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May 1, 2025

VIA ECF

Honorable J. Brendan Day, U.S.M.J.
United States District Court, District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

Re: *DUSA Pharmaceuticals, Inc., et al. v. Biofrontera Inc., et al.*
C.A. No.: 3:23-cv-20601(RK)(JBD)

Dear Judge Day:

This firm, together with Desmarais LLP, represents Plaintiffs, Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries, Ltd. (“Plaintiffs” or “Sun Pharma”). Pursuant to the Court’s Case Management Order, we write jointly with counsel for Biofrontera Inc. (“Defendant” or “BFRI”) to present disputes about the scope of discovery.

I. Topic: Whether and to What Extent Sun Pharma May Take Discovery of BFRI as to Alleged Off-Label Promotional Distribution of Ameluz

A. Plaintiffs’ Position

This is a continuation of a dispute the parties discussed with the Court at the February 25, 2025 hearing about the scope of discovery into alleged off-label promotion by BFRI. Sun Pharma’s First Amended Complaint asserts three causes of action against Defendants: (1) breach of an agreement not to engage in off-label promotion; (2) false advertising; and (3) deceptive and unfair trade practices. The First Amended Complaint includes examples of off-label promotion—readily available from public information—but the causes of action are not limited to such examples. *See, e.g.*, Dkt. 52 ¶¶ 58–65. Sun Pharma has sought narrow discovery into BFRI’s off-label promotion in the form of providing samples of its drug, Ameluz®, to healthcare providers who BFRI knew did not possess one of BFRI’s lamps, which are required under the FDA-approved use of Ameluz®. The purpose of such sampling is to get healthcare providers to buy Ameluz® even if the healthcare provider is a Sun Pharma customer and has only Sun Pharma’s lamps.

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Sun's Exhibit 1026

EX1026, Page 1



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Following the Court's guidance at the February 2025 hearing that Sun Pharma needed to "refine their requests to a scope that is much more limited than they currently are" (Dkt. 178 at 92:22–24), Sun Pharma twice narrowed its requests but BFRI rejected both on the basis that any discovery into sampling was off limits. BFRI's position is contrary to the Court's instructions at the February hearing that "I am not limiting the scope of relevant discovery solely to the two issues set forth in the complaint." (*Id.* at 93:17–18). Yet BFRI has continued to refuse to produce any documents responsive to Sun Pharma's requests for discovery beyond "promotional activities that go to one of the two topics" explicitly discussed in the First Amended Complaint, namely improper promotion of subclinical lesions and pre-cancerous/cancerous actinic keratosis (*see id.* at 31:22–33:16). Consequently, BFRI's production of documents responsive to RFP Nos. 1–11, 16–21, 25–26, 28–37, 73, and 79 and Interrogatory Nos. 6 and 14, served more than five months ago, remains deficient.

Background.

Since the February 2025 hearing, Sun Pharma has worked earnestly and in good faith to narrow its requests for production and interrogatories. For example, on March 10, two days before this Court even entered its Order memorializing its rulings, Sun Pharma provided the following proposal for RFP Nos. 1–11, 16–21, 25–26, 28–37, 73, and 79 and Interrogatory Nos. 6 and 14:

BFRI shall produce documents regarding BFRI's marketing, advertising, sales, and promotional materials to doctors that BFRI knows, has reason to believe, or understands do not have a RhodoLED or RhodoLED XL light.

See Ex. 1 (Email from Sun Pharma to BFRI Dated March 10, 2025). Sun Pharma's proposal targets specific information and is significantly narrower than some of Sun Pharma's initial requests. *Cf.* Ex. 2 at 10 (RFP No. 79, seeking "[d]ocuments sufficient to identify Biofrontera's target audience for any promotional statement made by Biofrontera referring or relating to the Biofrontera PDT Products"). Yet BFRI wholesale rejected Sun Pharma's proposal without even attempting to provide any counterproposal or compromise language. Ex. 3 (Email from BFRI to Sun Pharma Dated March 12, 2025). Despite BFRI's wholesale refusal to engage, Sun Pharma further revised in yet another attempt to reach a compromise:

BFRI shall produce documents regarding BFRI's marketing, advertising, promoting, and selling of Ameluz to doctors that BFRI knows, has reason to believe, or understands do not possess a BF-RhodoLED or RhodoLED XL illuminator and instead possess a photodynamic therapy illuminator other than a BF-RhodoLED or RhodoLED XL illuminator.

Ex. 4 at 4 (Letter from Sun Pharma to BFRI Dated March 19, 2025). BFRI took nearly a week to then reject this proposal out of hand as well, again refusing to make any effort to reach a



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compromise. Ex. 5 at 3–4 (Letter from BFRI to Sun Pharma Dated March 25, 2025). BFRI alleged that Sun Pharma’s proposal is an “improper expansion of discovery” into subject matter for which Sun Pharma purportedly did not follow the parties’ dispute resolution process under the Settlement Agreement. *Id.* Sun Pharma put BFRI on notice of breach in March 2025, but BFRI has failed to cure its improper promotional activities, including sampling.

BFRI is also continuing to use this dispute as a basis for refusing to produce responsive ESI. Sun Pharma served its first set of non-email ESI requests on October 10, 2024. Nearly **six months later**, BFRI confirmed that it is and will continue to withhold documents that “(i) relate to the provisioning of Ameluz samples by Biofrontera Inc. to healthcare providers, which is not within the scope of the instant lawsuit, and (ii) do not otherwise relate to any of the statements identified in Sun Pharma’s First Amended Complaint.” Ex. 6 (Email from BFRI to Sun Pharma Dated April 3, 2025). The parties met and conferred again on April 4, 2025, but BFRI continued to refuse to engage and later confirmed that the parties are at an impasse. *See* Ex. 7 (Email from BFRI to Sun Pharma Dated April 7, 2025). BFRI admitted that it withheld only 58 non-email ESI documents, but if that is the full extent of BFRI’s responsive information, it only demonstrates that production of this non-email ESI is not burdensome. *Id.*

Argument.

The Federal Rules of Civil Procedure permit parties to “obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense” Fed. R. Civ. P. 26(b)(1). While Sun Pharma’s First Amended Complaint identifies specific factual examples of BFRI’s unlawful promotional statements, courts do not limit discovery “to issues raised by the pleadings, for discovery itself is designed to help define and clarify the issues.” *See, e.g., Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978); *Unlimited Pins LLC v. Schenk, Price, Smith & King, LLP*, 2024 WL 4182547, at *3 (D.N.J. Sept. 12, 2024) (finding that the relevance of interrogatories did not depend “on their relationship to specific allegations in the Complaint”); *Cement Masons’ Union Loc. No. 592 Pension Fund v. Almand Bros. Concrete, Inc.*, 2015 WL 3604747, at *6 (D.N.J. June 8, 2015) (declining to limit discovery to a statute of limitations issue and stating that discovery is “not limited to issues raised by the pleadings”).

Sun Pharma’s requests are narrowly tailored to a specific form of off-label promotion, in line with the Court’s guidance on narrowing, and BFRI has never identified any significant burden or prejudice associated with responding to Sun Pharma’s narrowed requests. [REDACTED]

[REDACTED] The Court should order BFRI to respond to Sun Pharma’s narrowed requests and reasonably tailored search terms on the same topic in ESI discovery.



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First, Sun Pharma seeks discovery that is squarely within the scope of the claims in the First Amended Complaint, which is centered on off-label promotion. There is no dispute that the label for Ameluz® is limited to use in combination with the BF-RhodoLED or RhodoLED XL illuminator. (See Dkt. 52, Ex. C). The label does not permit the use of Ameluz® with other illuminators. Improper promotional activities of Ameluz® to customers who use other illuminators falls squarely within Sun Pharma's breach of contract, false advertising, and unfair competition claims: it relates to the same products, by the same actor, and to the same harm as the specific examples of off-label promotion identified in the First Amended Complaint.¹

Moreover, given BFRI contends it has not ever engaged in such activity, it has not and cannot argue that responding to Sun Pharma's requests imposes a significant burden. In any case, BFRI has had months since the February hearing to work cooperatively with Sun Pharma to narrow the scope of discovery on that issue—but not to zero, as BFRI wishes—and should not be rewarded for failing to do so.

See *Daily Palm, LLC v. Bird Rides, Inc.*, 2021 WL 6496853, at *1 (C.D. Cal. Oct. 18, 2021) (“Discovery is not to be denied because it relates to a claim or defense that is being challenged as insufficient.” (quoting 8 Wright, Miller & Marcus, Federal Practice & Procedure § 2008 (3d ed. 2010))); see also *Black-Meadows v. Deptford Twp.*, 2022 WL 16695191, at *4 (D.N.J. Nov. 3, 2022) (“Discovery is just that – the opportunity to *discover* whether evidence will support or disprove a claim.”). In *Daily Palm*, the defendant opposed discovery related to valuation because it challenged “the legal and factual viability” of the plaintiff’s copyright infringement claim. 2021 WL 6496853, at *1. The court held that “[s]uch challenges to the viability of Plaintiff’s claim do not affect the proper scope of discovery.” *Id.* Similarly, BFRI cannot use a defense as a way to unilaterally relieve itself of any obligation to produce responsive documents in this case.

Even if BFRI's arguments ██████████ had any merit—they do not—they would only relate to Plaintiffs' breach of contract claim, not Plaintiffs' false

¹ If BFRI insists that Sun Pharma must amend its complaint, and will not oppose Sun Pharma seeking leave to do so, Sun is willing to file an amended complaint. BFRI would suffer no prejudice because: (i) Sun has already served its discovery requests relating to the issue; (ii) Biofrontera has already identified relevant documents—those that it is withholding based on this dispute—so BFRI’s to produce such documents should be minimal; (iii) no depositions have occurred; and (iv) no deadlines beyond close of fact discovery has been set. Indeed, Biofrontera’s request to prolong discovery indefinitely—if granted—would further eliminate or minimize prejudice, if any.



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advertising or unfair competition claims, both of which are broad and independent of the breach of contract claim. *See, e.g., McCabe v. Ford Motor Co.*, 720 F. Supp. 3d 14, 31 (D. Mass. 2024) (stating that Massachusetts General Laws Chapter 93A, which Sun Pharma’s deceptive and unfair trade practices claim is based on, is “extremely broad”); *see also Butler v. Sigma-Aldrich, Inc.*, 2006 WL 8458677, at *5 (D. Mass. Aug. 31, 2006) (“[T]he Massachusetts Supreme Judicial Court has interpreted the scope of Chapter 93A extremely broadly.”).

BFRI argues that “Sun Pharma expressly elected not to pursue in litigation and to leave out of the Amended Complaint.” But BFRI neglects that Sun Pharma decided not to pursue the improper sampling claims in litigation based on BFRI’s representations that it had cured such practices. Now, over the course of this litigation, Sun Pharma has uncovered new evidence that BFRI has not cured its breach, but has instead continued its improper promotional practices, including sampling, with respect to Ameluz®. [REDACTED]

[REDACTED]. Sun Pharma should be permitted to obtain discovery regarding such allegations of sampling, which fall within the scope of Sun Pharma’s claims in the First Amended Complaint.²

Plaintiffs therefore ask that the Court adopt Sun Pharma’s proposal for narrowing the scope of discovery. BFRI should be ordered to: (1) produce documents responsive to RFP Nos. 1–11, 16–21, 25–26, 28–37, 73, and 79 in accordance with Sun Pharma’s March 19 proposal (*see* Ex. 4); (2) respond to Interrogatory Nos. 6 and 14 in accordance with Sun Pharma’s March 19 proposal (*see* Ex. 4); and (3) produce responsive non-email and email ESI pursuant to the discovery plan’s process for term-searching custodians without withholding documents that relate to the selling or sampling of Ameluz® to healthcare providers.

B. Defendant Biofrontera Inc.’s Position

In its March 12 Order (Dkt. 177), this Court found that Sun Pharma’s “discovery requests are overbroad,” and ordered *Sun Pharma* to “substantially narrow its requests for production and

² Evidence of sales of Ameluz® to customers who do not possess a BF-RhodoLED® or RhodoLED® XL is also probative of which customers BFRI provided samples of Ameluz, knowing that they did not possess a Biofrontera lamp. BFRI’s sales of Ameluz® to providers without Biofrontera lamps is also probative to the calculation of damages that resulted from its improper sampling. BFRI’s argument about preemption misses the point entirely by focusing on whether the sales themselves are illegal under the FDCA.



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interrogatories . . .” Dkt. 177 at 3. Despite this finding, Sun Pharma now returns to the Court again to compel discovery into completely different claims from those pleaded in the First Amended Complaint (Dkt. 52). The Court should reject Sun Pharma’s continued pursuit of this discovery and its purported “narrowing” proposal, for at least two reasons. First, Sun Pharma is now seeking discovery into the *sales* of Ameluz® to customers who do not own a BF-RhodoLED lamp in an effort to support a claim that such *sales* are unlawful. Yet “selling” is *not* marketing or promotion, and therefore it has no relevance to any of Sun Pharma’s causes of action in this case, all of which focus on specific promotional activities. It is a broadening proposal, not a narrowing one. Moreover, any attempted claim based on such sales is within the exclusive province of the Food & Drug Administration, meaning that Sun Pharma has no standing to bring it and it is precluded and/or preempted. Second, as to “BFRI’s marketing, advertising, [and] promoting,” Sun Pharma’s proposal seeks discovery into sampling issues that (i) Sun Pharma agreed pre-suit that BFRI had properly addressed and cured; (ii) Sun Pharma purposefully and correctly omitted from the scope of the Amended Complaint altogether; (iii) Sun Pharma has acknowledged fall outside of the Amended Complaint as evidenced by its recent efforts to re-initiate the mandatory pre-suit resolution process with respect thereto; and (iv) BFRI identified as particularly improper discovery during the February 25, 2025 hearing. *See* Dkt. 178 at 52:4-53:4; Dkt, 152. Sun Pharma’s allegation that BFRI has not in fact cured—based on a single email from one Sun Pharma employee to another, reciting hearsay—is false.

As to the first point (sales), Sun Pharma now seeks “documents regarding BFRI’s marketing, advertising, promoting, **and selling** of Ameluz to doctors . . .” Yet the issue of whether BFRI *sells* AMELUZ to healthcare providers, who may then elect to use it off-label, is irrelevant to any of Sun Pharma’s causes of action. As to Count I (breach of contract), [REDACTED]

[REDACTED] Likewise as to Count II, the Lanham Act’s false advertising provision only applies to “commercial advertising or promotion.” 15 U.S.C. § 1125(a)(1)(B). This provision does not apply to sales transactions. *See GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, No. CV 13-726, 2015 WL 12803588, at *1 (E.D. Pa. Apr. 10, 2015) (“Second, while Plaintiff’s illegal acts concerned off-label promotion, off-label sales are not illegal”). The same is true of Massachusetts’ Chapter 93A, which has the same elements as a false advertising claim under the Lanham Act. Dkt. 124 at 5, n.1.

Accordingly, even on Sun Pharma’s improperly broad reading that the Amended Complaint covers all promotional activities, when in reality it only covers two specific instances of alleged promotional statements (involving subclinical AKs and potential cancer progression of untreated AKs), discovery specifically into BFRI’s sales of Ameluz® to customers who do not own a BF-RhodoLED lamp is wholly irrelevant. Nor can Sun Pharma make any argument that the sought-after discovery is relevant to damages on its existing claims, as BFRI has already produced complete sales data for all of its sales of Ameluz®, collectively, irrespective of lamp ownership. What Sun Pharma unabashedly seeks instead is a fishing expedition into an unpleaded claim.



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Worse still, Sun Pharma cannot legally plead such a claim or pursue discovery in support of it, because any cause of action based on the sales of Ameluz® is precluded and/or preempted by the FDCA and Sun Pharma has no standing to bring it. See *Argueta v. Walgreens Co.*, No. 1:24-CV-00072-JLT-CDB, 2024 WL 5186825, at *6 (E.D. Cal. Dec. 20, 2024) (claims based on sales of FDA-regulated drug preempted by FDCA); *Novo Nordisk Inc. v. WELLHealth Inc.*, No. 3:23-CV-782-ACC-LLL, 2025 WL 699769, at *5 (M.D. Fla. Jan. 30, 2025) (finding “the existence of the FDCA is a critical element of Count I (‘Sale of New Drug Without Approval’), and the claim is impliedly preempted”); *Autin v. Solvay Pharms., Inc.*, No. 05-2213 MA/AN, 2006 WL 889423, at *4 (W.D. Tenn. Mar. 31, 2006) (“Plaintiffs’ Illegal Sales Theory is premised on the fact that Estratest cannot legally be sold because it does not qualify for the GRASE exception and has not been approved by the FDA”). While the Court’s order denying BFRI’s motion to dismiss relied on the Supreme Court’s decision in *POM Wonderful*, that decision involved commercial advertising under the Lanham Act, not sales activity that falls within the exclusive province of the FDA. Dkt. 124 at 6-7.

As to the second point (promotion), Sun Pharma's proposal seeks discovery into information concerning alleged "off-label" promotion of Ameluz® for use with blue light [REDACTED]

S.



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The promotional activities alleged in the Amended Complaint, which are limited to statements involving subclinical AKs and the potential cancer progression of untreated AKs, are the only claims [REDACTED]

[REDACTED] that can properly be pursued in the instant lawsuit and any corresponding discovery efforts. Sun Pharma's attempt to expand the scope of discovery to encompass entirely different subject matter [REDACTED]

.⁴

Sun Pharma's citations to *Daily Palm* and *Black-Meadows* are inapposite. In *Daily Palm*, the court permitted discovery into the defendant's financial valuations to support the plaintiff's pleaded claim for disgorgement of profits. 2021 WL 6496853, at *1. And in *Black-Meadows*, the court permitted discovery into a police department's internal affairs files to support the plaintiff's pleaded claim against the municipality based on an allegedly unconstitutional policy regarding excessive force. 2022 WL 16695191, at *3-4. In each instance, the claims were properly pleaded and the requested discovery related to "issues that are necessarily being litigated." *Id.* at *4. The opposite is true here. The issues into which Sun Pharma seeks discovery are neither within the scope of the pleadings nor are they necessarily being litigated as part of the pleaded claims. To the contrary, the discovery Sun Pharma seeks pertain to claims that it [REDACTED]

[REDACTED] intentionally omitted from the Amended Complaint altogether. Sun Pharma has not identified and cannot identify any authority supporting the discovery it seeks under these circumstances.

In sum, the Court should reject Sun Pharma's attempt to improperly expand the scope of this litigation though an abuse of the discovery process. *See Cooper Health Sys. v. Virtua Health, Inc.*, No. CV 09-735(RMB/JS), 2009 WL 10727974, at *3 (D.N.J. July 1, 2009) ("Discovery should not serve as a fishing expedition during which a party searches for evidence to support facts not yet pleaded.")⁵

⁴ Sun Pharma argues that the Settlement Agreement only applies to its breach of contract claim, and not its Lanham Act or state law claims. This is a distinction without a difference. All of Sun Pharma's legal theories are based on the same underlying factual allegation—that BFRI has engaged in off-label promotion as relates to statements regarding subclinical AKs and cancer progression.

⁵ Sun Pharma added Footnotes 1 and 2 to its portion of this dispute letter at 10:24 pm this evening, May 1. The arguments presented in those footnotes are new, have not been advanced in the parties' meet-and-confers and should be ignored accordingly as an abuse of the discovery process. Further, as to Footnote 1, BFRI would oppose any motion to amend the First Amended Complaint should Sun Pharma file one. BFRI will brief why Sun Pharma should not be granted leave if and when that issue is presented. Should such leave be sought, BFRI must also consider moving to amend its counterclaims to include, inter alia, an antitrust claim within the sham



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II. Topic: Fact Depositions of Drs. Pariser and Goldberg

A. Plaintiffs' Position

BFRI has unambiguously stated that it “intend[s] for Drs. Pariser and Goldberg to serve as both expert and fact witnesses.” Ex. 11 (Email from BFRI to Sun Pharma Dated April 15, 2025). BFRI does not dispute that Sun Pharma should be entitled to depose the doctors in both capacities, but BFRI insists that Sun Pharma cannot take fact depositions of the doctors until the expert discovery period. *Id.*

Drs. Pariser and Goldberg are not ordinary experts. Indeed, BFRI has disclosed five experts under the Confidentiality Order in this case, but only Drs. Pariser and Goldberg are identified on BFRI’s 26(a) disclosures. Documents produced by BFRI reveal the extent to which each doctor is likely knowledgeable of facts related to the issues in this case.

Dr. Goldberg’s name appears in 69 documents produced by BFRI, and the name of his dermatology practice appears on 203 documents.⁶ He has been identified as one of BFRI’s “[REDACTED]—influential physicians that BFRI “leverage[es] . . . in order to educate the market on the use and benefits of Ameluz® PDT.” See Ex. 12 (BFRI spreadsheet entitled “[REDACTED] produced as BFRI0000174); Ex. 13 (BFRI’s 2023 10-K, produced as BFRI0047418). Dr. Goldberg has personally participated in [REDACTED]. See, e.g., Ex. 14 (BFRI slide deck, produced as BFRI0129996) at _008-024; Ex. 15 (BFRI slide deck, produced as BFRI0128679) at _681–683. [REDACTED]. Ex. 16 (BFRI slide deck, produced as BFRI0058638) at _644.

Dr. Pariser’s ties run even deeper. His name appears in 100 documents produced by BFRI and the name of his dermatology practice appears on 455 documents.⁷ In 2022, [REDACTED]. Ex. 17 (BFRI spreadsheet, produced as

litigation exception, given the utter baselessness of Sun Pharma’s sampling allegations and the bad faith basis on which they are made, on top of the baseless, bad-faith allegations already asserted in the First Amended Complaint. As to Footnote 2, neither eleventh-hour argument made by Sun Pharma makes sense. Both arguments are doomed by the indisputable fact that whether a customer purchased Ameluz® says nothing about whether such customer received samples, as they are two totally separate activities. And both arguments improperly assume that Sun Pharma has asserted a claim for improper sampling in this case, when it indisputably has not.

⁶ Using “David w/3 Goldberg” and “Schweiger,” respectively, as the search strings.

⁷ Using “David w/3 Pariser” and “Pariser,” respectively, as the search strings.



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BFRI0050701). [REDACTED]

[REDACTED] See, e.g., Ex. 18 (BFRI clinical trial protocol, produced as BFRI0155710) at _710; Ex. 19 (BFRI's 2024 10-K) (indicating that the "[s]uperficial basal cell carcinoma" clinical trial is in the "approval process"). And like Dr. Goldberg, Dr. Pariser is also one of Biofrontera's [REDACTED]. Ex. 12 (BFRI0000174).

BFRI cannot be allowed to deprive Sun Pharma of **discovering facts** from people BFRI has stated are **fact witnesses** during **fact discovery**.

First, deposing Drs. Pariser and Goldberg during fact discovery is necessary because both parties' experts must be in possession of and allowed to consider the same set of facts when they prepare their initial expert reports. BFRI's proposed solution is that it "will consider permitting Sun Pharma's experts to supplement their opinions to respond to any fact testimony that arose in the reports or depositions of Drs. Pariser or Goldberg." Ex. 20 (Email from BFRI to Sun Pharma Dated April 25, 2025). But there is a reason that courts sequence fact discovery before expert discovery; supplementation cannot ameliorate the prejudice Sun Pharma will suffer if its experts are forced to opine on an incomplete record and its counsel learns only too late about facts that could have led it in various directions during fact discovery (e.g., exploring topics and facts stated by one witness when deposing other witnesses). Recognizing this prejudice, this Court has precluded, under Rule 37(c)(1), a party's expert from testifying where the expert relied on facts not disclosed during fact discovery. *Allstate Life Ins. Co. v. Stillwell*, 2020 WL 832898, at *7 (D.N.J. Feb. 20, 2020) ("While Defendants' expert may be able to address Mr. Spadea's opinions using the information included in the Spadea Report, that does not change the fact that Defendants were denied timely access to this information and the ability to obtain discovery on it.").

Second, federal courts routinely permit individuals with dual roles as both fact and expert witnesses to be deposed twice: once as a fact witness during fact discovery, and once as an expert witness during expert discovery. See, e.g., *Siegman v. Schneider Elec. United States*, 2017 WL 5513190, at *2 n.3 (D.N.J. Nov. 17, 2017) ("Mr. Antweiler was deposed twice, once on May 18, 2016 as a fact witness, and then again on February 14, 2017 as an expert witness."); *Winters v. Ocean Spray Cranberries, Inc.*, No. 12-12016-RWZ, Dkt. 352 (D. Mass. Oct. 22, 2019) ("Although Dr. Miller is Ocean Spray's designated expert, he is the so-called 'architect' of the challenged auction and thus may possess relevant information concerning those facts. Accordingly, plaintiffs may depose him as a fact witness.") (granting plaintiff's motion to compel designated expert's deposition during fact discovery) (internal citation omitted); *Meyer v. Delaware Valley Lift Truck, Inc.*, No. CV 18-1118, 2019 WL 2903666, at *2 (E.D. Pa. July 5, 2019) ("To the extent that the facts about which Jim will question McGuckin stem from McGuckin's personal knowledge . . . deposing him during fact discovery is appropriate."); *Res. Investments, Inc. v. United States*, 93 Fed. Cl. 373, 376 (Fed. Cl. 2010) ("Defendant twice deposed Barrows, first in Barrows's capacity as a fact witness in October 1999, then in his capacity as an expert witness in May 2000.") (internal citation omitted).



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Finally, the necessity and burden of repeat depositions of Drs. Pariser and Goldberg is a result of BFRI's choice in disclosing its experts as fact witnesses, not any act of Sun Pharma. Thus, to the extent that BFRI complains that it would be "burdensome" for Drs. Pariser and Goldberg to sit for a deposition during fact discovery, it would certainly be more unfair to require Sun Pharma to shoulder the burden of preparing supplemental expert reports and curtailing its ability to discovery all relevant facts during fact discovery.

To the extent that the Court permits Sun Pharma to depose Drs. Pariser and Goldberg during fact discovery, the Court should also recognize that good cause exists for Sun Pharma to conduct two depositions in excess of the 10-deposition limit as set forth in the parties' Joint Discovery Plan. Dkt. 84 at 10. Sun Pharma has good cause for this request because, at the time it agreed to the 10-deposition limit, BFRI did not disclose that it would designate its experts as fact witnesses.

Accordingly, the Court should permit Sun Pharma to depose BFRI's experts, Dr. David Pariser and Dr. David Goldberg, during fact discovery.

B. Defendant Biofrontera Inc.'s Position

Sun Pharma's motion is based on a misunderstanding of the roles of Drs. Pariser and Goldberg in this case. As this Court is already aware, BFRI disclosed both individuals as *expert* witnesses on December 11, 2024. See Dkt. 145 at 1-2. BFRI does not deny that Drs. Pariser and Goldberg both have personal knowledge of the parties' PDT treatments at issue in this case based on their own experience as practitioners. Indeed, [REDACTED]. This is unremarkable. Under FRE 703, "[a]n expert may base his opinion on facts that the expert has been made aware of or personally observed." *UPMC v. CBIZ, Inc.*, No. 3:16-CV-204, 2020 WL 2736691, at *7 (W.D. Pa. May 26, 2020). Consistent with FRCP 26(a)(2), BFRI will disclose the expert opinions of Drs. Pariser and Goldberg in their forthcoming expert reports, along with all of the facts and data upon which they rely (including their personal knowledge). Out of an abundance of caution, BFRI chose to list Drs. Pariser and Goldberg on its initial disclosures in the event that Sun Pharma later seeks to exclude portions of their expert opinions in whole or in part, including without limitation on the grounds of improper fact testimony by an expert.

The sole basis for Sun Pharma's insistence that it should be allowed to take two depositions apiece of Drs. Pariser and Goldberg is that "both parties' experts must be in possession of and allowed to consider the same set of facts when they prepare their initial expert reports." But that risk is not presented here, since all of the documents and witnesses that Drs. Pariser and Goldberg will rely on for their expert opinions will be disclosed during fact discovery. That makes *Allstate Life* inapposite. In *Allstate Life*, the court found that Allstate had failed to comply with Rule 26(a) because its expert relied on (1) conversations with individuals who were not disclosed during fact



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discovery, (2) documents that were not produced during fact discovery, and (3) a damages theory that was not included in Allstate's initial disclosures. *Allstate Life Ins. Co. v. Stillwell*, No. CV 15-8251 (AET), 2020 WL 832898, at *4-5 (D.N.J. Feb. 20, 2020). None of those issues apply here.

Furthermore, the Court can readily adopt an expert discovery schedule that permits the parties to submit a round of rebuttal reports, which would allow Sun Pharma's experts to respond to any alleged "fact testimony" in the reports of Drs. Pariser and Goldberg. And Sun Pharma will be able to probe any alleged "fact testimony" during the expert deposition period. These are routine occurrences in litigation, not the "burden" that Sun Pharma claims. To permit Sun Pharma to probe the expert opinions of Drs. Pariser and Goldberg before they have submitted their reports would be improper and prejudicial to BFRI. See *MSP Recovery Claims, Series, LLC v. Sanofi-Aventis U.S. LLC*, No. 218CV2211BRMLHG, 2022 WL 20359241, at *18 (D.N.J. Feb. 8, 2022) (denying motion to compel discovery responses where the answers sought were the subject of expert testimony and expert reports had not yet been served). Delaying the depositions of Drs. Pariser and Goldberg until after they serve their reports would also avoid "the needless expense of having two separate depositions." *Jowite Ltd. P'ship v. Fed. Ins. Co.*, No. CV SAG-18-2413, 2019 WL 1513457, at *4 (D. Md. Apr. 8, 2019); see also *Hudson v. ArcelorMittal Burns Harbor, LLC*, 2:16-cv-41, 2017 WL 344187, at *3 (N.D. Ind. Jan. 24, 2017) (denying motion to compel depositions of expert witnesses in their non-expert witness capacity, finding that "[defendant] will have adequate time after receiving the plaintiff's reports to depose Dr. Dali and Harris, as well as prepare its own consultants with the facts testified to by Dr. Dali and Harris").

Sun Pharma's cited authority does not change the analysis. In *Siegman*, the Court simply commented in a footnote that a witness was deposed twice (once as a fact witness and once as an expert) but offered no explanation or details as to why this was necessary or whether any party opposed. *Siegman v. Schneider Elec. United States*, 2017 WL 5513190, at *2 n.3 (D.N.J. Nov. 17, 2017). The same is true of *Res. Investments. Res. Investments, Inc. v. United States*, 93 Fed. Cl. 373, 376 (Fed. Cl. 2010). In *Winters*, the expert was also the architect of the auction at the heart of the case, and was therefore permitted to be deposed as a fact witness. *Winters v. Ocean Spray Cranberries, Inc.*, No. 12-12016-RWZ, Dkt. 352 at 2 (D. Mass. Oct. 22, 2019). Here, neither Drs. Goldberg nor Pariser are alleged to have played any role in preparing the challenged promotions at the heart of Sun Pharma's claims. And in *Meyer*, the witness in question had not yet been designated as an expert when the Court ordered their fact deposition. *Meyer v. Delaware Valley Lift Truck, Inc.*, No. CV 18-1118, 2019 WL 2903666, at *2 (E.D. Pa. July 5, 2019). There is simply no reason to apply these holdings here.

Lastly, not only does Sun Pharma seek to take two depositions of Drs. Pariser and Goldberg, but it also insists that "good cause exists for Sun Pharma to conduct two depositions in excess of the 10-deposition limit," because "at the time [Sun Pharma] agreed to the 10-deposition limit, BFRI did not disclose that it would designate its experts as fact witnesses." The Court should reject this out of hand. If Sun Pharma insists that it should be permitted separate fact depositions



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of Drs. Pariser and Goldberg, then Sun Pharma should have to make that choice within the 10-deposition limit, not in violation of that limit. Sun Pharma's argument is also hypocritical, since Sun Pharma has added eight (8) additional witnesses to its disclosures since the parties submitted the Joint Discovery Plan. Ex. A at 3-4. And Sun Pharma's request is entirely unnecessary, since BFRI has already agreed that the expert depositions of Drs. Pariser and Goldberg will not count towards the 10-deposition limit, even if those depositions happen to touch on fact testimony.

For these reasons, the Court should deny Sun Pharma's request.

III. Topic: Deposition of Dr. Annika Wedeking

A. Plaintiffs' Position

Sun Pharma requests that the Court compel the defendants to present for deposition Dr. Annika Wedeking, Senior Manager of Regulatory Affairs at Biofrontera Bioscience GmbH (one of the Biofrontera German Defendants) to occur before the close of fact discovery as to BFRI.

On May 10, 2024, BFRI identified Dr. Wedeking on its Rule 26(a) disclosures as an individual likely to have discoverable information regarding "Biofrontera's regulatory submissions to and communications with the FDA. . . ." Ex. 21 (BFRI's Initial Disclosures) at 8. On March 12, 2025, BFRI amended its disclosures to specify that Dr. Wedeking had knowledge specifically regarding **BFRI's** regulatory activities:

Initial Disclosures	Amended Initial Disclosures
Biofrontera's regulatory submissions to and communications with FDA relating to Biofrontera's PDT treatments; Biofrontera's FDA approval for its PDT treatments, including without limitation the label and indications; Biofrontera's promotional and marketing review process, procedures, and activities, including without limitation as relates to the materials that at issue in the First Amended Complaint. Ex. 21 at 8.	BFRI's regulatory submissions to and communications with FDA relating to BFRI's PDT treatments; BFRI's FDA approval for its PDT treatments, including without limitation the label and indications; BFRI's promotional and marketing review process, procedures, and activities, including without limitation as relates to the materials that at issue in the First Amended Complaint. Ex. 22 at 9.

Based on BFRI's own filings, Dr. Wedeking is central to the issues in this action—BFRI's off-label promotions and false advertising of its PDT products. Dr. Wedeking's name appears on 175 documents produced by BFRI thus far, [REDACTED]

[REDACTED]. See, e.g., Ex. 31 ([REDACTED]) produced as BFRI0067353.) Dr. Wedeking apparently has knowledge of



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BFRI's communications with the FDA, its process for getting FDA approval of its label and indications for Ameluz®, and its review process for the promotional materials at issue in Sun Pharma's Amended Complaint. In fact, Dr. Wedeking is the only person identified on BFRI's disclosures as having information related to regulatory approval of Ameluz®.

BFRI intends to call Dr. Wedeking at trial to rely on her knowledge of what BFRI told the FDA regarding Ameluz® and how BFRI reviews its marketing statements. However, BFRI has stymied any discovery into BFRI's communications with the FDA and Dr. Wedeking's knowledge of those communications. First, BFRI claimed that it had "few to no responsive documents in its possession, custody, or control" related to FDA approvals or the submission of marketing materials to the FDA because "that responsibility falls to Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH." Ex. 23 (Letter from BFRI to Sun Pharma Dated Dec. 26, 2024). Next, BFRI refused to produce any ESI from Dr. Wedeking, again claiming that the information was not in BFRI's control. Ex. 24 (BFRI's Objections and Responses to Sun Pharma's First Set of ESI Requests) at 4.

Most recently, BFRI has refused to accept Sun Pharma's May 14, 2025 Rule 30(b)(1) notice of deposition on Dr. Wedeking, Ex. 25 (30(b)(1) notice to Dr. Wedeking). BFRI claimed that Dr. Wedeking is not employed by Biofrontera Inc., and that it is not authorized to accept service of a deposition notice (or subpoena) for Dr. Wedeking. Ex. 11 (Email from BFRI to Sun Pharma Dated April 15, 2025). For its part, Biofrontera Bioscience GmbH has refused to produce Dr. Wedeking for a deposition as well. The Biofrontera German Entities have refused to schedule a Rule 26(f) conference with Sun Pharma until after those entities file answers to Sun Pharma's Amended Complaint. Ex. 26 (Email from BF German Entities to Sun Pharma Dated April 18, 2025). According to Bioscience, discovery is not open as to their employees, and a Rule 45 subpoena would be "insufficient" to take her deposition because she is a foreign witness. In its last correspondence, Bioscience claimed that the proposed extension of the deadline for depositions has mooted the deposition. In essence, BFRI seeks to rely on her for information about BFRI's own actions while distancing itself from her and pointing to the German entities as controlling her, and the German entities in turn refuse to make her available.

Sun Pharma requests that the Court order the deposition of Dr. Wedeking to occur at least before the close of fact discovery as to BFRI.

First, there is no need for Sun Pharma to seek service of a subpoena through the Hague Convention. Dr. Wedeking is the Senior Manager of Regulatory Affairs at Biofrontera Bioscience GmbH—a party to this action. Fed. R. Civ. P. 30(b)(1) permits her deposition through a notice of deposition—there is no requirement for a subpoena for a foreign party witness. *See Muehlberger v. Maxwell*, 1990 WL 4411, at *1 (E.D. Pa. Jan. 19, 1990) ("A subpoena is not necessary if the person to be examined is a party or an officer, director, or managing agent of a party." (citing Wright and Miller, Federal Practice & Procedure, Civil, § 2107)). Moreover, the Court has already



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recognized the delay and cost associated with that route when it granted the motion for alternative service on Biofrontera Bioscience GmbH.

Second, Dr. Wedeking is a managing agent of BFRI and thus BFRI must make her available. The Court explained in *Atotech* that “the question of whether or not an individual is a managing agent is to be answered pragmatically on an ad hoc basis, or functional basis and does not require the individual to possess general discretionary powers, but rather should be dependent largely on functions, responsibilities and authority of the individual involved respecting the subject matter of the litigation.” *Atotech USA Inc. v. MacDermid Inc.*, 2007 WL 9782931, at *2 (D.N.J. Mar. 14, 2007) (internal quotation marks and citations omitted). A “managing agent” for purposes of Rule 30(b)(1) is “an individual invested by the corporation with general powers to exercise his judgment and discretion in dealing with corporate matters.” *Loughran v. PepsiCo, Inc.*, 2024 WL 328740, at *2 n.3 (D.N.J. Jan. 29, 2024). The burden for establishing a managing agent under Rule 30 is minimal: “any doubts about an individual’s status as a managing agent are resolved in favor of the examining party.” *Atotech*, 2007 WL 9782931, at *2. “Although employees of a corporation may not be managing agents regarding their everyday duties, they may still be managing agents about their testimony concerning their important activities in the underlying facts or where their activities are closely linked with events giving rise to the lawsuit.” *In re Takata Airbag Prods. Liab. Litig.*, 2017 WL 8812735, at *3 (S.D. Fla. July 19, 2017).

Atotech is instructive. There, the Court found a notice of deposition sufficient to compel the testimony of an employee of the defendant’s indirect foreign subsidiary because of his role in the global research and development group, with a responsibility for the product at issue in that case. *Atotech*, 2007 WL 9782931, at *2.⁸ Here, Dr. Wedeking is a Senior Manager of Regulatory

⁸ BFRI misreads *Atotech* to **require** consideration of five factors for determining if Dr. Wedeking is the managing agent of BFRI with respect to these issues. *M.F. Bank Restoration*, whose recitation of factors is quoted by *Atotech*, makes clear that “[t]here is no clear definition of ‘managing agent’ in the case law, and **courts are to determine whether someone fits the bill ‘pragmatically on an ad hoc basis’.**” *M.F. Bank Restoration Co. v. Elliott, Bray & Riley*, 1994 WL 8131, at *3 (E.D. Pa. Jan. 11, 1994) (citing Wright & Miller, Federal Practice and Procedure § 2103). “Courts **may** apply a three-part test in making such determinations There is **no rigid rule** on how to apply the above-mentioned test.” *Id.*

Regardless, the factors quoted by BFRI do not change the analysis. First, Dr. Wedeking appears to be a person invested with power to exercise her discretion and judgment in dealing in corporate matters, as according to BFRI’s own representations, Dr. Wedeking is a Senior Manager of Regulatory Affairs. BFRI’s suggestion that only the corporate entity for whom she works can qualify as a managing agent makes no sense. *M.F. Bank* is again instructive: “Numerous courts, however, have held that the test should not be applied too literally to require general discretionary powers. Rather, courts should make the determination of managing agency depending largely on



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Affairs and apparently manages BFRI's regulatory submissions to the FDA, its communications with FDA, and BFRI's promotional and marketing review process, including for the promotions specifically listed in Sun Pharma's Amended Complaint. With respect to both Bioscience and BFRI, Dr. Wedeking acts as a managing agent for the subject matter of the litigation, such that a notice of deposition suffices. Dr. Wedeking's formal employment status is not dispositive given her degree of involvement on behalf of BFRI in managing regulatory submissions to the FDA and in reviewing BFRI's promotions. *See, e.g., Calderon v. Experian Info. Sols., Inc.*, 287 F.R.D. 629, 631 (D. Idaho 2012) ("[I]t is not necessary for Plaintiff to establish that an employment relationship *per se* exists" for finding a foreign employee of a related corporation to be the managing agent of the US defendant); *Panthera Rail Car, LLC v. Kasgro Rail Corp.*, 2014 WL 13133687, at *5 (W.D. Pa. June 3, 2014) (finding a minority owner who was neither an officer or an employee a "managing agent" of a party given the degree of involvement in decisions material to the dispute).

Finally, while Bioscience contends that this dispute is moot because of the parties' motion to extend the deadline for fact depositions, that is not necessarily true because the German entities have refused to commit to a close of fact discovery that aligns with the extended deadline for depositions that Sun Pharma and BFRI have agreed to.

Sun Pharma requests that the Court compel the deposition of Dr. Wedeking to occur before the end of fact discovery as to BFRI. BFRI should not be allowed to shield crucial facts about its communications with the FDA and its regulatory review process by relying on an affiliated foreign witness who will show up at trial, but will not be made available for a deposition during fact discovery.

B. Defendant Biofrontera Inc.'s Position

Sun Pharma's position that it can simply serve on BFRI a 30(b)(1) deposition notice for third-party witness Dr. Wedeking—and that BFRI is obligated to produce her or else sacrifice the ability to call her at trial—is wrong both as to the facts and the law. The Court should deny Sun

functions, responsibilities and authority of the individual involved respecting the subject matter of the litigation." *M.F. Bank Restoration Co.*, 1994 WL 8131, at *3 (quotation omitted). Second, there is no indication that Dr. Wedeking, who again, **BFRI identified** in its Initial Disclosures as having knowledge of **BFRI's** regulatory submissions, cannot be controlled by BFRI to attend a deposition—indeed, BFRI admits that her employer is contractually available to BFRI. Third, Dr. Wedeking has a clear alignment of interest with BFRI, as she is employed by a co-defendant and Plaintiffs have accused all defendants of off-label promotion of the product they jointly manage. Finally, as to the last two factors, Dr. Wedeking is the **only** individual listed as knowledgeable about "BFRI's regulatory submissions to and communications with FDA relating to BFRI's PDT treatments." Ex. 22 (Amended Initial Disclosures).



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Pharma's request as it pertains to BFRI and insist that Sun Pharma adhere to the Federal Rules of Civil Procedure.

First, while Sun Pharma insinuates that it only discovered Dr. Wedeking's true employment on April 15, 2025, nothing could be further from the truth. Rather, on **May 10, 2024**, BFRI identified Dr. Wedeking as the "Senior Manager, Regulatory Affairs of **Biofrontera Bioscience GmbH**." Ex. 21 at 8 (emphasis added). And unlike the remaining individuals listed on BFRI's initial disclosures who were all employed by BFRI at that time and thus could only be contacted through BFRI's litigation counsel, BFRI provided Dr. Wedeking's contact information at Biofrontera Bioscience GmbH ("Bioscience"). Later, in its November 12, 2024 objections to Sun Pharma's non-email ESI requests, BFRI objected to the requests "because the list of custodians includes Dr. Wedeking, **who is not a BFRI employee and whose custodial files are outside of BFRI's possession, custody, or control.**" Ex. B at 4 (emphasis added). BFRI *again* re-iterated Dr. Wedeking's independence in the parties' Joint Letter to the Court on January 27, 2025. See Dkt. 166 at 4 ("As to Dr. Wedeking, BFRI informed Plaintiffs that she is neither an employee nor a custodian of BFRI, and therefore BFRI does not have possession of her emails"). BFRI has never "stymied" Sun Pharma's attempts to obtain discovery of files that BFRI does not have, any more than BFRI can "stymie" discovery of the files of any other individual outside of BFRI's control.

Having known of Dr. Wedeking's employment with Bioscience (and *not* BFRI) since the beginning of discovery, Sun Pharma had two options: either (1) attempt service of a non-party deposition subpoena on Dr. Wedeking through the Hague Convention, or (2) wait until Bioscience joined the case as a party and then serve *Bioscience* with a Rule 30(b)(1) deposition notice, which Sun Pharma's own cited authority requires. *Muehlberger v. Maxwell*, 1990 WL 4411, at *1 (E.D. Pa. Jan. 19, 1990). Inexplicably, Sun Pharma chose a third option, which was to sit on its hands until April 11, 2025, and then serve *BFRI* with a Rule 30(b)(1) notice for the deposition of an individual that is neither an employee, officer, director, or agent of BFRI.

In the face of its own dilatory actions, and unwilling to wait to depose Dr. Wedeking through Bioscience later in the case (a deposition that BFRI has agreed can be used by all parties for any admissible purpose), Sun Pharma steps on the gas and alleges for the first time that Dr. Wedeking is a "managing agent of BFRI." Again, Sun Pharma is wrong.

First, Sun Pharma devotes nothing more than a footnote to the following factors this Court should apply to determine whether Dr. Wedeking is BFRI's managing agent:

- (1) whether the individual is invested with power to exercise his discretion and judgment in dealing with corporate matters;
- (2) whether the individual can be depended upon to carry out the employer's direction to give required testimony;
- (3) whether the individual has an alignment of interests with the corporation rather than one of the other parties [];
- (4) the individual's general responsibilities in regards to



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the issues being addressed by the litigation; and (5) whether there are individuals employed by the corporation ‘in positions of higher authority than the individual designated in the area regarding which the information is sought by the examination.’

Atotech USA Inc. v. MacDermid Inc., No. CV 05-5517 (FSH), 2007 WL 9782931, at *2 (D.N.J. Mar. 14, 2007) (quoting *United States v. Afram Lines, Ltd.*, 159 F.R.D. 408, 413 (SD.N.Y. 1994)) (internal citations omitted).⁹ Applying these factors here shows Dr. Wedeking is *not* BFRI’s managing agent.

First, Sun Pharma offers no argument or evidence that Dr. Wedeking is “invested with power to exercise [her] discretion and judgment in dealing with corporate matters.” The facts are quite the contrary. Under the Second Amended and Restated License and Supply Agreement between BFRI, Bioscience, and Biofrontera Pharma GmbH (“Pharma”), Bioscience and Pharma “**will be responsible** for obtaining and maintaining the rights to all FDA Approvals and any amendments or supplements required in order for [BFRI] to sell or distribute the Products in the Territory in the Field.” Ex. C at §10.1 (LSA) (emphasis added). Dr. Wedeking, an employee of Bioscience, is working at *Bioscience’s* direction pursuant to a supply agreement between Bioscience and BFRI. Second, Sun Pharma has offered no evidence (or argument) that BFRI can compel Dr. Wedeking to testify, because BFRI has made it repeatedly clear that it cannot. Third, Dr. Wedeking’s interests are already aligned with another party to this matter—Bioscience. And as to the last two factors, numerous high-ranking BFRI employees have knowledge of “BFRI’s FDA approval for its PDT treatments, including without limitation the label and indications,” and BFRI’s “promotional and marketing review process.” These witnesses include BFRI’s CEO (Hermann Luebbert), its Vice President of Scientific & Medical Affairs (Jon Lyons), and its Director of Marketing (Leslie Hopkins). Ex. 22 at 4-8. Sun Pharma has served Rule 30(b)(1) deposition notices for each of these witnesses, and BFRI will make them available for depositions during the fact discovery period. Thus, there are numerous individuals at BFRI with knowledge of “the area regarding which the information is sought by the examination” of Dr. Wedeking. *Atotech*, 2007 WL 9782931, at *2.

For those reasons, numerous courts have rejected the arguments Sun Pharma makes here, even when the sought-after deponent is an employee of an affiliate of the domestic entity. See, e.g., *In re: Benicar (Olmesartan) Prods. Liab. Litig.*, No. 15-2606 (RBK/JS), 2016 WL 5817262, at *5 (D.N.J. Oct. 4, 2016) (finding that employees of non-party foreign affiliate could not be compelled to testify pursuant to Fed. R. Civ. P. 30(b)(1)); *Newmarkets Partners, LLC v.*

⁹ Sun Pharma also tries to undermine *Atotech* with an out-of-district case (*M.F. Bank*), but *Atotech* cites two other cases for the five-factor test, and not *M.F. Bank*. *Atotech USA Inc. v. MacDermid Inc.*, No. CV 05-5517 (FSH), 2007 WL 9782931, at *2 (D.N.J. Mar. 14, 2007) (citing *United States v. Afram Lines, Ltd.*, 159 F.R.D. 408, 413 (SD.N.Y. 1994) and *Honda American Motor Co., Inc. v. Dealership Relations Lit.*, 168 F.R.D. 535, 540-41 (D. Md. 1996)).



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Oppenheim, No. 08 CIV. 04213 WHPTK, 2009 WL 1447504, at *1 (S.D.N.Y. May 22, 2009) (finding employee of non-party affiliate did not qualify as a managing agent despite involvement in the litigation); *Cambridge Cap. LLC v. Ruby Has LLC*, No. 20-CV-11118 (LJL), 2022 WL 889143, at *1-3 (S.D.N.Y. Mar. 24, 2022) (determining that proposed deponent was not a managing agent after analysis of all five relevant factors); *Glencore Ltd. v. Louis Dreyfus Co. B.V.*, No. 23-CV-11125 (ALC) (JW), 2025 WL 856116, at *4 (S.D.N.Y. Mar. 19, 2025) (declining motion to compel deposition of employee of non-party foreign affiliate where plaintiff did not establish that the witness was a managing agent). The fact that BFRI and Bioscience are not corporate affiliates makes Sun Pharma's position all the more untenable.

The cases Sun Pharma cites are distinguishable. In *Atotech*, the "managing agent" was an employee of the party's wholly-owned subsidiary. *Atotech*, 2007 WL 9782931, at *3, n.2. Bioscience is neither a subsidiary nor an affiliate of BFRI. And in *Atotech*, the party's president had testified that he and the managing agent worked together to run a global division of the company. *Id.* In *Panthera*, the managing agent was a one-third owner of plaintiff, and provided all of the funding for purchasing the rail cars at issue in the case. *Panthera Rail Car, LLC v. Kasgro Rail Corp.*, No. 2:13-CV-00679-NBF, 2014 WL 13133687, at *3 (W.D. Pa. June 3, 2014). And in *Calderon*, the managing agent worked for a sister corporation owned by the same parent of the defendant. *Calderon v. Experian Info. Sols., Inc.*, 287 F.R.D. 629, at 635 (D. Idaho 2012), *aff'd*, 290 F.R.D. 508 (D. Idaho 2013). Not only this, but the court in *Calderon* had previously determined that the two sister corporations could be considered the same entity for discovery purposes, and it then relied on that finding in its ruling that the sister corporation's employee was the defendant's managing agent. *Id.* This Court has made no such determination here, nor would such a finding of one entity status be remotely justified, for all the reasons given in BFRI's opposition to Sun Pharma's motion for alternative service, which BFRI incorporates by reference as if fully set forth herein. See Dkt. 92 at 15-23.

Accordingly, there is no sound basis to find that Dr. Wedeking is the managing agent of BFRI. Moreover, such a finding is entirely unnecessary. If Sun Pharma wants to depose Dr. Wedeking, Sun Pharma can do so by serving a Rule 30(b)(1) deposition notice on Dr. Wedeking's employer, Bioscience, at the appropriate time called for in FRCP 26 & 30, and BFRI has agreed to the use of that deposition by all parties even if the deposition occurs after a BFRI/Sun Pharma fact discovery cutoff. The Court should therefore deny Sun Pharma's request as to BFRI.

IV. Topic: Compliance with the Court's March 12, 2025, Order

A. Defendant Biofrontera Inc.'s Position

More than seven (7) weeks after being ordered by the Court to identify documents it had produced in response to BFRI's RFP Nos. 4, 25, 26, 33, 34, 36, 37, and 52-54, as well as Interrogatory No. 1, Sun Pharma has still failed to comply. BFRI asks the Court to order compliance—again



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On March 12, 2025, the Court issued the Order that “Sun shall identify the documents that it produced to Biofrontera, Inc. that are responsive to RFP Nos. 4, 25, 26, 33, 34, 36, 37, and 52-54.” Dkt. 177 at 2. Despite this order, Sun Pharma did not even attempt to comply until April 4, by letter to BFRI. Ex. D. However, Sun Pharma’s April 4 letter fails to do as ordered.

For example, BFRI’s RFP No. 4 seeks: “All documents relating to, supporting or refuting DUSA’s allegation that ‘[t]he term ‘field-directed treatment’ of AKs does not encompass the treatment of subclinical lesions and/or other cancerous/precancerous cells,’” as stated in Paragraph 64 of DUSA’s First Amended Complaint.” Ex. E at 1. Yet Sun Pharma’s April 4 letter identifies just two documents as “exemplary”—SunDNJ0045916 and SunDNJ0071558—both of which are merely the AMEULUZ FDA-approved label. Ex. D at 1; Ex. E at 1. This limited identification is inconsistent with both the scope of RFP No. 4 and Sun Pharma’s representation to the Court that all responsive documents had already been produced. See Dkt. 178 at 17:15–18 (“As for just the production of documents responsive to these RFPs, again, to the extent that we have documents that are responsive, we’re not withholding any.”). Nor is the Court’s March 12 Order limited to “exemplary” documents. If Sun Pharma is aware of *any* documents that support its contention that “field-directed treatment” of AKs does not encompass the treatment of subclinical lesions, it must identify them, as BFRI hasn’t located a single one in Sun Pharma’s production.

Likewise, RFP Nos. 33-34 seek documents showing when Sun Pharma first became aware of the promotional statements it now challenges as false or misleading. Sun Pharma’s April 4 letter cites pre-suit correspondence and email chains, including correspondence from BFRI to Sun Pharma. Ex. E at 3. None of the identified documents include metadata, headers, or other context establishing the date of first awareness for any particular statement Sun Pharma contends is misleading. Similarly, with respect to RFP No. 37, Sun Pharma’s April 4 letter identifies *two* (2) documents, which consist of undated comments. Ex. D at 3; Ex. E at 3. Sun Pharma’s identifications with respect to RFPs 25-26 and 52-54 are similarly deficient. Ex. E at 3-4.

With respect to Interrogatory No. 1, the Court’s Order also required Sun Pharma to supplement its response to BFRI’s Interrogatory No. 1 to “identify documents it produced to Biofrontera, Inc. that are responsive to those requests, including materials reflecting lost customers, lost profits, and communications with any lost customers or lost prospective customers.” Dkt. 177 at 2. Sun Pharma’s April 4 supplemental response to Interrogatory No. 1, however, merely identifies three Sun Pharma sales spreadsheets, along with sales data, customer lists, marketing plans and customer target lists **produced by BFRI**. Ex. E at 4; Ex. F at 8-9. Sun Pharma subsequently served an additional supplemental response to Interrogatory No. 1 on April 28, but again, this only identifies four more documents produced by Sun Pharma,¹⁰ none of which identify a single lost customer. Ex. F at 10.

¹⁰ One of these documents is a copy of a filing by BFRI with the SEC.



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On April 18, BFRI informed Sun Pharma of the deficiencies in its April 4 letter, and asked that Sun Pharma either (1) supplement its letter to fully comply with the Court's Order, or (2) confirm that it has not produced any other documents responsive to these requests. Ex. E. On April 24, the parties met and conferred to discuss this issue. At the meet and confer, Sun Pharma refused to identify additional responsive documents, or to even confirm whether it had produced any additional responsive documents. Ex. G at 1. Following the meet and confer, while maintaining that it was in compliance with the Court's Order, Sun Pharma stated it would "review its production and plans to supplement its responses by Friday, May 2, 2025." Ex. G at 2. Given the inexplicable passage of time, and to preserve its rights, BFRI respectfully brings this issue to the Court's attention and requests that the Court order Sun Pharma to immediately identify any additional documents responsive to these discovery requests. If Sun Pharma's promised May 2 supplement cures these deficiencies and complies with the Court's March 12 Order, BFRI will inform the Court that the dispute has been resolved.

B. Plaintiffs' Position

The purpose of an RFP is to ensure the production of relevant documents. It is not a tool by which one side can force its opponent to not only produce those documents, but serve up on a silver platter an identification of every responsive document. That is the job of an interrogatory. The dispute that precipitated the Court's order was whether Sun "failed to produce a single document that is responsive to any of the [RFPs]." Dkt. 152 at 2. Sun Pharma has complied with the Court's order by producing any relevant documents—subject to the fact that some productions are ongoing, particularly emails—and by identifying documents it produced. Not satisfied with that, BFRI is attempting to weaponize the Court's order casting it as a full-throated backing of BFRI's view that each RFP should essentially be treated as a contention interrogatory by which Sun Pharma must catalogue its entire production for BFRI in certain categories. The Court previously rejected that argument. See Dkt. 177 at 3 ("In identifying and/or producing materials responsive to the foregoing discovery requests that are in its possession, custody, or control, Sun shall not be required at this time to state its contentions as to the meaning or consequence of those materials as they relate to the claims asserted in this case.").

Contrary to BFRI's assertions, Sun Pharma did not represent that it has already produced all responsive documents. Instead, Sun Pharma merely represented that it is not withholding responsive documents (see Dkt. 178 at 17:15–18) and explained that the "discovery process is still ongoing" and that the parties "still have ESI and emails that still need to be produced." (*Id.* at 23:16–23). Since then, Sun Pharma has produced more than 5,000 emails in response to BFRI's email ESI requests.¹¹

¹¹ For its part, BFRI has yet to produce any emails in response to Sun Pharma's email ESI requests based on objections to "unreasonable" hit counts. While Sun Pharma has been willing to revise its hit counts to narrow the scope of its searches, those efforts have been impeded by BFRI's taking weeks to provide hit counts responsive to Sun Pharma's revisions.



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As to BFRI's RFP No. 4, Sun Pharma has produced [REDACTED] [REDACTED] See, e.g., SunDNJ0045331; SunDNJ0045335; SunDNJ0045603; SunDNJ0045635. Sun Pharma has also produced other versions of the Ameluz® label. See, e.g., SunDNJ0045373; SunDNJ0045377; SunDNJ0045380; SunDNJ0045472. BFRI's disagreement that the Ameluz® label itself shows that BFRI's promotional activities are off-label does not make production of the label non-responsive to this RFP. [REDACTED]

As to BFRI's RFP Nos. 25–26, Sun Pharma has produced spreadsheets that describe its employees' compensation, which BFRI had alleged was missing in Sun Pharma's prior identification of responsive documents. *See* SunDNJ0071532; SunDNJ0071533; SunDNJ0071534; SunDNJ0109616.

As to BFRI's RFP Nos. 33–34, Sun Pharma has already produced non-privileged documents located after a reasonable search. [REDACTED]

documents are responsive to RFP No. 33, which seek documents about Sun Pharma's "first knowledge or awareness" of Biofrontera's promotional statements. As to RFP No. 34, Sun Pharma has not located additional non-privileged documents after a reasonable search.

As to BFRI's RFP No. 37, Sun Pharma has not located additional responsive documents to date after a reasonable search.

As to BFRI's RFP Nos. 52–54 and Interrogatory No. 1, Sun Pharma has produced comprehensive spreadsheets identifying its customers and prospective customers. *See* SunDNJ0053985 (financial data from late 2018 to 2024); SunDNJ0111239 (Sun Pharma's targets for Levulan); SunDNJ0114974 (Levulan sales from 2019 to 2024); SunDNJ0057487 (Levulan sales data); SunDNJ0059891 (Levulan forecasts). Moreover, to the extent that any emails constitute communications that identify particular lost customers, Sun Pharma will continue to produce non-privileged, responsive emails.



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Sun Pharma has produced documents responsive to BFRI's requests and identified to BFRI documents falling within each category. The Court should deny BFRI's request to interpret an order resolving a dispute about whether Sun Pharma produced documents in response to RFPs into requiring something more than that.

V. Topic: BFRI's Deficient Response to Interrogatory No. 9

A. Plaintiffs' Position

Sun Pharma has identified deficiencies in BFRI's responses to Interrogatory No. 9. *See* Ex. 27 Objections and Responses to Sun Pharma's First Set of Interrogatories. BFRI has refused to meet and confer about this deficiency, and others, in a timely manner since Sun Pharma raised the issues on April 26, 2025, offering only to meet and confer the afternoon of May 1—the parties' deadline to raise disputes about written discovery. *See* Ex. 28 (Email Correspondence). Following that meet and confer, BFRI requested another 6 days to contemplate to what extent it would supplement its answer, if at all. *See* Ex. 29 (May 1 Email from BFRI to Sun Pharma). Sun Pharma respectfully requests that the Court order BFRI to supplement its responses to Interrogatory No. 9.

Interrogatory 9 asks BFRI to "[e]xplain in detail the processes You use to determine whether to seek approval of a supplemental indication of a drug or device from the FDA, including specifically identifying all persons involved in designing and implementing those processes, and including how those processes were applied with regard to any advertising or promotional materials relating to the Biofrontera PDT Products." Ex. 27 at 32. This is relevant because any deliberation about possibly expanding the scope of the label of the Biofrontera PDT Products would reveal what BFRI understands is, and is not, currently covered by the label. BFRI responded that it "[REDACTED]". *Id.* at 32–33. The parties conferred about BFRI's response, at which time "[REDACTED]". Ex. 30 (December 27 email correspondence from Sun to BFRI memorializing meet-and-confer). On that basis, Sun did not further press BFRI about its response at the time.

But more recently, it became clear that BFRI's representation is in conflict with its own recently released public statements, which reveal that BFRI's "research and development ('R&D') program is focused on label expansion for Ameluz®." *See Biofrontera Annual Report* (Mar. 20, 2025). Ex. 19. That same Annual Report reveals that BFRI in fact sought FDA approval for the treatment of basal cell carcinoma with Ameluz® in 2024 and is currently engaged in several other clinical trials related to expanding the Ameluz® label. *Id.* Basal cell carcinoma is a form of cancer and BFRI's deliberations about the Ameluz® label as it relates to cancer may well shed light on BFRI's understanding of the scope of the label. BFRI's response to the interrogatory is insufficient because it fails to explain BFRI's processes (e.g. deliberations) and other details requested by the



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interrogatory as to at least the request for FDA approval for the treatment of basal cell carcinoma with Ameluz®.

Accordingly, the Court should require BFRI to supplement its response to Interrogatory No. 9.

B. Defendant Biofrontera Inc.'s Position

Sun Pharma raised issues with BFRI's responses to 14 different discovery requests for the first time in an email sent at 1 AM on Saturday, April 26, demanding that BFRI cure these "deficiencies" and meet and confer by the following Monday, April 28. Despite Sun Pharma's gamesmanship, BFRI worked in good faith to resolve the issues raised in Sun Pharma's email as to all but one of the discovery responses.¹²

Concerning Interrogatory No. 9, Sun Pharma fails to explain the relevance of what it seeks in light of BFRI's response. Sun Pharma argues that BFRI's "deliberation about expanding the scope of the label of the Biofrontera PDT Products would reveal what BFRI understands is, and is not, currently covered by the label." But this case is not about whether the AMELUZ label needs to be expanded in the abstract. Instead, as set forth in Sun Pharma's First Amended Complaint, this case is about whether the AMELUZ label, in its current form, is consistent with BFRI's statements that Sun Pharma challenges. This is why BFRI's answer to Interrogatory No. 9 resolves the issue, [REDACTED]

Nor does BFRI's answer conflict with its own public statements. BFRI's response to Interrogatory No. 9 states that BFRI "[REDACTED] [REDACTED] [REDACTED]."

[REDACTED]

"That remains true today. To the extent BFRI is seeking other supplemental new drug applications for the Biofrontera PDT Products, it is for uses that have nothing to do with Plaintiffs' claims, and is therefore irrelevant to the issues in this case. This includes any alleged supplemental indication related to *basal* cell carcinoma, which is not the type of cancer (squamous cell carcinoma) that is the subject of the allegedly off-label promotions in Sun Pharma's First Amended Complaint. Dkt. 52 at ¶ 60.

Lastly, Sun Pharma apparently misunderstand the scope of its own Interrogatory. On Sun Pharma's reading, Interrogatory No. 9 requires BFRI to disclose its specific decision-making

¹² At least one of the alleged “deficiencies” was due to Sun Pharma’s failure to read BFRI’s previously-served supplemental discovery responses. Four other “deficiencies” were resolved by documents that BFRI produced months ago, which Sun Pharma had likewise failed to read.



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processes as to every instance in which it has filed a supplemental new drug application (or chosen not to file one). But that is not what Interrogatory No. 9 seeks. Instead, it asks BFRI to “explain in detail the processes You use to determine whether to seek approval of a supplemental indication of a drug or device from the FDA.” It does not seek an explanation of BFRI’s reasons for *every single* supplemental indication it has ever sought (or not sought). The Court should therefore reject Sun Pharma’s attempts to expand the scope of Interrogatory No. 9 beyond its plain language

* * *

We thank the Court for its attention to this matter.

Respectfully submitted,
RIVKIN RADLER LLP

s/ Gregory D. Miller
Gregory D. Miller

cc: All Counsel of Record (via ECF)

Enclosures