Paper No. 14
Filed: December 1, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

BAUSCH HEALTH IRELAND LIMITED,

Patent Owner.

IPR2023-01114
U.S. Patent No. 11,311,482

PATENT OWNER'S CORRECTED PRELIMINARY RESPONSE

TABLE OF CONTENTS

I. Summary of Argument 1

II. Background 6

A. Prosecution History of the ’482 Patent 7

B. Prosecution of Patent Owner’s Related Applications 10

1. The ’871 Application 10

2. The ’576 Application 16

C. Padagis’s Identified Purported Prior Art 17

1. WO ’001 [Ex. 1007] 17

2. IDP-118 Study [Ex. 1014] 19

3. ’824 Publication [Ex. 1012] 20

4. Tazorac® Label [Ex. 1013] 22

5. Shalita [Ex. 1011] 22

6. Kircik [Ex. 1009] 24

7. Anderson [Ex. 1008] 24

8. Chim [Ex. 1010] 25

D. Procedural History 27

1. Bausch Ireland prevails over Padagis in prior litigation involving the same art asserted here. 27

2. Bausch Ireland sues Padagis for infringing the ’482 Patent more than a year ago. 28

3. Bausch Ireland sues Padagis for infringing the ’116 Patent. 29

4. Padagis files its Petition three days before the deadline. 30

5. The current state of the DNJ4248 Case. 30

III. Level of Ordinary Skill in the Art 31

IV. Claim Construction 31

V. The Board Should Exercise its Discretion to Deny Institution Under 35 U.S.C. § 325(d) 31

A. Padagis's Purportedly New References are Cumulative of Art of Record 33

1. Anderson 34

2. Chim 36

3. IDP-118 Study 37

B. Padagis's Contention the Board Should Grant Institution Based on the '824 Publication, Shalita, and/or Kircik Because the Examiner Did Not Apply Them Is Without Merit 38

C. The Arguments Presented in the Petition Are Substantially the Same as Arguments Already Presented to the Examiner 40

D. Padagis Has Not Demonstrated that the USPTO Materially Erred 46

VI. The Board Should Deny Institution in Light of Parallel District Court Proceedings 51

A. The Circumstances Here Satisfy *Fintiv* 51

B. The Director's Interim Guidance Does Not Change the Application of *Fintiv* Here 55

VII. The Board Should Deny Institution Under 35 U.S.C. § 314(a) 56

A. Grounds 1-4 Fail at Least Because a POSA Would Not Have Been Motivated to Select the 0.045% Tazarotene Lotion Disclosed in WO ’001 with a Reasonable Expectation of Success 57

B. Padagis’s Arguments for Grounds 5-9 Retread Ground Already Lost in its Litigation with Bausch Ireland Regarding Bryhali® and Duobrii® 57

VIII. Conclusion 61

TABLE OF AUTHORITIES

Cases

Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) 32, 33, 38, 44, 46, 47

Amgen Inc. v. Sandoz Inc., 66 F.4th 952 (Fed. Cir. 2023) 50

Apotex Inc. v. Auspex Pharms., Inc., IPR2021-01507, Paper 9 (P.T.A.B. Mar. 9, 2022) 49

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) 2, 51, 54

Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd., No. 20-5426 (D.N.J. Dec. 1, 2022) 2, 27, 28, 29, 60, 61

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) 31, 32, 33

Complete Genomics, Inc. v. Illumina Cambridge Ltd., IPR2017-02172, Paper 22 (P.T.A.B. Aug. 2, 2018) 34

In re Corkill, 771 F.2d 1496 (Fed. Cir. 1985) 50

Galderma Laboratories, L.P. v. Tolmar, Inc., 737 F.3d 731 (Fed. Cir. 2013) 4, 5, 6, 50

Gesture Tech. Partners, LLC v. LG Elecs. Inc., No. 21-19234, 2022 WL 1002101 (D.N.J. Apr. 4, 2022) 51, 52

Google LLC v. Valtrus Innovations Ltd., IPR2022-01197, Paper 9 (P.T.A.B. Jan. 3, 2023) 47

Harmonic Inc. v. Avid Tech., Inc., 815 F.3d 1356 (Fed. Cir. 2016) 6

Kirsch Rsch. & Dev., LLC v. GAF Materials, LLC,
No. 20-13683, 2021 WL 2434082 (D.N.J. June 15, 2021) 52, 53

Lite-On Technology Corp. v. Sensor Electronic Technology, Inc.,
IPR2022-00780, Paper 11 (P.T.A.B. Oct. 28, 2022).....39

Medtronic Corevalve LLC v. Speyside Medical, LLC,
IPR2021-00240, Paper 9 (P.T.A.B. July 23, 2021).....38

Microsoft Corp. v. Surfcast, Inc.
IPR2022-00590, Paper 9 (P.T.A.B. Oct. 7, 2022).....38, 39

Nespresso USA, Inc. v. K-Fee Sys. GmbH,
IPR2021-01221, Paper 9 (P.T.A.B. Jan. 18, 2022) 38, 47

OANDA Corp. v. GAIN Cap. Holdings, Inc.,
No. 20-05784, 2021 WL 1186778 (D.N.J. Mar. 30, 2021).....52

Regeneron Pharms., Inc. v. Merus N.V.,
864 F.3d 1343 (Fed. Cir. 2017) 34, 35

In re Soni,
54 F.3d 746 (Fed. Cir. 1995) 50

Unigene Labs., Inc. v. Apotex, Inc.,
655 F.3d 1352 (Fed. Cir. 2011) 28

Vital Connect, Inc. v. Bardy Diagnostics, Inc.,
IPR2023-00381, Paper 7 (P.T.A.B. July 11, 2023).....47

ZTE (USA) Inc. v. Fractus, S.A.,
IPR2018-01457, Paper 20 (P.T.A.B. Oct. 4, 2019).....44

10X Genomics, Inc. v. President & Fellows of Harvard Coll.,
IPR2020-01468, Paper 22 (P.T.A.B. Feb. 22, 2021).....54

Statutes

35 U.S.C. § 314(a) 3, 51, 56

35 U.S.C. § 325(d) 1, 31, 34, 51

Other Authorities

MPEP § 716.02 .....16, 50

TABLE OF EXHIBITS

Exhibit No.	Description
2001	*Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 20-5426 (D.N.J. Dec. 1, 2022).
2002	U.S. Pat. No. 11,679,116.
2003	Notice of Abandonment of U.S. Patent Application No. 16/179,576.
2004	Plaintiffs' Proposed Findings of Fact and Conclusions of Law, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 20-5426 (D.N.J. Nov. 1, 2022).
2005	Defendants Padagis Israel Pharmaceuticals Ltd and Padagis US LLC's Opening Post Trial Brief, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 20-5426 (D.N.J. Nov. 15, 2022).
2006	Defendants Padagis Israel Pharmaceuticals Ltd and Padagis US LLC's Proposed Findings of Fact and Conclusions of Law, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 20-5426 (D.N.J. Nov. 15, 2022).
2007	Complaint, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 22-4248 (D.N.J. June 24, 2022).
2008	Stipulation, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 22-4248 (D.N.J. June 24, 2022).
2009	Waiver of the Service of Summons, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 22-4248 (D.N.J. June 28, 2022).
2010	Complaint, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 23-3393 (D.N.J. June 21, 2023).
2011	Order Consolidating Cases, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 22-4248 (D.N.J. Sept. 15, 2023).
2012	Defendants Padagis Israel Pharmaceuticals Ltd, Padagis US LLC, and Padagis LLC's Invalidity Contentions, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms Ltd.*, No. 22-4248 (D.N.J. Dec. 22, 2022).
2013	Stipulation and Order on Pretrial Schedule and Discovery, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms Ltd.*, No. 22-4248 (D.N.J. Sept. 22, 2023).

2014	Letter from William P. Deni, Jr. to Hon. Madeline Cox Arleo, U.S.D.J., *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No 22-4248 (D.N.J. Aug. 31, 2023).
2015	Joint Proposed Discovery Plan, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 22-4248 (D.N.J. Nov. 17, 2022).
2016	Defendants Padagis Israel Pharmaceuticals Ltd, Padagis US LLC, and Padagis LLC's Amended Invalidity Contentions, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 22-4248 (D.N.J. June 6, 2023) (excerpt).
2017	Memorandum from Katherine K. Vidal, Under Sec'y of Com. for Intell. Prop. & Dir. of the USPTO to Members of the Pat. Trial & Appeal Bd. (June 21, 2022).
2018	U.S. Patent Assignment Reel 059759, Frame 0311-15.
2019	First Amended Complaint, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 22-4248 (D.N.J. April 25, 2023).
2020	Opening Statement on Behalf of the Padagis Defendants, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 20-5426 (D.N.J. Oct. 4, 2022) (excerpt).
2021	Trial Transcript, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 20-5426 (D.N.J.).
2022	Defendants Padagis Israel Pharmaceuticals Ltd, Padagis US LLC, and Padagis LLC's Answer to Complaint, Affirmative Defenses and Counterclaims, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 22-4248 (D.N.J. Aug. 26, 2022).

Patent Owner Bausch Health Ireland Limited ("Patent Owner" or "Bausch Ireland") submits this Corrected Preliminary Response to the Petition for *Inter Partes* Review of U.S. Patent No. 11,311,482 (the "'482 Patent") filed by Padagis Israel Pharmaceuticals Limited ("Petitioner" or "Padagis").

I. Summary of Argument

The Board should deny institution for several reasons:

First, the Board should exercise its discretion to deny institution under 35 U.S.C. § 325(d) because the Petition presents the same or substantially the same prior art and arguments as those previously considered by the United States Patent and Trademark Office ("USPTO"). Padagis relies on eight references: five were before the Examiner and the other three are cumulative and do not add any new information. The Examiner for the '482 Patent considered these references and, as Padagis admits, they were also considered by a different Examiner issuing a different patent covering closely-related subject matter.

Moreover, Padagis's art and arguments have not just been presented to and considered by the USPTO, but also, unsuccessfully, in a federal court. Last year, in the United States District Court for the District of New Jersey ("D.N.J."), Padagis and Bausch Ireland litigated patents covering Bryhali® and Duobrii® (the "Prior Case"). Duobrii® is a topical medication for the treatment of psoriasis with a combination of active ingredients, namely halobetasol propionate 0.01% and

tazarotene 0.045%, in the same vehicle as claimed in the ’482 patent. Padagis argued at trial in the Prior Case that the Duobrii® patents-in-suit, as they relate to tazarotene 0.045%, were obvious based on many of the same references and arguments included in the Petition. The D.N.J. rejected Padagis’s arguments in a 76-page opinion, criticizing Padagis for presenting a “hindsight-driven” case that was “laid out with little explanation of how the POSA would find and select each reference” and which failed to “ma[k]e the necessary showing” that a POSA “would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.” Ex. 2001, *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, No. 20-5426, slip op. at 67-69 (D.N.J. Dec. 1, 2022) (hereinafter “Prior Decision”) (quoting *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011)).

Second, the Board should exercise its discretion to deny institution under the factors set out in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (designated precedential May 5, 2020) because the ’482 Patent is also the subject of parallel proceedings before the D.N.J. (the “DNJ4248 Case”). Padagis waited until the eve of the one-year statutory deadline to file the Petition, and during that time the DNJ4248 Case advanced. Based on the current DNJ4248 Case schedule, it is highly unlikely that the Board would render a decision in this IPR before trial in the DNJ4248 Case. Furthermore, the DNJ4248 Case is before

the same Judge that presided over the Prior Case, and who has significant knowledge of, and recent experience with, the underlying technology, similar patents, prosecution history, fact witnesses, and invention story. That experience should weigh heavily in favor of declining institution under *Fintiv* where (as shown herein) the Petition presents no compelling evidence of unpatentability to warrant institution.

Third, the Board should deny institution under 35 U.S.C. § 314(a) because the Petition fails to establish a reasonable likelihood the Petitioner would prevail with respect to any of the claims challenged in the Petition.

The Petition's central argument is that it would have been obvious to use the claimed 0.045% tazarotene lotion to treat acne because 0.045% tazarotene lotion was disclosed in a prior art reference for the treatment of a different skin disease – psoriasis – and a person of ordinary skill in the art ("POSA") would have been motivated to use that 0.045% tazarotene lotion to treat acne because clinical studies showed 0.05% tazarotene was safe and effective for treating acne and dermatologists had been prescribing the commercial 0.05% tazarotene product (Tazorac® 0.05%) off-label to treat acne for nearly two decades.

But even setting aside that the Patent Office has already rejected the idea that the claimed 0.045% tazarotene lotion would have been obvious over the same art, the very art and arguments Padagis asserts fundamentally contradict the

conclusions it asks the Board to draw. Why? Because if dermatologists were commonly using Tazorac® 0.05% off-label to treat acne for nearly two decades, as Padagis asserts, there would have been no motivation for a POSA to use the claimed 0.045% tazarotene lotion to treat acne given that Tazorac® 0.05% was readily available. Dermatologists who wished to use a lower concentration of tazarotene than the approved Tazorac® 0.1% for treating acne could simply prescribe Tazorac® 0.05% off-label, which is exactly what Padagis asserts dermatologists did as a matter of common practice for many years. Thus, there would have been no motivation for a POSA to use the claimed 0.045% tazarotene lotion to treat acne. Padagis's motivation argument is self-defeating.

Moreover, Padagis's argument that the claimed 0.045% tazarotene lotion did not demonstrate unexpected results for these same reasons is also without merit. The unexpected result was not (merely) that the claimed 0.045% tazarotene lotion was ***effective*** for treating acne, as the Petition asserts, but that it was ***more effective*** in treating acne and ***more tolerable*** than Tazorac® 0.1% cream and, by extension, the Tazorac® 0.05% cream, whose tolerability was found in clinical studies to be comparable to Tazorac® 0.1%.

Padagis relies heavily on *Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731 (Fed. Cir. 2013), but this case is nothing like *Galderma*. In *Galderma*, the challenged patent claimed compositions comprising 0.3% adapalene (a retinoid)

for treating acne. *See id.* at 734. The asserted prior art patents disclosed topical adapalene compositions for treating the same disease – acne – in a preferred range of 0.01% to 1%, which encompassed the claimed 0.03% adapalene. *Id.* at 736. Other prior art also demonstrated that "0.03% and 0.1% adapalene products were effective against acne and well tolerated." *Id.* at 735. In short, the patent claimed "nothing more than the use of an old compound for a known purpose in a concentration that falls within a range disclosed in the prior art as preferred for that purpose." *Id.* at 736.

Here, unlike *Galderma*, the two primary references asserted in the Petition (WO '001 and the '824 Publication) are both directed to compositions for use in a ***different*** disease – psoriasis, not acne. Moreover, WO '001 is directed to ***combination*** formulations containing both a corticosteroid (halobetasol propionate) and a retinoid (tazarotene), not to compositions with a single active ingredient as in *Galderma*. The Petition's other primary reference, the '824 Publication, does not even disclose compositions with a retinoid, much less the specific claimed active ingredient (as in *Galderma*), but rather only compositions with corticosteroids. And none of the other references asserted in the Petition disclose or teach a preferred range of tazarotene concentrations for treating acne that encompasses 0.045% tazarotene, as had been the case in *Galderma*. In short,

while the challenger's case in *Galderma* was "both straightforward and potent," *id.* at 736, the facts here are nothing like those of *Galderma*.

By congressional mandate, "the PTO is permitted, but never compelled, to institute an IPR proceeding." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016). Based on the foregoing, as explained in detail herein, the Board should deny institution.

II. Background

The '482 Patent covers an FDA-approved product called Arazlo®, a unique lotion combined with a specific amount of tazarotene (0.045%) for treating acne. Prior to the invention claimed in the '482 Patent, neither the lotion vehicle nor tazarotene 0.045% had been used for the treatment of acne.

In fact, prior to the invention claimed in the '482 patent, the state of the tazarotene acne market was singular and problematic. In 1997, Allergan sought FDA approval for the use of tazarotene at 0.05% and 0.1% concentrations for the treatment of acne; and, the FDA approved only 0.1% ("Tazorac® 0.1%") because the 0.05% concentration was found to be insufficiently efficacious.[1] In the 20 years following approval of Tazorac® 0.1% cream, many more 0.1% tazarotene products

[1] However, 0.05% tazarotene was approved for the treatment of psoriasis ("Tazorac® 0.05%").

were approved; and, as Padagis correctly points out, these tazarotene products were known to cause significant irritation, such that it made them intolerable for many patients. Then came the invention claimed in the ’482 patent; and, it proved even better than expected: with less than half of the amount of tazarotene, namely 0.045% versus 0.1%, and in a lotion vehicle, Arazlo® was able to achieve superior efficacy to Tazorac® 0.1% cream, while at the same time not causing the extensive irritation patients experienced with Tazorac® 0.1% and other 0.1% tazarotene products. The invention claimed in the ’482 Patent is an unexpectedly better product and with no tradeoffs.

A. Prosecution History of the ’482 Patent

The ’482 Patent resulted from prosecution of U.S. Patent Application No. 16/179,561 (the “’561 Application”). During prosecution, the Examiner issued rejections based on the combination of WO 2016/205001 (“WO ’001”) and U.S. Patent Application Publication No. US 2012/0328670 (“US ’670” or “Donello”). Ex. 1002 at 213-17. According to the Examiner, WO ’001 (there referred to as “Dow”) discloses 0.045% tazarotene for treating psoriasis but does not teach the use of tazarotene to treat acne, while Donello teaches the use of tazarotene to treat acne. *Id.* The Examiner asserted it would have been obvious to use the claimed 0.045% tazarotene lotion to treat acne based on the disclosure of tazarotene in WO

’001 and Donello’s disclosure of using tazarotene to treat acne “with a reasonable expectation of success in the absence of evidence to the contrary.” *See id.* at 217.

The applicants traversed, acknowledging that WO ’001 discloses a 0.045% tazarotene formulation for treating psoriasis but arguing Donello provided no reasonable expectation of success in using 0.045% tazarotene to treat acne. *Id.* at 202-04. Applicants argued Donello was inapposite because it taught using “microspheres” of a polymer and tazarotene to treat acne and that non-microspheres were not effective, while the lotions claimed in the ’482 Patent do not use microspheres. *Id.* at 203-04. The applicants further asserted that the Examiner had not articulated why there would be a reasonable expectation of success for achieving the results of the claimed invention. *Id.* at 204-05. The Examiner remained unpersuaded, however, and maintained the obviousness rejection based on WO ’001 and Donello through a second final rejection on August 10, 2020. *Id.* at 144-48.

On December 10, 2020, the applicants filed a Pre-Appeal Brief Request for Review seeking to traverse the obviousness rejection. *Id.* at 122-27. A Pre-Appeal Brief conference was held and a panel of three Examiners directed that the applicants proceed to the Board of Patent Appeals and Interferences. *Id.* at 121.

Thereafter, on July 15, 2021, the applicants filed a Request for Continued Examination (RCE) (*id.* at 65-66) along with an Amendment/Response to Office

Action (*id*. at 74-85). The claims were amended to recite tazarotene as a sole active pharmaceutical ingredient. *Id.* at 75. In their remarks, the applicants traversed the obviousness rejection based on WO '001 in view of Donello by explaining that "[o]ne of skill in the art would not have expected the surprising efficacy and tolerability of the claimed method," pointing out "[t]he application describes a side-by-side comparison of acne treatment using tazarotene 0.045% lotion according to the present claims and TAZORAC 0.1% cream." *Id.* at 81. The applicants noted there was a "**31.8% improvement**" in efficacy for the claimed 0.045% tazarotene lotion as compared to the Tazorac® 0.1% cream, which was "particularly surprising when considering that the method employed *less than half* the tazarotene dose of TAZORAC." *Id.* at 82 (original emphasis). The applicants observed that "the skilled artisan would *not* expect to increase the efficacy when decreasing the amount [of] the active agent by over half. On the contrary, one of skill in the art would expect that decreasing the amount of tazarotene would decrease the efficacy of the method." *Id.* (original emphasis).

The applicants also noted that Table 8 of the application "shows that a dramatically higher tolerability was achieved using tazarotene 0.045% lotion than when using TAZORAC 0.1% cream." *Id.* at 83. Specifically, the experimental data reported in Table 8 showed a "**90.3% improvement**" in tolerability as compared to Tazorac® 0.1% cream. *Id.* (original emphasis).

The applicants asserted "that one of skill in the art could *not* expect to decrease adverse events by 90.3% ***and*** increase efficacy by 31.8% by using a formulation with a decreased concentration of active agent, as recited in the present claims." *Id.* at 84 (original emphasis).

On January 4, 2022, the Examiner allowed the claims of the '482 Patent. *Id.* at 55. In the notice of allowance, the Examiner wrote: "Applicants [sic] amendment of claims to recite tazarotene as a sole active agent renders the obviousness rejection moot. Because Dow [WO '001] teaches that tazarotene and halobetasol is synergistically [sic] and there is no motivation to administer tazarotene alone in view of Dow. Thus, the instant claims are free of art." *Id.* at 55.

B. Prosecution of Patent Owner's Related Applications

1. The '871 Application

The Petition identifies U.S. Patent Application No. 17/366,871 (the "'871 Application") as a related application. Pet. 15. The '871 Application was filed on July 2, 2021 and, as the Petition notes, shares a substantively identical specification as the WO '001 reference. *Id.* The allowed claims of the '871 Application issued as U.S. Patent No. 11,679,116 (the "'116 Patent") on June 20, 2023. Ex. 2002 at 1. The claims of the '116 Patent recite a composition that is essentially identical to the composition recited in certain method claims of the '482 Patent, as shown in the chart below:

Claim 11 of ’482 Patent	Claim 1 of ’116 Patent
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 suffering from acne vulgaris; wherein the composition consists essentially of: 0.045 weight % tazarotene; 2.97 weight % diethyl sebacate; 8.03 weight % light mineral oil; 0.1 weight % sorbitan monooleate; 10.7 weight % sorbitol solution, 70%; 0.17 weight % methylparaben; 0.03 weight % propylparaben; 0.05 weight % edetate disodium dihydrate; 0.4 weight % carbomer copolymer type B; 0.6 weight % carbomer homopolymer type A; sodium hydroxide, q.s. to pH 5.5±0.5; and purified water, q.s. to 100 weight %.	1. A pharmaceutical composition consisting essentially of: tazarotene, 0.045% w/w, diethyl sebacate, 2.97% w/w, light mineral oil, 8.03% w/w, sorbitan monooleate, 0.1 w/w, sorbitol solution (70%), 10.7 w/w, methyl paraben, 0.17% w/w, propyl paraben, 0.03% w/w, edetate disodium dihydrate, 0.05% w/w, carbomer copolymer type B, 0.4% w/w, carbomer homopolymer type A, 0.6% w/w, sodium hydroxide, q.s. to pH of 5.5±0.5, and purified water, q.s. to 100% w/w; wherein the composition is a lotion. Ex. 2002 at 16.

Ex. 1001.	

The Examiner initially rejected the claims on November 16, 2021, as obvious based on WO2012/087443 (WO '443) (which the Examiner referred to as "Dow") and two other references. Ex. 1047 at 299-315. As the Petition notes in its discussion of the '871 Application, WO '443 is the PCT publication of U.S. Patent Application Publication No. US 2012/129824 (the "'824 Publication") (Pet. 15 n.3), which is one of two primary references Padagis relies upon in its Petition. For illustrative purposes and ease of reference, Patent Owner will refer herein to WO '443 as the "'824 Publication," with the understanding the actual reference is WO '443.

Thereafter, on February 16, 2022, the applicants amended the claims from "comprising" to "consisting essentially of" the specific 0.045% tazarotene formulation and traversed the rejection. Ex. 1047 at 283-86.

On March 15, 2022, the Examiner issued a final rejection, rejecting the claims as obvious based on '824 Publication, the Tazorac® Label (which describes Tazorac® 0.1% cream and Tazorac® 0.05% cream), and WO2000/047211 ("Bershad"). *Id.* at 191-94. The Examiner stated the Tazorac® Label teaches 0.05% tazarotene cream and the '824 Publication teaches topical formulations for psoriasis, and thus it would have been obvious to combine the 0.05% tazarotene

from the Tazorac® Label with the topical formulations taught by the ’824 Publication. *Id.* at 187-95. The Examiner further asserted it would have been obvious to adjust the amount of tazarotene in Tazorac® 0.05% cream from 0.05% wt. to 0.045% wt. in view of Bershad. *Id.* at 193.

On May 20, 2022, the applicants filed a request for continued examination, along with an amendment/response to office action. *Id.* at 172-80. Applicants attempted to traverse the ’824 Publication/Tazorac® Label rejection on the grounds a POSA would not be motivated to combine the cited references and would not expect success in reducing side effects by formulating tazarotene with excipients from a halobetasol propionate composition disclosed in the ’824 Publication. *Id.* at 178.

On September 8, 2022, the Examiner maintained the rejection based on the ’824 Publication, the Tazorac® Label and Bershad, finding the applicants’ arguments unpersuasive. *Id.* at 153-63.

On March 8, 2023, the applicant filed a further amendment/response to office action traversing the rejection. The applicant again argued that a POSA would not have been motivated to combine the cited references but focused particularly on the “surprising properties” of the claimed composition as evidence of non-obviousness. *Id.* at 63-68.

Applicants submitted a declaration from inventor Dr. Dow that highlighted the "surprising improvement[s]" that the claimed 0.045% tazarotene lotion provides "in both efficacy and tolerability as compared to the known TAZORAC 0.1% and 0.05% creams." *Id.* at 65.

In terms of tolerability, Dr. Dow pointed out the irritation levels observed for Tazorac® 0.1% cream were "*markedly higher*" than the irritation level observed for the claimed tazarotene 0.045% lotion, which "exhibited very little irritation relative to placebo." *Id.* at 66 (original emphasis). Dr. Dow explained he would not have expected this result, particularly because tazarotene is understood to be the most irritating retinoid approved for treating acne. *Id.* Dr. Dow further explained that Tazorac® 0.05% cream was shown to be "*as irritating*" as the Tazorac® 0.1% cream and concluded that the "unexpected reduction in side effects of the claimed 0.045% tazarotene lotion vs. 0.1% TAZORAC cream is translatable to 0.05% TAZORAC cream." *Id.* at 67 (original emphasis). Thus, "the irritation level observed for 0.05% TAZORAC cream would also be *markedly higher* than the irritation level observed for the claimed 0.045% tazarotene lotion." *Id.* (original emphasis).

With regard to efficacy, Dr. Dow noted the data showed the claimed 0.045% tazarotene lotion provided greater efficacy than Tazorac® 0.1% cream using less than half the dose. *Id.* at 68. Dr. Dow explained a "skilled artisan would *not* expect

to increase the efficacy when decreasing the amount by over half." *Id.* (original emphasis).

Thus, the applicants asserted that even if a POSA were motivated to combine the '824 Publication and the Tazorac® Label, "one of skill in the art would *not* have expected the surprising combination of efficacy and tolerability provided by the claimed lotion" and thus that the claims are not obvious over the cited references. *Id.* (original emphasis).

The Examiner agreed, issuing a notice of allowance on April 12, 2023. *Id.* at 8-15. In the notice of allowance, the Examiner stated the arguments and the data provided in Dr. Dow's declaration "are both convincing to overcome a prima facie case." *Id.* at 13. The Examiner noted Dr. Dow declared that "the 0.05% wt. tazarotene cream yields the same incidence of erythema and similar incidence of burning skin as the 0.1% wt. tazarotene cream." *Id.* at 13. Thus, the Examiner stated, "the unexpected reduction in side effect of the claimed 0.045% wt. tazarotene composition vs the 0.1% wt. tazarotene composition is also translatable to the prior art 0.05% wt. tazarotene composition." *Id.* at 13-14. The Examiner also stated the data showed that the claimed 0.045% tazarotene lotion was more effective than the higher concentration cream, Tazorac® 0.1%. *Id.* at 14. The Examiner further stated that a POSA could not have predicted at the time of the invention that administering the claimed lower dose of tazarotene would result in

improved efficacy in addition to greater tolerability. *Id.* Thus, the Examiner concluded, in view of MPEP § 716.02, "the unexpected results of the presently claimed 0.045% wt. tazarotene lotion are commensurate in scope and represent a significant and practical advantage over the prior art." *Id.* Accordingly, the claims were allowed.

2. The '576 Application

Padagis contends U.S. Patent Application No. 16/179,576 (the "'576 Application") reflects "inconsistent patentability decisions reached by different examiners on the same evidence and argument" as the '871 Application. Pet. 16. This is not the case. It is undisputed the Examiner for the '576 Application issued a final rejection based on the combination of the '824 Publication and the Tazorac® Label. Pet. 13-14. But the Examiner in the '871 Application made the same final rejection based on the same art. Ex. 1047 at 187-95. The difference was that in the '871 Application, the applicants continued to prosecute the application through issuance, while in the '576 Application the applicant simply elected to abandon the application. *Compare* Ex. 1047 at 1, *with* Ex. 2003 at 2. Thus, Padagis's argument that these "inconsistent decisions" highlight "the need for the Board to address the patentability issues raised in this Petition" (Pet. 16) is meritless.

C. Padagis's Identified Purported Prior Art

Padagis asserts nine grounds of unpatentability based on combinations of eight pieces of purported prior art. Pet. 27. Each piece of purported prior art is addressed below.[2]

1. WO '001 [Ex. 1007]

WO '001 (referred to as "Dow") was the primary reference asserted by the Examiner during prosecution of the '482 Patent. It is also the primary reference in Petitioner's Grounds 1-4.

WO '001 discloses topical pharmaceutical compositions comprising halobetasol propionate ("HP") (a corticosteroid) and tazarotene ("Taz") (a retinoid) for treating psoriasis. Among other things, it also discloses the Phase II clinical trial of IDP-118, a composition comprising HP and Taz. Ex. 1007 at [0061]. It discloses that the study was a double-blind, four-arm study for the treatment of ***psoriasis*** comparing the efficacy of IDP-118, placebo (vehicle), vehicle + HP, and vehicle + Taz. *Id.* at [0061-62]. It further discloses the specific formulations for each of the four compositions used in the study, including the composition wherein the sole active ingredient is tazarotene at a concentration of 0.045%. *Id.* at Table 4.

---

[2] If necessary at a later stage, Bausch Ireland may challenge the purported prior art as not constituting prior art.

It further discloses the Phase II trial demonstrated that IDP-118 showed synergistic efficacy in treating psoriasis, as well as a reduction in adverse events compared to those treated with HP or Taz. *Id.* at [0078-80]. It does not state or suggest any of the compositions disclosed therein could be used to treat acne.

While WO ’001 discloses the 0.045% tazarotene composition used in the IDP-118 Study, the disclosure does not point a POSA to that composition for the treatment of acne. The Taz-only arm was an experimental design arm, not a target medication; and it underperformed IDP-118 when it came to treating psoriasis – the goal of the study. *Id.* at Table 7.

More fundamentally, WO ’001 is directed to *combination psoriasis* products, not single-active-ingredient acne products. *E.g., id.* at [0002] (“[T]his invention relates to topical pharmaceutical compositions comprising a combination of a corticosteroid and a retinoid, and methods using the same, for treating psoriasis.”). It is not limited to selection of tazarotene as the retinoid, and in fact, expressly includes five different retinoids in various potential concentrations. *See id.* at [0030-33]. Moreover, the specification describes the utility of the inventive combination in multiple dosage forms – not just the oil-in-water emulsions claimed in the ’482 Patent. *See id.* at [0038] (“In one aspect, a topical pharmaceutical composition of the present invention is in the dosage form of gel, emulsion (including lotion, cream, and milk), shampoo, foam, suspension, liquid, spray,

paste or ointment."). Only in "certain preferred embodiments" are the dermatological formulations oil-in-water emulsions, *id.*, and in fact, Table 14 of the WO '001 specification discloses many other embodiments in forms other than oil-in-water emulsions. As for the ingredients, the WO '001 specification also discloses numerous alternatives. *See, e.g.*, *id.* at [0039-51].

2. IDP-118 Study [Ex. 1014]

The IDP-118 Study is one of the three references (along with Anderson and Chim) asserted in the Petition not expressly before the USPTO during prosecution of the '482 Patent. The IDP-118 Study was submitted in prosecution of the closely-related '871 Application in an IDS signed by the Examiner (Ex. 1047 at 350-52) and is listed on the face of the resulting '116 Patent (Ex. 2002 at 3).

The IDP-118 Study is a ClinicalTrials.Gov posting describing the then-future conduct of the Phase II study disclosed in WO '001. *See* Ex. 2004 at ¶¶ 679-81.

The IDP-118 Study discloses the same information disclosed in WO '001 regarding the clinical study, but provides significantly less detail, as seen in the comparative chart below:

IDP-118 Study

▶ **Purpose**

The objective of the study is to evaluate the safety and efficacy of a topical lotion when applied once daily to adult subjects with moderate to severe plaque psoriasis.

Condition	Intervention	Phase
Plaque Psoriasis	Drug: IDP-118 Lotion Drug: IDP-118 Monad HP 0.01% Lotion Drug: IDP-118 Monad Taz 0.045% Lotion Drug: IDP-118 Vehicle Lotion	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Factorial Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Phase 2, Multicenter, Double-Blind, Randomized, Vehicle Controlled Clinical Study to Assess the Safety and Efficacy of IDP 118 in the Treatment of Plaque Psoriasis

…

Arms	Assigned Interventions
Experimental: IDP-118 Lotion halobetasol propionate [HP] 0.01%, tazarotene [Taz] 0.045%	Drug: IDP-118 Lotion
Active Comparator: IDP-118 Monad HP 0.01% Lotion HP 0.01%	Drug: IDP-118 Monad HP 0.01% Lotion Active Comparator
Active Comparator: IDP-118 Monad Taz 0.045% Lotion Taz 0.045%	Drug: IDP-118 Monad Taz 0.045% Lotion Active Comparator
Placebo Comparator: IDP-118 Vehicle Lotion Vehicle	Drug: IDP-118 Vehicle Lotion Vehicle

Ex. 1014.

WO '001

Table 4

Compositions for Clinical Studies

Ingredient	Function	Concentration (wt%)			
		IDP-118 (Present Invention)	Placebo (Vehicle)	Halobeta-sol propio-nate only	Tazaro-tene only
Halobetasol propionate, micronized	Active Ingredient	0.01	0	0.01	0
Tazarotene	Active Ingredient	0.045	0	0	0.045
Diethyl sebacate	Emollient & Solvent	2.97	2.97	2.97	2.97
Light mineral oil	Emollient & Solvent	8.03	8.03	8.03	8.03
Sorbitan monooleate	Surfactant/ Emulsifying Agent	0.1	0.1	0.1	0.1
Sorbitol solution, 70%	Humectant	10.7	10.7	10.7	10.7
Methyl paraben	Antimicrobial Preservative	0.17	0.17	0.17	0.17
Propyl paraben	Antimicrobial Preservative	0.03	0.03	0.03	0.03
Edetate disodium dihydrate	Chelating Agent	0.05	0.05	0.05	0.05
Carbomer copolymer type B (Pemulen™ TR-1)	Emulsifying Agent	0.4	0.4	0.4	0.4
Carbomer homopolymer type A (Carbomer 981)	Thickener	0.6	0.6	0.6	0.6
Sodium hydroxide	pH-adjusting agent	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5
Purified water	Solvent	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100

Ex. 1007 at 21.

Thus, the IDP-118 Study discloses only the four arms of the study and the concentrations of the active ingredients in three of the four arms (plus placebo in the fourth). Like WO '001, the IDP-118 Study discloses that one of the four compositions used in the study is "Monad Taz 0.045% Lotion Active Comparator," Ex. 1014 at 6, but the IDP-118 Study does not disclose the vehicle formulation, which as seen above is disclosed in Table 4 of WO '001.

3. '824 Publication [Ex. 1012]

The PCT publication of the '824 Publication, WO '443, was the primary reference asserted by the Examiner in the '871 Application prosecution. Pet. 15-16,

15 n.3.[3] The ’824 Publication is also the primary reference in Petitioner’s Grounds 5-9. Pet. 27.

The ’824 Publication discloses topical formulations with a corticosteroid as the active ingredient. Ex. 1012 at [0013]. It published on May 24, 2012 and names Dow and Angel as inventors. *Id.* at Cover.

The ’824 Publication discloses corticosteroid formulations that were intended to treat dermatologic conditions that are typically treated with corticosteroids, “such as eczema, psoriasis, and chronic dermatitis.” *Id.* at [0002]. The ’824 Publication does not mention either tazarotene or the treatment of acne.

The ’824 Publication discloses a wide range of potential vehicles, including topical formulations that contain a corticosteroid, a liquid oil component with certain types of carboxylic acid esters, and certain solubilization requirements. *See id.* at claim 1. Although Padagis (with impermissible hindsight) focuses on one of the vehicles disclosed in Table 4, it ignores the range of disclosed embodiments, including Example 5 – a lotion *different than* those in Table 4 – that meets FDA stability requirements. *Id.* at [0046-49].

---

[3] The Examiner in the ’871 Application referred to WO ’443 as “Dow,” while the Examiner in the prosecution of the ’482 patent referred to WO ’001 as “Dow.”

4. Tazorac® Label [Ex. 1013]

The Tazorac® Label was asserted in combination with WO '443 in the prosecution of the '871 Application. *E.g.*, Ex. 1047 at 191-94. The Tazorac® Label is also asserted in the Petition in combination with the '824 Publication in Grounds 5 and 6. Pet. 27.

The Tazorac® Label describes Tazorac® 0.1% and Tazorac® 0.05% creams. As previously stated, while the FDA approved both concentrations for treating psoriasis, only Tazorac® 0.1% was approved for treating acne. Ex. 1013 at 2.

5. Shalita [Ex. 1011]

Shalita was disclosed in an IDS during prosecution of the '482 Patent in an IDS, and the Examiner notated considering it. *See* Ex. 1002 at 228 (on page listing Shalita, "ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.A.C/"); *id.* at 229 (reflecting Examiner signature and date considered 10/23/2019). Padagis asserts Shalita in Ground 4 of the Petition. Pet. 27.

Shalita disclosed an experimental clinical study evaluating 0.1% and 0.05% tazarotene gels for treating acne. Ex. 1011 at 350. It disclosed 0.1% tazarotene gel was more effective than the 0.05% tazarotene gel, but the 0.05% tazarotene gel was more effective than the vehicle gel alone. *Id.* at 351.

Specifically, Shalita discloses a 12-week multicenter, double-blind, vehicle-controlled study evaluating 375 patients who used tazarotene in concentrations of 0.05% and 0.1% for the treatment of acne. *Id.* at 349. The study demonstrated the superiority of the 0.1% gel over the 0.05% gel in treating acne. Shalita concluded "[e]fficacy was concentration-dependent, as demonstrated by significant differences favoring the 0.1% concentration over the 0.05% concentration." *Id.* at 353.

The irritability results, however, were very close for both the 0.05% group and the 0.1% group. "Treatment-related withdrawals, due primarily to local irritation, occurred in 8.7% of patients (13 of 150 patients) in the tazarotene 0.1% group," compared to 8.1% (12 of 148) in the tazarotene 0.05% group. *Id.* at 352. The difference was attributable to only one individual.

To combat irritation, Shalita recommended reducing the concentration of tazarotene from 0.1% to 0.05% temporarily "until the skin adjusts," suggesting that the lower concentration was not a viable long-term treatment option. *Id.* at 354. Shalita reported this use would be off label, because "in the United States, tazarotene gel is only approved for the treatment of acne vulgaris at a concentration of 0.1%." *Id.* at 353.

6. Kircik [Ex. 1009]

Like Shalita, Kircik was submitted to the Examiner in an IDS during prosecution of the ’482 Patent, and the Examiner noted consideration. Ex. 1002 at 228-29. The Petition asserts Kircik in Grounds 2 and 8. Pet. 27.

Kircik also disclosed an experimental clinical study involving the use of 0.05% tazarotene for treating acne. Ex. 1009 at 650. Specifically, Kircik disclosed a 12-week study comparing 0.04% tretinoin microsphere gel delivered by pump to 0.05% tazarotene cream in the treatment of mild-to-moderate facial acne. *Id.*

7. Anderson [Ex. 1008]

Anderson is an article that appeared in *Cutis* in 2004, entitled “Topical Tazarotene in Acne Vulgaris: Treatment Approaches.” Ex. 1008 at 16. Anderson is one of the three references cited by Padagis not expressly before the USPTO during prosecution of the ’482 Patent.

As the title suggests, Anderson describes treatment approaches of its five authors for using topical tazarotene in treating acne vulgaris. Anderson discloses that three of the five authors prescribe 0.05% tazarotene cream as part of a tazarotene ladder for treating acne. Specifically, Anderson discloses Dr. Callender “initiates treatment with tazarotene 0.05% cream applied every night,” then “[a]fter 2 or 3 weeks, she switches patients to a stronger concentration (tazarotene 0.1% cream) for an additional 3 weeks,” then reassesses the patient. *Id.* at 17. Anderson

further discloses Dr. Emil Tanghetti "starts treatment with lower-strength tazarotene cream or gel and increases (or decreases) the strength according to tolerability." *Id.* at 20. Anderson further discloses Dr. Lee Zane "thinks that topical tazarotene can be a useful part of the treatment regime and that tazarotene 0.05% cream fits well into the retinoid ladder in moderate to severe inflammatory acne or comedonal acne, with every-other-night dosing (advancing to nightly, as tolerated), often in conjunction with an oral antibiotic." *Id.*

At best, Anderson discloses anecdotal evidence some physicians prescribe 0.05% tazarotene cream as part of a tazarotene ladder to treat acne. Contrary to Padagis's contention, Anderson does not show "in real-world clinical practice, over a more than ten-year period before the priority date of the '482 [P]atent, POSITAs were commonly prescribing and using compositions with 0.05% tazarotene as the sole active ingredient to treat acne." Pet. 31.

8. Chim [Ex. 1010]

Chim is a review article entitled "Acne Vulgaris" which appears to have been published as a section of a book in 2016. Ex. 1010 at 7. Chim is another of the three references not expressly before the USPTO during prosecution of the '482 Patent.

Chim discloses a wide variety of acne treatments, their benefits, and their drawbacks. *Id.* at 11-15; *see also id.* at 15-19. In describing retinoids, Chim

identifies a preference for ***adapalene***, not tazarotene. *See id.* at 13, 22 ("Adapalene is the best tolerated [topical retinoid] and may be the first choice of therapy.").

As Padagis notes, Chim sets out a table (partially reproduced below) entitled "Available Prescription Options to Treat Acne Vulgaris."

Table 1-3. Available Prescription Options to Treat Acne Vulgaris

Drugs	Available Formulations (Concentrations)	Dose	Common Adverse Effects	Place in Therapy
Topical Retinoids				
Adapalene	Cream (0.1%) Gel (0.1%, 0.3%) Lotion (0.1%)	Once daily (cream, gel: daily in the evening)	Dryness, erythema, photosensitivity, pruritus, scaling, stinging	Any stage
Tazarotene	Cream (0.05%, 0.1%) Foam (0.1%) Gel (0.05%, 0.1%)	Once daily in the evening		
Tretinoin	Cream (0.025%, 0.05%, 0.1%) Gel (0.01%, 0.025%) Micronized gel (0.04%, 0.08%, 0.1%)	Once daily in the evening		

Id. at 14 (Table 1-3).

The full table lists topical retinoids, topical antibiotics, topical combinations, and oral antibiotics. It is not clear from this table that Chim is suggesting all of the available formulations listed for each type of topical retinoid (adapalene, tazarotene, tretinoin) are available options to treat acne, rather than simply listing all of the available concentrations of the drugs. There is no other specific reference to 0.05% tazarotene in Chim.

At best, Chim discloses 0.05% tazarotene cream is one of dozens of available options for treating acne. Contrary to Padagis's contention, Chim does not show that "in real-world clinical practice, over a more than ten-year period

before the priority date of the ’482 [P]atent, POSITAs were commonly prescribing and using compositions with 0.05% tazarotene as the sole active ingredient to treat acne.” Pet. 31.

D. Procedural History

1. Bausch Ireland prevails over Padagis in prior litigation involving the same art asserted here.

The parties’ ’482 Patent dispute is not the first time Bausch Ireland and Padagis have litigated patents covering Bausch Ireland’s dermatological innovations. *See, e.g.*, Ex. 2001 at 1-2. A few years ago, Bausch Ireland brought a Hatch-Waxman patent infringement case against Padagis for filing ANDAs seeking FDA approval to market generic versions of Bryhali® (IDP-122) and Duobrii® (IDP-118) products, the Prior Case, presided over by Judge Chesler. *Id.* In the Prior Case, Padagis raised obviousness challenges to the four asserted patents, relying on many of the references Padagis relies on here, including the ’824 Publication, Tazorac® Label, and IDP-118 Study. Ex. 2005 at 44-47. After a three-day bench trial, Judge Chesler upheld the validity of all asserted claims, rejecting the arguments Padagis repackages here. Ex. 2001 at 2.

For example, to invalidate patents covering IDP-118, Padagis argued that a POSA would combine (a) the ’824 Publication and the Tazorac® Label (like Grounds 5-6 here) and/or would combine (b) the ’824 Publication and IDP-118

Study (like Grounds 7-9 here), along with a third reference not relevant here. Ex. 2005 at 44-46; Ex. 2006 at ¶¶ 310-12, 326-28; Ex. 2001 at 67-68.

For these combinations, Judge Chesler concluded Padagis "ha[d] not made the necessary showing" under *Unigene*, 655 F.3d 1352, that a POSA "would have selected and combined [Padagis's claimed] prior art elements in the normal course of research and development to yield the claimed invention." Ex. 2001 at 67-69. For instance, Judge Chesler found that Padagis failed to identify the problem that would cause a POSA to combine these references, let alone that a POSA "would have had a motivation to select HP .01%, tazarotene .045%, and the vehicle taught by the '824 Publication." *Id.* at 69. Rather, said Judge Chesler, "Padagis begins in the middle, with the POSA already having found and selected all the pieces." *Id.* Judge Chesler further criticized Padagis for failing to show a motivation to "select .045% as the concentration of tazarotene." *Id.* Judge Chesler found that Padagis "does not place its prior art references" – *i.e.*, references that were to be combined like the grounds here – "into the context of a theory that accounts for the motivation to select the elements and then combine them." *Id.*

2. Bausch Ireland sues Padagis for infringing the '482 Patent more than a year ago.

On June 24, 2022, Bausch Ireland (along with Bausch Health US, LLC, and Bausch Health Americas, Inc.) sued Padagis for infringing the '482 Patent under

the Hatch-Waxman Act, the DNJ4248 Case. Ex. 2007. Padagis stipulated to waiver of service in a stipulation attached to the Complaint. Ex. 2008. The waiver of service was filed on June 29, 2022. Ex. 2009.

3. Bausch Ireland sues Padagis for infringing the ’116 Patent.

On June 21, 2023, Bausch Ireland (along with Bausch Health US, LLC, and Bausch Health Americas, Inc.) filed a new complaint under the Hatch-Waxman Act against Padagis asserting infringement of the ’116 Patent based on Padagis’s generic Arazlo® ANDA filing. Ex. 2010. The ’116 Patent case was subsequently consolidated with the ongoing DNJ4248 Case. Ex. 2011. The consolidated cases were assigned to Judge Chesler, who had presided over the Prior Case. *Compare id.*, *with* Ex. 2001.

The DNJ4248 Case is thus proceeding before a Judge who already has intimate experience with the underlying formulation technology, the state of the art regarding tazarotene, and many of the same prior art references raised here. Ex. 2001. Indeed, the same Judge has already considered the ’824 Publication, Tazorac® Label, and IDP-118 Study, *see id.* at 9, 66-70, and is familiar with the specification of WO ’001, which is substantively the same as that of the combination patents whose validity he adjudicated in the Prior Case.

4. Padagis files its Petition three days before the deadline.

On June 21, 2023 – just three days before the statutory deadline – Padagis filed the Petition. It is not apparent why Padagis waited until the last minute to seek the Board's review. Padagis sent Bausch a detailed, preliminary statement of its invalidity theories in May 2022 in its PIV Notice Letter. And then, it served its 127-page invalidity contentions in the DNJ4248 Case on December 22, 2022 – 6 months before it filed its Petition. Ex. 2012.

5. The current state of the DNJ4248 Case.

The DNJ4248 Case has been ongoing for 16 months. It was recently consolidated with the '116 Patent case, and a schedule has been entered for the consolidated cases. Ex. 2013 at ¶ 1. The parties will largely complete document production on November 6, 2023; depositions are likely to take place in December 2023, with fact discovery ending on January 9, 2024; and expert discovery ends on May 31, 2024. Padagis is unencumbered by the typical stay of FDA approval in Hatch-Waxman cases, upon FDA approval and absent a preliminary injunction, Padagis can launch with 60 days' notice to Bausch. In light of this fact, it is reasonably likely the Court will move the litigation expeditiously to avoid the burden of preliminary injunction proceedings. Based on the timeline from the Prior Case, the case will likely be tried in mid-summer 2024.

III. Level of Ordinary Skill in the Art

For purposes of this proceeding, Patent Owner accepts the definition of a POSITA set out in the Petition, also referred to as a POSA herein.

IV. Claim Construction

Although Padagis claims it "does not believe that any claim terms require express construction," Pet. 35, the term "about 0.045%" would require construction if the Board institutes the proceeding.

The Petition asserts, in several places, "about 0.045%" tazarotene is "the same or nearly the same" as 0.05% tazarotene. *See, e.g.*, Pet. 3-4. If Padagis contends 0.05% tazarotene is ***the same*** as "about 0.045%" tazarotene, then claim construction would be required, as the intrinsic record makes clear that "about 0.045%" tazarotene is ***not*** the same as 0.05% tazarotene but rather means, in pertinent respect, "lower than 0.05%." *See, e.g.*, Ex. 1001 at 1:35-50, 2:48-64, Tables 1 & 2; Ex. 1002 at 126, 165, 168, 249, 250-51, 203, 205, 397-400.

However, Patent Owner respectfully submits a decision not to institute can be made without requiring construction of this term.

V. The Board Should Exercise its Discretion to Deny Institution Under 35 U.S.C. § 325(d)

35 U.S.C. § 325(d) provides that the Director may elect not to institute a proceeding when a petitioner raises "the same or substantially the same" art or arguments the USPTO has previously considered. *See Becton, Dickinson & Co. v.*

B. Braun Melsungen AG, IPR2017-01586, Paper 8, 17-18 (P.T.A.B. Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph).

Employing a framework that "reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown," the Director will discretionarily deny institution when two conditions are satisfied: (1) "the same or substantially the same art previously was presented to the Office" ***or*** "the same or substantially the same arguments previously were presented to the Office"; and (2) the petitioner does not "demonstrate[] that the Office erred in a manner material to the patentability of the challenged claims." *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8 (P.T.A.B. Feb. 13, 2020) (precedential).

In applying the *Advanced Bionics* two-part framework, the Board considers a number of non-exclusive factors, as set forth in *Beckton, Dickinson*, IPR2017-01586, Paper 8 at 17-18 (the "*Becton, Dickinson* factors"):

> (a) the similarities and material differences between the asserted art and the prior art involved during examination;
>
> (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
>
> (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;

(d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;

(e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and

(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

For part one of the *Advanced Bionics* two-part framework, the Board evaluates *Becton, Dickinson* factors (a), (b), and (d). *Advanced Bionics*, IPR2019-01469, Paper 6 at 10. If it is determined that the same or substantially the same art or arguments were previously presented to the USPTO, the Board then considers *Beckton, Dickinson* factors (c), (e) and (f) in part two of the *Advanced Bionics* framework. *Id*.

A. Padagis's Purportedly New References are Cumulative of Art of Record

It is common ground that only three of the eight references raised in the Petition were not expressly before the Examiner in prosecution of the '482 Patent: Anderson, Chim, and IDP-118 Study. *Compare* Pet. 27*, with* Ex. 1001 at Cover (identifying '824 Publication, Tazorac® Label, Kircik, Shalita, and WO '001 as cited references).

As discussed below, each of the three references are cumulative of, and thus substantially the same as, art that was before the Examiner. A "reference is cumulative when it 'teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO.'" *Regeneron Pharms., Inc. v. Merus N.V.*, 864 F.3d 1343, 1350 (Fed. Cir. 2017) (quoting *Regents of the Univ. of Calif. v. Eli Lilly & Co.*, 119 F.3d 1559, 1575 (Fed. Cir. 1997)). The first criterion for exercising discretion under Section 325(d) – the Petition relies on the same or substantially the same art – is satisfied on this basis alone. *Complete Genomics, Inc. v. Illumina Cambridge Ltd.*, IPR2017-02172, Paper 22, 4-5 (P.T.A.B. Aug. 2, 2018) ("Section 325(d) does not require, as a precondition to the exercise of discretion and denial of a petition, a showing that the same or substantially the same arguments were advanced previously before the Office.").

1. Anderson

Anderson is cumulative of Kircik and Shalita, which the Examiner already considered.

Anderson at most discloses anecdotal evidence some physicians were prescribing 0.05% tazarotene as part of a tazarotene ladder to treat acne. As the Petition acknowledges, both Kircik and Shalita, which were before the USPTO and considered during prosecution of the '482 Patent, disclosed clinical data showing

0.05% tazarotene had some level of efficacy in treating acne and could be used for that purpose (Ex. 1009 at 651-52; Ex. 1011 at 351), with Shalita and the Tazorac® Label disclosing this use would be off label (Ex. 1011 at 353; Ex. 1013 at 2). Moreover, Shalita disclosed that both tazarotene 0.1% and 0.05% "were safe and shown to have acceptable tolerability profiles," but recommended the irritation associated with use of tazarotene could be managed by "reducing the strength of the treatment, from 0.1% gel to 0.05% gel until the skin adjusts," suggesting 0.05% tazarotene was not sufficiently effective. Ex. 1011 at 353-54. This is precisely the tazarotene ladder that the three dermatologists in Anderson who prescribe 0.05% tazarotene in their practice say they employ.

Shalita and Kircik disclose substantial data from clinical trials regarding the safety and efficacy of 0.05% tazarotene for acne patients. Shalita discloses 0.05% tazarotene is safe and has an acceptable tolerability profile and further recommends 0.05% tazarotene can be used off-label in a tazarotene ladder with 0.1% tazarotene to manage irritation. Ex. 1011 at 353-54. Anderson adds simply that three dermatologists were actually doing what Shalita recommends. Given the extensive teachings of Shalita and Kircik about the safety, efficacy, and use of 0.05% tazarotene to treat acne patients, a reasonable examiner would consider that Anderson teaches no more than what is taught in Shalita and Kircik and is thus cumulative of those references. *Regeneron,* 864 F.3d at 1350.

2. Chim

Chim discloses even less information regarding 0.05% tazarotene than Anderson. The only disclosure in Chim of 0.05% tazarotene is the listing of 0.05% tazarotene as one of the "Available Formulations (Concentrations)" in a table entitled "Available Prescription Options to Treat Acne Vulgaris." That information is also disclosed in Shalita and Kircik. Chim teaches nothing more than what is taught in Shalita and Kircik and is thus cumulative of the art that was before the USPTO and considered during prosecution of the '482 Patent.

Padagis argues that "Anderson and Chim show that in real-world clinical practice, over a more than ten-year period before the priority date of the '482 [P]atent, POSITAs were commonly prescribing and using compositions with 0.05% tazarotene as the sole active ingredient to treat acne." Pet. 31. Padagis claims this "additional evidence and the motivation it would have provided POSITAs is not cumulative and warrants reconsideration of the prior art, such as WO '001, that was before the Examiner during prosecution." *Id.* at 31-32.

However, Anderson and Chim show no such thing. Anderson shows only that three dermatologists used 0.05% tazarotene as part of a tazarotene ladder for treating acne, consistent with the teachings of Shalita and Kircik. Anderson does not disclose or suggest the approach used by these three dermatologists was

common practice among physicians. Chim only discloses 0.05% tazarotene was an available option for treating acne, which is also taught in Shalita and Kircik.

In short, there is nothing material in Anderson and Chim that goes beyond the teachings of Shalita and Kircik, which were submitted to and considered by the Examiner. Anderson and Chim are cumulative of, and thus substantially the same as, the art that was before the USPTO.

3. IDP-118 Study

The IDP-118 Study is cumulative of WO ’001. WO ’001 discloses all of the same information and significantly more detail regarding the same IDP-118 clinical study, including the concentrations of the active ingredients and a list of the excipients and their exact concentrations for each of the four compositions used in the study. *See supra* § II.C.2.

Thus, the IDP-118 Study does not disclose any information that is not already disclosed in WO ’001 and is therefore cumulative of WO ’001, the primary reference asserted by the Examiner during prosecution. Padagis’s claim that “the IDP-118 Study is not cumulative of the prior art submitted to and/or considered by the Examiner” (Pet. 32) is baseless and simply wrong.

B. Padagis's Contention the Board Should Grant Institution Based on the '824 Publication, Shalita, and/or Kircik Because the Examiner Did Not Apply Them Is Without Merit

Padagis contends the Board should not deny institution based on the citation of the '824 Publication, Shalita, and Kircik on an IDS because the Examiner did not apply them during prosecution. Pet. 32-33. This argument is without merit.

Art presented in an IDS is deemed to be art considered by the examiner for purposes of part one of the *Advanced Bionics* two-part analysis. IPR2019-01469, Paper 6 at 7-8 ("Previously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an [IDS], in the prosecution history of the challenged patent."). Most IPR decisions that have considered the issue have found part one of the *Advanced Bionics* framework to be satisfied with regard to art presented in an IDS but not applied by the examiner. *See, e.g., Medtronic Corevalve LLC v. Speyside Medical, LLC*, IPR2021-00240, Paper 9, 12-32 (P.T.A.B. July 23, 2021) (rejecting argument that the relevant *Becton, Dickinson* factor is limited to "references that are expressly included in a rejection by the examiner"); *Nespresso USA, Inc. v. K-Fee Sys. GmbH*, IPR2021-01221, Paper 9, 12-14 (P.T.A.B. Jan. 18, 2022) (same). Even two cases Padagis cites in the Petition for the contrary proposition (Pet. 32-33) find the submission of a reference in an IDS is sufficient to satisfy part one of the *Advanced Bionics* framework. In *Microsoft Corp. v. Surfcast, Inc.*, the Board found "part one of the

Advanced Bionics framework has been satisfied" through the submission of a reference in an IDS, though it concluded in part two of the analysis that the examiner had made a material error, finding the referenced art was not considered and the petitioner had presented "compelling evidence" that the art anticipates at least one of the claims. IPR2022-00590, Paper 9, 15-16 (P.T.A.B. Oct. 7, 2022) (cited in Pet. at 33). Similarly, in *Lite-On Technology Corp. v. Sensor Electronic Technology, Inc.*, IPR2022-00780, Paper 11, 31-32 (P.T.A.B. Oct. 28, 2022) (cited in Pet. at 33), the Board found part one of the analysis was satisfied by the submission of a reference in an IDS, but also found in part two of the analysis that the reference was not extensively evaluated and that the petitioner had shown a reasonable likelihood of prevailing.

Moreover, the '824 Publication was, in fact, applied as the primary reference by the Examiner in the prosecution of the closely related '871 Application. *See, e.g.*, Ex. 1047 at 299-305.

Here, Padagis has not explained ***why*** it was wrong of the Examiner not to apply these references in light of the art it ***did*** apply. The Petition lacks the detail necessary to show material error because there was no material error.

C. The Arguments Presented in the Petition Are Substantially the Same as Arguments Already Presented to the Examiner

The Petition's nine grounds of unpatentability can be grouped into two basic subsets.

First, Grounds 1-4 assert that the claims of the '482 Patent are obvious based on WO '001 as the primary reference, in combination with Anderson, Kircik, Chim, and Anderson + Shalita, respectively. Pet. 27. The Petition contends that "WO '001 disclosed a 0.045% tazarotene lotion that is ***identical*** to the composition disclosed and claimed in the '482 [P]atent" for use in psoriasis (Pet. 35 (original emphasis)), while Anderson, Kircik, Chim, and Anderson + Shalita teach the use of "nearly the same" concentration of tazarotene to treat acne and thus provide motivation to use the 0.045% tazarotene formulation of WO '001 to treat acne with a reasonable expectation of success. *Id.* at 35-36, 57.

Second, Grounds 5-9 assert the claims of the '482 Patent are obvious based on the '824 Publication as the primary reference in combination with the Tazorac® Label alone; the Tazorac® Label and Anderson; and IDP-118 and Anderson, Kircik, or Chim. *Id*. at 27. The Petition contends the '824 Publication discloses the identical lotion vehicle used in the claimed 0.045% tazarotene lotion formulation, while the other references (Tazorac® Label; Tazorac® Label and Anderson; IDP-118 and Anderson, Kircik, or Chim) provide motivation to "replace the active

ingredient in the ’824 [P]ublication’s formulations with 0.045% tazarotene” and to use the 0.045% tazarotene lotion to treat acne. *Id*. at 59-60, 75, 77.

For both groups, the Petition’s arguments are substantially the same as arguments made and overcome at the USPTO.

In the ’482 Patent file wrapper, the primary reference asserted by the Examiner was WO ’001 (referred to as “Dow”), the same primary reference asserted in Padagis’s Grounds 1-4. Exactly as in the Petition’s argument, the Examiner relied on WO ’001 for its disclosure of the 0.045% tazarotene formulation in Table 4. Ex. 1002 at 216 (identifying “the specific amounts in table 4 (which are the same amounts as disclosed in instant claim 40”); *see also id*. at 203, 123. The Examiner further asserted that Donello taught the use of tazarotene to treat acne. *Id.* at 186, 217. Putting the two principles together, the Examiner had considered the combination of 0.045% tazarotene in the WO ’001 vehicle to be obvious. *Id.* The Examiner maintained that rejection, even to the point of a notice of appeal. *Id.* at 121, 122-27. It was only after the applicants amended the claims to recite 0.045% tazarotene as the sole active ingredient and highlighted the surprising efficacy and tolerability of the claimed method (*id.* at 75-85) that the Examiner concluded the application was allowable (*id.* at 53-56).

The Petition makes substantially the same arguments. For example, for Grounds 1-3, Padagis defines the central issue as “whether POSITAs would have

found it obvious to use th[e] [WO ’001] 0.045% tazarotene lotion to treat acne, rather than psoriasis.” Pet. 35. That is precisely the question the Examiner already considered many times throughout prosecution. *E.g.*, Ex. 1002 at 147 (“It would have been obvious to employ tazarotenic acid as the sole agent in the treatment of acne in view of [WO ’001].”). Similarly for Ground 4. Pet. 57 (claiming “Shalita” – an already-before-the-Examiner reference – “would have provided POSITAs with even further motivation to use the 0.045% tazarotene lotion from WO ’001 to treat acne”).

Thus, the Petition’s arguments in Grounds 1-4 are substantially the same arguments addressed by the Examiner, only substituting Anderson, Kircik, Chim, and Shalita for the Donello reference asserted by the Examiner. *See, e.g.*, Pet. 41-42 (“POSITAs would have been motivated to combine the teachings of WO ’001, which focused on treating psoriasis with tazarotene compositions, and Anderson, which focused on treating acne with tazarotene.”); *id.* at 43 (“Kircik’s teachings of the efficacy of 0.05% tazarotene composition in the topical treatment of acne would have motivated POSITAs to use the 0.045% tazarotene composition disclosed by WO ’001 with a reasonable expectation of success.”); *id.* at 57 (“Shalita would have provided … even further motivation to use the 0.045% tazarotene lotion from WO ’001 to treat acne.”).

The situation is similar for Grounds 5-9. There, the Petition relies on the ’824 Publication for its disclosure of the ***vehicle*** of the claimed 0.045% tazarotene lotion in combination with either the disclosure of 0.05% tazarotene in the Tazorac® Label (alone or in combination with Anderson) or 0.045% tazarotene in the IDP-118 Study (in combination with Anderson, Kircik, or Chim), to arrive at the claimed 0.045% tazarotene lotion and its use for the treatment of acne with a reasonable expectation of success. Pet. 59-60, 75, 76-77.

But the combination of the vehicle from the ’824 Publication and the Tazorac® Label or the IDP-118 study, at best, results in the 0.045% tazarotene lotion disclosed in WO ’001, which was the starting point for the Examiner’s analysis in prosecution, coupled with the argument based on Donello that it would have been obvious to use that 0.045% tazarotene lotion to treat acne.

In other words, Grounds 5-9 simply repackage the same arguments made during prosecution by relying on a combination of the ’824 Publication and the Tazorac® Label or the IDP-118 Study to get to the 0.045% tazarotene lotion composition as the starting point for the analysis, rather than just WO ’001 which discloses the vehicle and the 0.045% tazarotene concentration together. After that, the rest of the analysis – that a POSA would have been motivated to use the 0.045% tazarotene lotion to treat acne – is the same.

Moreover, substantially the same art and arguments advanced in Grounds 5-9 were directly addressed during prosecution of the ’871 Application cited in the Petition, which resulted in the ’116 Patent. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 10-11 (holding *Becton, Dickinson* factor (d) evaluates “whether the arguments presented in the petition are ‘the same or substantially the same’ as the arguments previously presented to the Office during ***any*** proceeding”); *ZTE (USA) Inc. v. Fractus, S.A.*, IPR2018-01457, Paper 20, 5 (P.T.A.B. Oct. 4, 2019) (“Neither Section 325(d) nor *Becton Dickinson* appears to limit the inquiry to a particular examiner” and thus the Board may consider “asserted prior art by the Office during previous examination of … closely related patents.”). As Padagis has argued elsewhere, “[t]he ’482 [P]atent and the ’116 [P]atent recite claims to a nearly identical topical pharmaceutical composition of the drug tazarotene.” Ex. 2014 at 3. During prosecution of these “nearly identical” claims, the Examiner considered ***nearly all*** of the art identified in Padagis’s combinations here – *i.e.*, the ’824 Publication, IDP-118 Study, the Tazorac® Label, Shalita, and Kircik. Ex. 1047 at 344-52, 201-02.

As in Grounds 5-9, one of the primary references asserted by the Examiner in prosecution of the ’871 Application was the ’824 Publication.[4] The Examiner asserted multiple rejections, including a final rejection, that the claims were obvious based on the ’824 Publication, the Tazorac® Label, and a third reference. The Examiner stated that the Tazorac® Label teaches 0.05% tazarotene cream, while the ’824 Publication teaches topical formulations for psoriasis and that it would have been obvious to combine 0.05% tazarotene from the Tazorac® Label with the vehicle disclosed in the ’824 Publication and to adjust the 0.05% concentration to 0.045%. Ex. 1047 at 187-95, 193.

That is substantially the same argument, based on the same art, advanced in the Petition’s Grounds 5 and 6. Grounds 7-9 simply substitute the IDP-118 Study for the Tazorac® Label for the same purpose, *i.e.*, to arrive at the 0.045% tazarotene concentration in the claimed vehicle. During prosecution of the ’871 Application, as for the ’482 Patent, the applicants traversed the rejection by highlighting the “surprising improvement[s]” that the claimed 0.045% tazarotene

---

[4] As noted *supra*, the actual reference cited during the prosecution of the ’871 Application was WO ’443, which Petitioner acknowledges is the PCT publication of the ’824 Publication (Pet. 15 n.3). Patent Owner refers to WO ’443 herein as “the ’824 Publication.”

lotion provides "in both efficacy and tolerability as compared to the known TAZORAC 0.1% and 0.05% creams." *Id.* at 65. And for the '871 Application, as for the '482 Patent, the claims were allowed, with the '116 Patent issuing on June 20, 2023. Ex. 2002 at 1.

D. Padagis Has Not Demonstrated that the USPTO Materially Erred

Where, as here, the same or substantially the same art or arguments previously were presented to the USPTO, the Board should exercise its discretion to deny institution unless the Petitioner demonstrates the USPTO made a material error in granting the patent. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8-9. The standard for demonstrating material error imposes a heavy burden on Padagis: "If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability." *Id.*

The Petition does not meet this burden. To evaluate material error, the Board weighs *Becton, Dickinson* factors c, e, and f. *Id.* at 10. The Petition barely refers to these factors. The Petition's only explicit application of the material-error standard is the following sentence: "Accordingly, to the extent that the references relied on herein were before the Examiner during prosecution, this Petition demonstrates that the Examiner materially erred in allowing the challenged claims over those references." Pet. 33.

But the material-error standard isn't license to incorporate an entire petition by reference; rather, Padagis needed to direct the Board to evidence showing the Examiner made a mistake "in the evaluation of the prior art, for example, by showing that the Examiner misapprehended or overlooked specific teachings in the relevant prior art such that the error by the Office was material to the patentability of the challenged claims." *Advanced Bionics*, IPR2019-01469, Paper 6 at 21; *Vital Connect, Inc. v. Bardy Diagnostics, Inc.*, IPR2023-00381, Paper 7, 20 (P.T.A.B. July 11, 2023) ("[W]hile there are no 'magic words' necessary to address material error, Petitioner's alleged grounds of unpatentability cannot establish material error *per se* under our binding precedent.… Otherwise, the reasonable likelihood standard of § 314(a) and the second part of the *Advanced Bionics* framework ('material error') would collapse into one."); *Google LLC v. Valtrus Innovations Ltd.*, IPR2022-01197, Paper 9, 22-23 (P.T.A.B. Jan. 3, 2023) (finding failure to demonstrate material error when argument "does not address the Office's consideration of this reference with any degree of specificity"); *Nespresso USA, Inc.*, IPR2021-01221, Paper 9 at 25 ("To the extent Petitioner argues that the relative strength of the grounds stated in the Petition, standing alone, supports a finding of material Examiner error, that argument is not developed adequately and, therefore, is unpersuasive on this record."). Its failure to do so is fatal.

Even setting this aside, the Petition does not show material error, for several reasons. First, as noted above, Padagis's central argument that it would have been obvious to use 0.045% tazarotene to treat acne because "POSITAs were commonly prescribing and using compositions with 0.05% tazarotene as the sole active ingredient to treat acne" (Pet. 31) fundamentally contradicts the conclusions Padagis seeks to draw. If dermatologists were commonly using Tazorac® 0.05% cream off-label to treat acne, as Padagis asserts based on Anderson (Ex. 1008), Chim (Ex. 1010), IQVIA Sales Data (Ex. 1015) and expert declarations of Dr. Schwartz (Ex. 1003) and Dr. Murthy (Ex. 1005), there would have been no motivation for a POSA to use the claimed 0.045% tazarotene lotion in light of the fact Tazorac® 0.05% cream was readily available.

Second, Padagis does not, and cannot, rebut the showing of unexpected results, let alone show material error in crediting it. The '482 patent applicants demonstrated a significant unexpected result, namely that the claimed 0.045% tazarotene lotion surprisingly was ***31.8% more effective*** than Tazorac® 0.1% cream and ***90.3% less irritating*** than Tazorac® 0.1% cream and, by extension, Tazorac® 0.05% cream whose tolerability was found in clinical studies to be comparable to Tazorac® 0.1% cream. A POSA would not have expected to increase efficacy by 31.8% and to decrease adverse events by 90.3% by using a tazarotene concentration that is less than half the concentration of Tazorac® 0.1% cream. Ex.

1002 at 81-84. At the very least, "reasonable minds can disagree" whether unexpected results were presented, which negates a possible finding of material error under the *Advanced Bionics* standard. Any room for reasonable disagreement means Padagis has not shown material error. *See, e.g.*, *Apotex Inc. v. Auspex Pharms., Inc.*, IPR2021-01507, Paper 9, 35 (P.T.A.B. Mar. 9, 2022) ("But in the absence of any showing that the Examiner relied upon materially false or incomplete statements during prosecution, or otherwise failed to properly apply the standard for assessing unexpected results, we find Petitioner's information insufficient to support a finding of material Examiner error.").

Padagis argues the results for the claimed 0.045% tazarotene lotion would not have been unexpected because clinical studies allegedly showed that 0.05% tazarotene was effective for treating acne and it had been common practice for physicians to prescribe Tazorac® 0.05% cream off-label to treat acne for nearly 20 years. However, this argument is unavailing. The unexpected result was not solely that the claimed 0.045% tazarotene lotion was ***effective*** for treating acne, but that it was ***31.8% more effective*** than Tazorac® 0.1% cream – with more than twice the tazarotene concentration – and ***90.3% more tolerable*** than Tazorac® 0.1% cream and, by extension, than the Tazorac® 0.05% cream, whose tolerability was found in clinical studies to be roughly comparable to Tazorac® 0.1% cream.

Padagis argues these clinical results "merely demonstrate a difference in degree, not in kind, and therefore cannot demonstrate that the claimed methods would not have been obvious." Pet. 3. However, the Federal Circuit recently explained, "[t]here is no specific fold-difference that defines what may, or may not, support a finding of nonobviousness. Nor do we draw a line between a difference in degree insufficient to rebut a showing of obviousness and a difference in kind that may be sufficient to do so; each inquiry need be fact-specific." *Amgen Inc. v. Sandoz Inc*., 66 F.4th 952, 964 (Fed. Cir. 2023); *see also In re Soni*, 54 F.3d 746, 751 (Fed. Cir. 1995) ("When an applicant demonstrates *substantially* improved results … and *states* that the results were *unexpected*, this should suffice to establish unexpected results *in the absence* of evidence to the contrary." (original emphasis)); *In re Corkill*, 771 F.2d 1496, 1501 (Fed. Cir. 1985) ("A greater than expected result is an evidentiary factor pertinent to the legal conclusion of [nonobviousness]."); MPEP § 716.02.

In *Galderma*, the court wrote "where an unexpected increase in efficacy is measured by a ***small percentage***, as here, and the evidence indicates that skilled artisans were capable of adjusting the percentage, the result constitutes a difference in degree, not kind." 737 F.3d at 739 (emphasis added). Here, the increase in efficacy was not a "small percentage" but rather a marked improvement over the prior art – 31.8% greater efficacy and 90.3% greater tolerability than Tazorac®

0.1% cream. As the USPTO previously found, that is more than sufficient to establish patentability.

The Petition presents no basis for finding material error. Accordingly, the Board should exercise its discretion under § 325(d) to not institute review.

VI. The Board Should Deny Institution in Light of Parallel District Court Proceedings

A. The Circumstances Here Satisfy *Fintiv*

When parallel district court litigation is pending, the Board considers six factors under 35 U.S.C. § 314(a) that "relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding." *Fintiv*, IPR2020-00019, Paper 11 at 5-6. Analysis of these factors supports denial of institution.

Factor 1: Likelihood of a Stay. There is no reason for the Board to assume that a stay is forthcoming. In the DNJ4248 Case, Padagis agreed not to seek a stay until the Board issues its decision on institution, which would be within about half a year of a trial date by Bausch Ireland's calculation. Ex. 2013 at ¶ 9.

In any event, a stay is unlikely in the DNJ4248 Case. D.N.J. courts typically consider three factors when deciding whether to stay: "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set." *Gesture*

Tech. Partners, LLC v. LG Elecs. Inc., No. 21-19234, 2022 WL 1002101, at *2 (D.N.J. Apr. 4, 2022) (quoting *Stryker Trauma S.A. v. Synthes (USA)*, No. 01-3879, 2008 WL 877848, at *1 (D.N.J. Mar. 28, 2008)).

"In determining whether undue prejudice or an unfair tactical advantage would result from a stay, courts consider the following subfactors: (1) the timing of the request for reexamination; (2) the timing of the request for a stay; (3) the status of reexamination proceedings; and (4) the relationship of the parties." *Id.* at *3 (citing *Depomed Inc. v. Purdue Pharma L.P.*, No. 13-571, 2014 WL 3729349, at *2 (D.N.J. July 25, 2014)).

Here, all four factors weigh against a stay. *First*, Padagis has stretched the timing to the outer limit by filing just three days before the statutory deadline. *Second*, as mentioned above, Padagis has eschewed seeking a stay until at least six months after the submission of its Petition. *Finally*, as one New Jersey court explained, "courts are hesitant to stay patent cases when direct market competitors are involved." *OANDA Corp. v. GAIN Cap. Holdings, Inc.*, No. 20-05784, 2021 WL 1186778, at *8 (D.N.J. Mar. 30, 2021) (citations omitted). And another explained "[w]hen courts generally find prejudice related to a stay, it is because the parties are directly competing in a specific market, head-to-head, and there is some tangible evidence that a stay will cause harm." *Kirsch Rsch. & Dev., LLC v. GAF Materials, LLC*, No. 20-13683, 2021 WL 2434082, at *3 (D.N.J. June 15, 2021)

(citations omitted). This describes the circumstances here: Padagis, were it to launch its generic Arazlo® product, would strongly diminish the market for branded Arazlo®. And, unlike in the typical Hatch-Waxman case, because there is no 30-month stay, Padagis is free to launch its product upon obtaining FDA approval unless the district court enters a preliminary injunction. A stay would likely significantly prejudice Bausch Ireland.

Finally, the DNJ4248 Case is at an advanced stage. As it relates to the '482 Patent, the parties have exchanged contentions and written discovery, and fact discovery is likely to be substantially complete by the time the Board makes its decision on institution.

Accordingly, the D.N.J. is likely to deny a stay.

Factors 2&3: Proximity to Trial/Investment in District Court Proceedings. Trial in the DNJ4248 Case is likely to occur well before the Board could reach decision here. When the parties submitted their joint discovery plan, they agreed an appropriate trial date would be March 2024. Ex. 2015 at 9. Accounting for the fact the current fact discovery deadline is now six months later than projected, the current status would suggest a trial date of September 2024. *Compare id.* at 8 (July 14, 2023 fact discovery deadline), *with* Ex. 2013 at ¶ 1 (January 9, 2024 fact discovery deadline). By contrast, if this case is instituted, the Board's final written

decision is statutorily due in December 2024. Thus, even if the trial date were pushed out a few months, the parties' proximity to trial favors non-institution.

The closeness to trial is largely a function of Padagis's own delay. Nothing prevented Padagis from filing its Petition well before the statutory deadline, but it did not do so. Padagis's tactical decision to delay filing its Petition weighs heavily against institution. The Board has found even less investment in parallel district court litigation sufficient to deny institution. *See, e.g.*, *10X Genomics, Inc. v. President & Fellows of Harvard Coll.*, IPR2020-01468, Paper 22, 12-14 (P.T.A.B. Feb. 22, 2021) (concluding *Fintiv* factor three "weighs heavily" against institution where the petitioner filed its petition after six months of district court litigation and within three months of serving its invalidity contentions).

Factor 4: Overlap of Issues. Where "the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial." *Fintiv*, IPR2020-00019, Paper 11 at 12. Here, the issues not only overlap; they are identical. Padagis's amended contentions included the same nine grounds included in the Petition. *Compare* Pet. 27, *with* Ex. 2016 at 11-13.

Factor 5: Same Parties. This factor supports denying institution, because the parties here are all parties to the DNJ4248 Case. Ex. 2007 at ¶¶ 1-6.

Factor 6: Other Circumstances. There is another circumstance that supports denying institution here – the D.N.J.'s significant experience with the technology at issue. As already explained above and throughout, Judge Chesler has a significant command of the issues regarding this technology, including the functions of the vehicle and tazarotene. He has heard about much of the same prior art – prior art likely to be at issue again in review of the '116 Patent. It is efficient, for all involved, for the Board to spend its resources elsewhere.

B. The Director's Interim Guidance Does Not Change the Application of *Fintiv* Here

The Director-promulgated interim guidance creates two exceptions to the ordinary application of *Fintiv* that require denial of institution where (1) the petition presents "compelling evidence of unpatentability," or (2) the patent challenger provides a *Sotera* stipulation agreeing it will not raise in a district court proceeding the same challenge, or any challenge it reasonably could have raised, in the petition. Ex. 2017 at 9. Neither applies here.

First, there is not even sufficient evidence to institute, let alone the "compelling" evidence required for the *Fintiv* exception. *See infra*, Part VIII. And second, Padagis has not submitted a *Sotera* stipulation, here or in the DNJ4248 Case. Rather, Padagis states only "***if*** the Board believes it necessary, [Padagis] ***is willing*** to file a *Sotera* stipulation in the district court." Pet. 84-85 (emphasis

added). But it is not for the Board to advise Padagis on whether to file a *Sotera* stipulation; rather, the Board's duty under *Fintiv* is to evaluate the efficiency of instituting the Petition. Padagis has not opted to avail itself of an unequivocal disclaimer of the grounds presented or that could be presented in the Petition. Put another way, Padagis is hedging its bet. And so, as of this filing, nothing prevents Padagis from raising the same or other obviousness grounds in the DNJ4248 Case.

VII. The Board Should Deny Institution Under 35 U.S.C. § 314(a)

For reasons discussed above, the Board should deny institution because the Petition fails to establish there is a reasonable likelihood Padagis will prevail with respect to any of the claims of the '482 Patent as required by 35 U.S.C. § 314(a).[5]

[5] Bausch Ireland reserves all rights to present more detailed analysis, if necessary.

A. Grounds 1-4 Fail at Least Because a POSA Would Not Have Been Motivated to Select the 0.045% Tazarotene Lotion Disclosed in WO ’001 with a Reasonable Expectation of Success

As discussed above, the Petition’s central argument that a POSA would have been motivated to use the 0.045% tazarotene composition disclosed in WO ’001 fails because if dermatologists were commonly using Tazorac® 0.05% cream to treat acne, as the Petition asserts, there would have been no motivation to develop or use the claimed 0.045% tazarotene lotion with a different formulation in light of the fact Tazorac® 0.05% was readily available. The allegedly “common” use of Tazorac® 0.05% cream to treat acne also does not establish that a POSA would have expected the dramatically superior results achieved by the claimed 0.045% tazarotene lotion. Accordingly, the Petition’s central arguments fail to present a reasonable likelihood Petitioner will prevail with respect to ***any*** of the claims based on any of the alleged grounds of unpatentability, including Grounds 1-4.

B. Padagis’s Arguments for Grounds 5-9 Retread Ground Already Lost in its Litigation with Bausch Ireland Regarding Bryhali® and Duobrii®

During the Prior Case, Padagis urged the D.N.J. to invalidate the patents covering the Duobrii® combination product based on, among other combinations of art, the ’824 Publication together with Tazorac® Label, and the ’824 Publication with the IDP-118 Study. *See* Ex. 2020 at 2; Ex. 2021 at 31:11-15. These arguments proved unsuccessful there for reasons that also apply here.

Padagis's experts gave key admissions on cross-examination that undermined Padagis's proposed combinations and conflict with Padagis's expert testimony here.

Here, Padagis's experts claim that a POSA "would have been highly motivated to use the '824 [P]ublication's formulations to develop lower-concentration tazarotene formulations" because it supposedly "enabl[es] lower concentrations of the active ingredient to be used while maintaining efficacy." Ex. 1005 at ¶ 41. Notwithstanding the '824 Publication is specifically about corticosteroid, not retinoid, formulations, and about treating corticosteroid-responsive diseases like psoriasis, of which acne is not one, in the Prior Case, Padagis's experts both said the opposite about the '824 Publication. Specifically, Dr. Stern, Padagis's retained dermatologist, did not believe "that the '824 Publication stood out amongst the crowded field of topical psoriasis treatments." Ex. 2021 at 219:11-14. Similarly, Padagis's topical formulation expert, Dr. Michniak-Kohn, agreed the "'824 Publication [did] not stand out from the overall literature available to a POSA as of 2015." *Id.* at 423:25-424:3.

Furthermore, Dr. Murthy opines a POSA "would have been particularly drawn to Formula 4A in Table 4." Ex. 1005 at ¶ 42. However, in the Prior Case, Padagis's experts testified otherwise. Dr. Michniak-Kohn admitted the "inventors had a particular preference for" the Example 5 lotion, not Formula 4A, as

evidenced by the performance of the stability studies. Ex. 2021 at 428:5-429:14, 430:18-22. In her view, a POSA would have considered all of the formulations – not be "drawn" to Formula 4A. *Id*. at 431:21-432:1.

For Dr. Stern's part, when explaining why Formulation 4A was allegedly the "preferred" one, he expressly relied on hindsight – concluding it was preferred because it was the "exact formulation that [was] used in the combination patents" covering Duobrii®. *Id.* at 222:9-12, 223:1-7.

Moreover, Padagis's expert declarations here conflict with the testimony of their experts in the Prior Case about the claimed concentration of tazarotene. In the Prior Case, Dr. Stern admitted that "there's nothing in the Tazorac® [L]abel that would teach a POSA to use the specific 0.045 percent concentration of tazarotene," and eschewed having "any evidence that 0.045 percent [wa]s the optimal concentration for tazarotene in [the] combination." *Id.* at 284:1-4, 285:1-12. He admitted he had no "actual evidence that a POSA would have arrived at the specific 0.045 percent concentration" based on the same references in hand that Padagis relies on here. *Id.* at 285:22-286:1. Similarly, Dr. Michniak-Kohn admitted she had no "experimental evidence to establish that the optimal concentration of tazarotene in the formulations of the '824 patent [publication] would have been 0.045 rather than 0.040 percent or 0.035 percent." *Id.* at 435:22-436:2.

In support of the Petition, neither expert explains how, based on the Tazorac® Label, a POSA would arrive at the concentration of "about 0.045%." Dr. Schwartz merely refers to the language of the Tazorac® Label and Dr. Murthy relies on routine optimization, which was undercut by both of Padagis's experts in the Prior Case. *See* Ex. 1003 at ¶ 136 and Ex. 1005 at ¶ 138, respectively.

Finally, Padagis's expert, Dr. Stern, when questioned about the IDP-118 Study, admitted "there's no motivation in the pharmaceutical industry for someone to make a drug that somebody else already has" "in a Phase 2 clinical trial." Ex. 2021 at 287:8-17. This conflicts with the testimony of Drs. Murthy and Schwartz that a POSA would have relied on the disclosure of 0.045% tazarotene in the IDP-118 Study to arrive at the claimed invention. Ex. 1005 at ¶ 43; Ex. 1003 at ¶ 43.

The Prior Decision rejects the same arguments Padagis presents in its Petition and through its experts. Just like here, Padagis's theories were deemed "hindsight-driven." Ex. 2001 at 67. The Prior Decision found that Padagis failed to "ma[k]e the necessary showing" that a POSA "would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention." *Id.* at 69 (quoting *Unigene*, 665 F.3d at 1360). Two such failures the Court expressly identified: a failure to show motivation to select "tazarotene .045%" and a failure to select "the vehicle taught by the '824

Publication." *Id.* at 69. Rather, the Court chastised Padagis for its failure, based on the same types of arguments presented here, to show a motivation:

> Padagis begins in the middle, with the POSA already having found and selected all the pieces as well as a prior art reference that does not teach applying them simu[l]taneously. This is pure hindsight, analogous to a meal delivery service that puts all the ingredients for your dinner in a box with a recipe and gives it to you.

Id. at 69.

Padagis's expert admissions in the Prior Case undercut its current arguments; and the Prior Decision confirms the same arguments Padagis presents here should be rejected.

VIII. Conclusion

For these reasons, the Board should deny institution.

Dated: December 1, 2023

Respectfully submitted,

/April E. Weisbruch/

April E. Weisbruch (No. 65,783)
Ian B. Brooks (No. 66,709)
Thomas P. Steindler (*pro hac vice*)
Christopher M. Bruno (*pro hac vice*)
McDermott Will & Emery LLP

Counsel for Patent Owner
Bausch Health Ireland Limited

CERTIFICATE OF COMPLIANCE WITH WORD COUNT

Pursuant to 37 C.F.R. § 42.42(d), the undersigned certifies that this **Patent Owner's Corrected Preliminary Response** complies with the type-volume limits of 37 C.F.R. § 42.24(b)(1), because it contains 13,173 words, according to the word-processing system used to prepare this Patent Owner's Corrected Preliminary Response, excluding the word count in the Table of Contents, Table of Authorities, Certificate of Compliance with Word Count, and Certificate of Service, as set forth in 37 C.F.R. § 42.24(a)(1).

Dated: December 1, 2023

/April E. Weisbruch/
April E. Weisbruch (No. 65,783)

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Patent Owner's Corrected Preliminary Response** was served electronically on December 1, 2023, via e-mail to the attorneys of record at the following addresses.

Carol Pitzel Cruz
KNOBBE, MARTENS, OLSON & BEAR, LLP
925 Fourth Ave., Ste. 2500
Seattle, WA 98104

Brian Barnes
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614

Andrea Cheek
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Ave., N.W., Ste. 900
Washington, D.C. 20006

PadagisIPR482@knobbe.com

/April E. Weisbruch/
April E. Weisbruch (No. 65,783)