VIA ECF**

Honorable Madeline Cox Arleo, U.S.D.J.
United States District Court
District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

**Re: *Bausch Health Ireland Limited, et al. v. Padagis Israel Pharmaceuticals Ltd., et al.*, Civil Action No. 22-4248 (MCA) (AME)**

***Bausch Health Ireland Limited, et al. v. Padagis Israel Pharmaceuticals Ltd., et al.*, Civil Action No. 23-3393 (SRC) (CLW)**

Dear Judge Arleo:

This firm, together with McDermott Will & Emery LLP, represents Plaintiffs in the above-referenced actions. We write, jointly with counsel for Defendants, pursuant to Local Civil Rule 42.1, to respectfully request consolidation of Civil Action No. 22-4248 (the "'482 Patent Action"), currently pending before Your Honor, and Civil Action No. 23-3393 (the "'116 Patent Action"), currently pending before Judge Chesler, according to the terms of the proposed stipulation and order attached hereto. The parties are the same in both of these actions. Both cases are Hatch-Waxman cases involving the same branded product, Arazlo®, and the same Padagis ANDA product.

The parties take no position regarding who should preside over the consolidated action but offer the following information for the Court's consideration.

**Status of Pending Actions**

- The '482 Patent Action, filed June 24, 2022, is currently assigned to the Honorable Madeline Cox Arleo, U.S.D.J. and the Honorable André M. Espinosa, U.S.M.J. Fact discovery in the '482 Patent Action is currently set to end on September 13, 2023 (although this date is proposed to be modified in the attached proposed stipulation and order). Several discovery disputes are pending before Judge Espinosa (ECF Nos. 66 and 72). A motion for judgment on the pleadings is pending before Judge Arleo (ECF No. 73).

  The '116 Patent Action, filed June 21, 2023, is currently assigned to the Honorable Stanley R. Chesler, U.S.D.J. and the Honorable Cathy L. Waldor, U.S.M.J. Defendants' response to the Complaint in the '116 Patent Action is presently due to be filed September 20, 2023 (although this date is proposed to be modified in the attached proposed stipulation and



IPR2023-01114
Padagis v. Bausch
Bausch Ex. 2014

order). No substantive motions have been filed, and no court conferences have been held in the '116 Patent Action.

**Plaintiffs' Identification of Relationship to Other Cases and Adjudicated Patents and Response to Defendants' Statement**

- The '116 patent derives from the same provisional application, has the same earliest effective filing date, and has substantially similar specifications, as two of the asserted patents in *Bausch Health Ireland Limited, et al. v. Padagis Israel Pharmaceuticals Ltd., et al.*, Civil Action No. 20-5426 (SRC) (CLW) (the "Prior Action"), which involved the same parties. The Prior Action is now closed and concluded with a bench trial before the Honorable Stanley R. Chesler, U.S.D.J., resulting in a decision and judgment in December 2022. The products at issue in the Prior Action were Bryhali® and Duobrii®. The product at issue in the '482 Patent Action and the '116 Patent Action is Arazlo®.

- The '116 patent also derives from the same provisional application, has the same earliest effective filing date, and has substantially similar specifications, as several asserted patents in *Bausch Health Ireland Limited, et al. v. Taro Pharmaceutical Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW) and *Bausch Health Ireland Limited, et al. v. Taro Pharmaceutical Inc., et al.*, Civil Action No. 23-2684 (SRC) (CLW) (the "Taro Actions"), which are currently pending before the Honorable Stanley R. Chesler, U.S.D.J. and the Honorable Cathy L. Waldor, U.S.M.J. The product at issue in the Taro Actions is Duobrii®.

- The '482 patent does not derive from an application common to the asserted patents in the Prior Action. The '482 patent has a substantially different specification than the '116 patent and the asserted patents in the Prior Action, and has an effective filing date approximately two years after the effective filing date of the '116 patent and the asserted patents in the Prior Action and the Taro Actions.

- Defendants, for the first time in this letter, have expressed disagreement with Plaintiffs' Certification Pursuant to Local Civil Rules 11.2 and 40.1 filed in the '116 Patent Action. Plaintiffs, however, filed the Certification in compliance with recently amended Local Civil Rule 40.1(c), which requires counsel to, "at the time of filing the action, inform the Clerk" if the civil action "relates to any property included in a case already or previously pending in this Court" or "involves the validity or infringement of any patent … which is involved in a case already or previously pending in this Court." The rule further explains that, "[w]henever possible, such action shall be assigned to the same Judge to whom the pending or previously related action is or was assigned," which is presumably why the action was assigned to Judge Chesler even though Plaintiffs also identified the '482 Patent Action pending before Judge Arleo as a related case in their Certification due to the '482 Patent Action involving the same drug product Arazlo®. Contrary to Defendants' position

that Plaintiffs' Certification was improper, for the reasons already stated, the '116 patent relates to the patents identified in Plaintiffs' Certification, and Plaintiffs' Certification apprised the court of the relevant facts regarding the relationships amongst the various identified cases and patents. As to Defendants' statement regarding Plaintiffs not identifying the Taro Actions or Prior Action in their Local Civil Rule certification filed in the '482 Patent Action, the explanation for that is simple—as to the Taro Actions, at the time the '482 Patent action was filed, the Taro Actions had not even been filed yet, and as to the Prior Action, at the time the '482 Patent action was filed, Local Civil Rule 40.1 only required disclosure of cases "already pending" and was amended in December 2022 to also require disclosure of cases "previously pending."

**Defendants' Response and Identification of Information for the Court's Consideration**

Defendants disagree that Plaintiffs' statements above are necessary or appropriate; however, to ensure a more complete and accurate summary of the record, Defendants provide the following information omitted from Plaintiffs' statements above:

- In its 11.2 related case Certification for the '116 Patent Action, Bausch identified three cases: *Bausch Health Ireland Limited, et al. v. Padagis Israel Pharmaceuticals Ltd., et al.*, Civil Action No. 20-5426 (SRC) (CLW), *Bausch Health Ireland Limited, et al. v. Taro Pharmaceutical Inc., et al.*, Civil Action No. 22-4670 (SRC) (CLW) and *Bausch Health Ireland Limited, et al. v. Taro Pharmaceutical Inc., et al.*, Civil Action No. 23-2684 (SRC) (CLW). Defendants disagree that any of those three cases should have been identified in the 11.2 Certification under Local Rule 40.1(c) and notes that Plaintiffs did not identify any actions as related in its 11.2 Certification with its Complaint in the '482 Action. Defendants disagree with Plaintiffs' assertion that the '116 Action "relates to any property included" in Case Nos. 20-5426, 22-4670, or 23-2684, all of which involved different asserted patents and different accused products. *See* Local Rule 40.1(c). Defendants also disagree with Plaintiffs' assertion that the '116 Action "involves the validity or infringement of any patent . . . involved in" Case Nos. 20-5426, 22-4670, and 23-2684. *See id.* The validity or infringement of the patents asserted in the cases identified by Plaintiffs are not at-issue in the '116 Action, as none of those patents have been asserted by Plaintiffs in the '116 Action.

- The '482 patent and the '116 patent recite claims to a nearly identical topical pharmaceutical composition of the drug tazarotene, illustrated by the following chart:

| **'482 patent – Claim 11** | **'116 Patent – Claim 1** |
|---|---|
| 11. A method of treating acne vulgaris, the method comprising topically applying a pharmaceutical composition to an affected area of a body of a subject | 1. A pharmaceutical composition consisting essentially of: tazarotene, 0.045% w/w, diethyl sebacate, 2.97% w/w, |