

**ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER**

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

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BAUSCH HEALTH IRELAND  
LIMITED, et al.,

Plaintiffs,

v.

PADAGIS ISRAEL  
PHARMACEUTICALS LIMITED, et  
al.,

Defendants.

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Civil Action No. 20-5426 (SRC)  
(CLW) (CONSOLIDATED)

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Trial: October 4, 2022

**DEFENDANTS PADAGIS ISRAEL PHARMACEUTICALS LTD AND  
PADAGIS US LLC'S OPENING POST TRIAL BRIEF**

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| <b>Short Title</b> | <b>Title/Information</b>                                                                                                                                                                                                                                                 | <b>Trial Ex. No.</b> |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| '307 patent        | Certified Copy of U.S. Patent No. 8,809,307 to Angel                                                                                                                                                                                                                     | JTX-001              |
| '895 patent        | Certified Copy of U.S. Patent No. 10,251,895 to Dow                                                                                                                                                                                                                      | JTX-002              |
| '787 patent        | Certified Copy of U.S. Patent No. 10,426,787 to Dow                                                                                                                                                                                                                      | JTX-003              |
| '502 patent        | Certified Copy of U.S. Patent No. 10,478,502 to Angel                                                                                                                                                                                                                    | JTX-004              |
| N/A                | IND P-111218, Briefing Package for the June 15, 2011 Type B Meeting (Pre-IND)                                                                                                                                                                                            | JTX-009-2            |
| N/A                | IND 111218 Section 2.5 Clinical Overview                                                                                                                                                                                                                                 | JTX-009-3            |
| N/A                | IND 111218 Section 1.6.2 Meeting Background Materials                                                                                                                                                                                                                    | JTX-009-5            |
| N/A                | IND 111218 Section 2.3.P - Drug Product                                                                                                                                                                                                                                  | JTX-011-3            |
| Blum               | Blum G., <i>et al.</i> , "Multicenter, Double-Blind Comparative Observation of Application of 0.02%, 0.05% CGP 14 458 Ointments and Dermovate Ointment in the Treatment of Chronic Psoriasis," <i>Chinese Journal of Dermatology</i> , Vol. 19, Issue 3, 139-141 (1986). | DX-002               |
| '295 Patent        | U.S. Patent No. 4,233,295                                                                                                                                                                                                                                                | DX-003               |
| '566 Patent        | U.S. Patent No. 5,326,566                                                                                                                                                                                                                                                | DX-004               |

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| <b>Short Title</b>    | <b>Title/Information</b>                                                                                                                                                                       | <b>Trial Ex. No.</b> |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| JP '228               | Japanese Patent Application Pub. No. S63-255228                                                                                                                                                | DX-005               |
| Temovate E Label      | Prescribing Information for Temovate E® (clobetasol propionate) Emollient, 0.05% (2000)                                                                                                        | DX-006               |
| Ultravate Cream Label | Ultravate Cream Label (April 2003)                                                                                                                                                             | DX-009               |
| Tazorac Label         | Prescribing Information for Tazorac® (tazarotene) Cream, 0.05% and 0.1% (December 2013)                                                                                                        | DX-010               |
| IDP-118 Study         | ClinicalTrials.gov entry for Study: NCT02045277, Safety and Efficacy of IDP 118 in the Treatment of Plaque Psoriasis, Version 1                                                                | DX-064               |
| Gollnick              | Gollnick et al., "Combination Therapy with tazarotene plus a topical corticosteroid for the treatment of plaque psoriasis," <i>British Journal of Dermatology</i> 1999: 140 (Suppl. 54): 18-23 | DX-140               |
| Gandhi                | Indian Patent Application IN 2461/MUM/2009                                                                                                                                                     | DX-141               |
| '824 Publication      | U.S. Patent Application Publication No. US 2012/0129824                                                                                                                                        | DX-142               |

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| N/A                  | Stein Gold, et al., “Safety and Efficacy of a Fixed Combination of Halobetasol and Tazarotene in the Treatment of Moderate to Severe Plaque Psoriasis: Results of Two Phase III Randomized Controlled Trials,” Journal of the American Academy of Dermatology, Vol. 79, Issue 2, p 287-293, 2018 | DX-151               |
| N/A                  | 7/2/2021 [059-2] Declaration of Majella E. Lane ISO Plaintiffs’ Opening Claim Construction Brief                                                                                                                                                                                                 | DX-383               |
| N/A                  | Bausch Health Presentation: US Ortho Q4’20 Quarterly Business Review, January 27, 2021                                                                                                                                                                                                           | DX-527               |
| Gao                  | H.Y Gao, A Li Wan Po, Topical formulations of flucinolone acetonide (May 15, 1993)                                                                                                                                                                                                               | DX-196               |
| Handbook             | Handbook of Pharmaceutical Excipients (6th ed. 2009)                                                                                                                                                                                                                                             | DX-201               |
| Ultravate Label 1995 | Prescribing Information for Ultravate® (halobetasol propionate) Cream 0.05% (1995)                                                                                                                                                                                                               | DX-212               |
| Kircik               | Kircik, Leon, Synergy and Its Clinical Relevance in Topical Acne Therapy, J. Clin. Aesthet Dermatol. 4(11):30–33 (2011)                                                                                                                                                                          | PTX-043              |

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| <b>Short Title</b> | <b>Title/Information</b>                                                                                                                                                                                            | <b>Trial Ex. No.</b> |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| N/A                | Kircik et al., Assessing the Synergistic Effect of a Fixed Combination Halobetasol Propionate 0.01% and Tazarotene 0.045% Lotion in Moderate-to-Severe Plaque Psoriasis, J. of Drugs in Derm., 18(3):279–284 (2019) | PTX-044              |
| N/A                | Lebwohl et al., Fixed-Combination Halobetasol Propionate and Tazarotene in the Treatment of Psoriasis: Narrative Review of Mechanisms of Action and Therapeutic Benefits, Dermatol. Ther. 11:1157–1174 (2021)       | PTX-380              |

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**I. INTRODUCTION**

This case does not involve a new drug, new excipients, or treatment of a new disease. Instead, Bausch used a combination of well-known drugs and excipients to develop their Bryhali and Duobrii psoriasis products and the patents at issue.

Defendants Padagis Pharmaceuticals Ltd and Padagis US LLC (“Padagis”) seek FDA approval to market generic versions of Bryhali and Duobrii, marketed by Plaintiffs Bausch Health Ireland Limited, Bausch Health Americas, Inc., and Bausch Health US, LLC (“Bausch”). Bausch asserts that Padagis’s products infringe U.S. Patent Nos. 8,809,307; 10,478,502; 10,215,895; and 10,426,787.<sup>1</sup> The ’307 and ’502 patents (“HP Patents”) are directed to topical corticosteroid compositions with a liquid oil component and varying concentrations of the prior art corticosteroid halobetasol propionate (“HP”). The ’895 and ’787 patents (“Combination Patents”) are directed to topical compositions that combine a prior art 0.01% HP formulation and a prior art retinoid, tazarotene, at a concentration of 0.045%.

The parties agree that both HP and tazarotene were known drugs that were commercially marketed to treat psoriasis for years before Bausch filed the asserted

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<sup>1</sup> In view of the Court’s ruling on Bausch’s Motions *in Limine* Nos. 1 and 3-4, Padagis stipulated to infringement of the Combination Patents. D.I. 197 at ¶¶ 1-7. Padagis reserves its right to appeal the Court’s exclusion of testimony regarding statistical significance and the FDA letter and to appeal infringement of the Combination Patents.

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patents – 0.05% HP (Ultravate®) and 0.1% and 0.05% tazarotene (Tazorac®). Bausch's alleged invention in the HP Patents was merely to reduce the concentration of HP, but this was an obvious solution to addressing the known side effects of Ultravate®. The prior art expressly disclosed lower concentration HP compositions (0.02%) that effectively treated psoriasis, and Bausch's HP formulation merely used well-known methods of drug formulation and excipients that would have been routine to an ordinarily skilled formulator. Thus, the evidence demonstrates that the claimed formulations would have been obvious.

Padagis also demonstrated that the “liquid oil component” required by every asserted claim of the HP Patents is indefinite. The patents provide inconsistent disclosures regarding the scope of that limitation, preventing one of ordinary skill in the art from ascertaining its meaning with reasonable certainty. Indeed, Bausch's own expert confirmed that these inconsistencies cannot be reconciled.

The Combination Patents merely add tazarotene to a prior art 0.01% HP formulation. The prior art expressly encouraged the combination of tazarotene and corticosteroids because it would provide better efficacy, reduce tazarotene side effects, and likely provide synergistic effects. Bausch repeatedly confirmed this in its FDA filings. Moreover, the choice to use tazarotene in combination with a corticosteroid “was an automatic choice because that was the only retinoid approved

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at that point.” T. 69:1-2.<sup>2</sup>

Bausch attempts to sidestep the invalidating disclosures of the prior art by claiming that its combination product provides certain unexpected synergistic effects, but that argument is unavailing. Any synergies provided by the Combination Patents are merely the inherent results of applying the drug formulation to psoriatic skin. Such inherent results are not afforded patentable weight in a proper obviousness analysis. In addition, the prior art expressly stated that combinations of tazarotene with topical corticosteroids, such as HP, provided synergistic effects. Indeed, in its FDA filings, Bausch told the FDA that synergy was expected based on what was known in the prior art. To avoid these statements, Bausch now argues that “synergy” did not mean “synergy” as construed in this case when it appears in the prior art or Bausch’s FDA filings. But Bausch’s litigation-inspired position is inconsistent with Bausch’s claim construction positions, requires unreasonable readings of both the prior art and Bausch’s FDA submissions, and is contradicted by Bausch’s own evidence. As one example, Bausch asks this Court to find that the statement in Gollnick, repeated by Bausch to FDA, that the combination of tazarotene and a topical corticosteroid is likely to provide “additive *or* synergistic

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<sup>2</sup> Padagis’s Proposed Findings of Fact and Proposed Conclusions of Law are referred to herein as “F. [paragraph #]” and “C. [paragraph #],” respectively. Citations to the trial transcript are referred to herein as T. [page:line].

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effects” really means “additive or additive.” Such a result is not plausible. Thus, every asserted claim of the Combination Patents would have been obvious.

Bausch’s trial presentation attempted to distract from the obviousness of the HP and Combination Patent claims by arguing that in the “real-world” no one had developed the claimed formulations or products like Duobrii and Bryhali, despite the known problems associated with HP and tazarotene. But the [REDACTED] of Duobrii directly contradict this “real-world” story. Notably, Bausch has not even asserted that Bryhali, which is also an embodiment of the HP Patents, is commercially successful. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>3</sup> F.218-219; DX-527 at 23; T. 756:21-757:24.

**II. THE ASSERTED CLAIMS OF THE HP PATENTS ARE INVALID**

**A. The Asserted Claims Of The Halobetasol Patents**

Bausch asserts claims 13, 16, and 20 of the ’307 patent and claims 4 and 16 of the ’502 patent against both Padagis’s proposed HP ANDA Product and proposed HP and tazarotene ANDA Product (Padagis’s “Combination ANDA Product”).<sup>4</sup>

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<sup>3</sup> Emphasis added unless noted otherwise.

<sup>4</sup> The asserted claims are included in Appendix A. The claims are broken down limitation-by-limitation, as presented by Padagis at trial.

**ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER****B. The Person Of Ordinary Skill In The Art**

The person of ordinary skill in the art (“POSA”) related to the HP Patents in November 2010 would have worked as part of a multi-disciplinary team of scientists and medical professionals, which included at least: (i) a person with an advanced degree in chemistry, pharmacy, or a related discipline and several years of experience developing topical pharmaceutical formulations; or, alternatively, a person with a Bachelor’s degree in chemistry, pharmacy, or a related discipline and a greater degree of experience developing topical pharmaceutical formulations; and (ii) a clinician with several years of experience using topical pharmaceutical formulations to treat patients with skin disorders (including psoriasis) and an understanding of the considerations relevant to evaluating the clinical effects, for example safety and efficacy, of topical pharmaceutical formulations. F. 54; T. 156:16-157:10, 313:6-314:6.<sup>5</sup>

**C. The Asserted Claims Of the HP Patents Are Indefinite**

“[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). “[A] claim is

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<sup>5</sup> Padagis’s experts testified that their opinions would not change under Bausch’s definition of a POSA. F. 55-56; T. 157:11-17, 314:10-15.

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indefinite if its language ‘might mean several different things and no informed and confident choice is available among the contending definitions.’” *Media Rights Techs. v. Cap. One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed. Cir. 2015) (quoting *Nautilus, Inc.*, 134 S.Ct. at 2130 n.8). Courts have held claims indefinite where a claim term is used in one part of a patent “in a manner that is inconsistent with the use of that same term” in another part of the patent. *See TVnGo Ltd. v. LG Elecs., Inc.*, No. 18-10238-RMB-KMW, 2020 WL 1899781, at \*3 (D.N.J. Apr. 17, 2020), *aff’d*, No. 20-1837 (Fed. Cir. June 28, 2021).

All asserted claims of the HP Patents recite a “liquid oil component.” App’x A at I.A-B. “Liquid oil component” is not a term of art and does not have a customary meaning in the art. F. 226; T. 579:23-580:1. The specification explains that the “liquid oil component includes all ingredients of the formulation that are practically insoluble or insoluble in water and which are liquid at room temperature of 22° C.” JTX-001 at 4:17-20; F. 227. The Court adopted this language as the construction for “liquid oil component.” D.I. 83 at 23-24; F. 227. Table 2 of the HP Patents uses the term “liquid oil component” “in a manner that is inconsistent with the use of that same term” in the earlier parts of the specification, rendering the term indefinite. *TVnGo Ltd.*, 2020 WL 1899781, at \*3; F. 232; T. 360:25-361:22, 581:6-23; DX-383 at ¶60; C.2-4.

The Court’s construction and the identical language in the specification means

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the “liquid oil component” includes all ingredients, including emulsifying agents, that are liquid at room temperature of 22°C and practically insoluble or insoluble in water. F. 227; T. 356:14-22, 575:23-576:4. Claim 8 of the ’502 patent, which states that “the liquid oil component further comprises an emulsifying agent,” further supports this understanding. JTX-004 at claim 8; F. ¶229; T. 357:14-358:1. One such emulsifier disclosed in the HP Patents is sorbitan monooleate. F. 229; T. 358:2-5; JTX-001 at 6:40-51. The parties agree that sorbitan monooleate falls within the Court’s construction of “liquid oil component” – it is liquid at room temperature and practically insoluble in water. F. 230; T. 358:6-359:15, 576:17-577:7. The parties also agree that Table 2 of the HP Patents *excludes* sorbitan monooleate when calculating the “concentration of liquid oil component.” F. 231; T. 361:10-22, 580:10-14. Table 2 is thus inconsistent with the description of “liquid oil component” in other portions of the specification and this Court’s construction, and the HP Patents provide no guidance on which meaning to apply when determining the components or concentration of the “liquid oil component.” F. 232; T. 360:25-361:22.

Due to the inconsistent uses of “liquid oil component” in the HP Patents, a skilled artisan cannot determine how to assess the scope and concentration of the “liquid oil component” for any particular formulation. F. 235. For example, Claim 4 (’307 patent) requires a “concentration of the liquid oil component” “sufficient to

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dissolve the halobetasol propionate” at room temperature. App’x A at I.A. Claim 7 requires “the concentration of esters in the liquid oil component is at least 30% of the concentration of the liquid oil component.” JTX-001 at claim 7 (non-asserted claim). A POSA would not know whether to include emulsifiers, such as sorbitan monooleate, and all other ingredients that are liquid at room temperature of 22°C and practically insoluble or insoluble in water, or whether to exclude sorbitan monooleate, and anything other than diethyl sebacate or light mineral oil as was done in Table 2, in their calculation of “liquid oil component.” The term “liquid oil component” is therefore indefinite. *See, e.g., Media Rights Techs.*, 800 F.3d at 1371.

Plaintiffs’ expert, Dr. Lane, previously declared to this Court that a POSA would not be able to reconcile the inconsistencies between Table 2 and the Court’s construction of “liquid oil component.” F. 233; T. 361:10-22, 581:6-23; DX-383 at ¶60. Dr. Lane’s only attempt to reconcile these inconsistencies at trial was to read the “concentration of liquid oil component” in Table 2 as limited to *solvents*, despite the fact that Table 2 refers to the “concentration of liquid oil component,” not the “concentration of solvent component.” F. 234; T. 578:14-579:8, 582:2-8. This is the exact argument that Bausch and Dr. Lane advanced during claim construction, which this Court rejected. D.I. 83 at 23-24; F. 234. Dr. Lane’s renewed insistence that “liquid oil component” in Table 2 only includes solvents is an improper attempt to rewrite this Court’s construction; it does not reconcile Table 2 with the rest of the

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specification and this Court's construction. Thus, the term "liquid oil component," and all asserted claims of the HP Patents, are invalid as indefinite. C.2-4.

**D. The Asserted Claims Of The HP Patents Would Have Been Obvious in View Of The Prior Art**

The asserted claims of the HP Patents would have been obvious to a POSA in November 2010 in view of the following prior art combinations: (1) U.S. Patent No. 4,233,295 ("295 Patent") and Blum (all claims); (2) the '295 Patent, Blum, and U.S. Patent No. 5,326,566 ("566 Patent") (all claims); (3) the '295 Patent, Blum, and Japanese Patent App. Pub. No. S63-255228 ("JP '228") (claims 13, 16, and 20 of the '307 patent and claim 4 of the '502 patent); and (4) the '295 Patent, Blum, and the Temovate E Label (claim 16 of the '502 patent). F. 19-23, 94-95; C.90-95.

**1. Halobetasol Propionate Was An Established Corticosteroid With Well-Known Risks Of Serious Side Effects**

Halobetasol propionate ("HP") is not a new drug. The HP product Ultravate had been commercially available for decades before the priority date of the HP Patents at a concentration of 0.05%. F. 60-61; T. 43:14-44:1, 160:22-161:6; DX-009 at 1. Ultravate was classified as a super-potent steroid, and, like other super-potent steroids, could cause serious systemic side effects, including hypothalamic-pituitary-adrenal ("HPA") axis suppression, if too much steroid penetrated through the patient's skin into the blood stream. F. 61, 63; T. 41:18-25, 161:14-162:2. Thus, by at least 1995, the FDA's labeling for Ultravate warned that it should not be used

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for more than two consecutive weeks. F. 63; T. 50:6-14, 108:14-24, 161:14-22, 319:13-19; DX-009 at 2; DX-212 at 2.

**2. A POSA Would Have Been Motivated To Lower The Concentration Of HP To Concentrations As Low As 0.01%**

The parties agree that psoriasis is a chronic condition and treatment for longer than two weeks is required to effectively treat most patients. F. 64; T. 38:19-39:14, 50:15-18, 162:5-7, 165:20-24. The parties also agree that prior to 2010, a POSA would have known that the risk of systemic side effects with topical corticosteroids is reduced by lowering the concentration of the steroid. F. 76, 107, 167; T. 123:7-14, 166:9-167:10, 673:13-674:6; 794:20-795:4. Given this knowledge and the known limitations on duration of treatment with 0.05% HP, a POSA would have been motivated to reduce the concentration of HP below 0.05% to reduce the risk of systemic side effects and enable treatment for periods longer than two consecutive weeks. F. 74, 107, 167; T. 162:15-163:9, 165:11-19, 212:4-24, 331:8-333:9.

A POSA would have expected that the concentration of HP could be reduced while remaining efficacious. Blum disclosed that HP at 0.02% produced clinical success in over 80% of patients treated after 3 weeks. F. 66, 108, 168; T. 163:21-164:10, 324:14-325:15; DX-002 at 5, Table 1. The clinical success rates for the 0.02% HP ointment were similar to those for Dermovate (81% vs. 86%), the most effective topical corticosteroid on the market at the time, and were only 9% less than 0.05% HP. F. 67-69, 109-110, 169-170; T. 163:21-164:10, 324:14-325:15; DX-002

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at 5, Table 1. Blum concluded that there were no statistically significant differences in the efficacy rates between 0.02% HP, 0.05% HP, and Dermovate. F. 70, 111, 171; T. 164:11-21, 325:20-326:9, 595:8-596:4, 675:14-16; DX-002 at 6.

Bausch's experts ignore Blum's finding that there were no statistically significant differences between the three treatment groups and focus exclusively on Blum's statement that 0.05% HP would likely be a "favorite treatment weapon." T. 595:8-596:22, 675:14-676:16. But nothing in Blum teaches away from the 0.02% HP concentration. F. 113, 173. Blum does not criticize or discredit the efficacy of the 0.02% HP ointment or suggest that it would be ineffective in treating psoriasis. *Id.* To the contrary, a POSA would have understood that the efficacy of Blum's 0.02% HP ointment was statistically indistinguishable from that of the 0.05% HP and Dermovate treatments. F. 70, 111, 171; T. 164:11-21; DX-002 at 6. Blum also teaches that "it is most important to conduct double blind trials to find the right concentration in the treatment of patients with chronic plaque psoriasis." F. 114, 174; DX-002 at 6; T. 596:11-22. Bausch's experts ignored this teaching and failed to consider the reference as a whole. *See, e.g., EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985). Even if Blum expressed a preference for the 0.05% HP ointment, it is well established that "just because 'better alternatives' may exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes." *Dome Patent L.P. v. Lee*, 799 F. 3d 1372, 1381 (Fed. Cir.

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2015) (internal quotations omitted); *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012).

Armed with Blum's teachings on the efficacy of 0.02% HP and the knowledge that reducing corticosteroid concentration lowers the risk of adverse events, a POSA would have been motivated to explore further reductions in HP concentration, including concentrations as low as 0.01%, to minimize the risk of adverse events. F. 112, 172; T. 162:15-163:9, 165:11-19, 212:4-21, 331:8-333:9. Given Blum's teaching that reducing the concentration of HP by 60%, from 0.05% to 0.02%, resulted in only a minor difference in efficacy, a POSA would have reasonably expected concentrations of HP as low as 0.01%<sup>6</sup> to remain efficacious. F. 115, 175; T. 164:22-165:10, 321:15-322:13, 329:21-330:25; F. 73; DX-196 at 3-4.

**3. Dicarboxylic Acid Esters, Including Diethyl Sebacate, Were Well Known Solvents For Topical Corticosteroids**

A POSA prior to 2010 would have known that the active drug in a topical composition must be dissolved for the drug to be absorbed by the skin and exert its therapeutic effect. F. 78; T. 72:6-16, 343:2-6; DX-003 at 1:10-16. Dicarboxylic acid esters, including diethyl sebacate, were a well-known and obvious excipient for

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<sup>6</sup> A concentration of 0.01% HP falls within the concentration range recited by every asserted claim of the HP Patents. *See* JTX-001 at claims 1, 13, 16, 20 (0.04% or less – claims 16 & 20; 0.025% or less – claim 13), JTX-004 at claims 1, 4, 16 (0.01% or less – claim 4; less than 0.05% – claim 16).

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dissolving lipophilic corticosteroids, like HP, to improve and control their delivery into the skin. F. 79-80; T. 319:20-321:6. Such liquid oils were ubiquitous in the prior art for dissolving and delivering corticosteroids.

**a. The '295 Patent In View Of Blum Renders Claims 13 And 16 Of The '307 Patent Obvious**

Blum provided a POSA with motivation and a reasonable expectation of success in reducing the concentration of HP to as low as 0.01%. *Supra* §II.D.2. The '295 Patent would have provided a vehicle with the claimed “liquid oil component” to enable a POSA to achieve an effective low-dose HP composition.

The '295 Patent teaches that dialkyl sebacates, with the alkyl containing 1 to 10 carbons, are “excellent vehicles for corticosteroids.” F. 84, 104, 120; T. 328:11-25, 599:15-600:1; DX-003 at 1:40-44. Diethyl sebacate is a dialkyl sebacate with two carbons, and selecting diethyl sebacate from the list of dialkyl sebacates in the '295 Patent would have been a matter of routine optimization involving common solubility studies conducted during any development program. F. 84-85, 104-105; T. 328:20-329:2, 329:9-19, 371:15-372:10, 600:6-8, 612:10-25, 794:20-23.

The '295 Patent also teaches that its dialkyl sebacate vehicles can be used to dissolve and enhance delivery of corticosteroids from 0.001% to about 3% by weight (preferably 0.02% to 0.05% for lotions), and that its teachings can be generally applied to any topically applied corticosteroid. F. 82, 83, 116, 176; T. 326:18-327:7, 327:12-328:9, 329:21-330:4; DX-003 at 1:45-51, 2:6-10. HP is in the same class of

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steroids as those disclosed in the examples of the '295 Patent. F. 83, 116, 176; T. 330:5-8; DX-003 at 6:60-10:68. Thus, a POSA would have been motivated to combine the '295 Patent with Blum to formulate a lower concentration HP composition with a "liquid oil component" as claimed in claims 13 and 16 of the '307 patent, particularly because a POSA would desire a vehicle that would facilitate adequate drug delivery, like those disclosed in the '295 Patent. F. 117-120; T. 329:21-331:3. It would have been obvious for a POSA to then apply that composition in "an amount to the skin that is effective in ameliorating the signs or symptoms of the disorder" as required by claim 16, as this was standard dermatologic practice and disclosed by Blum. F. 143; T. 163:110-164:21, 346:25-347:3. Accordingly, claims 13 and 16 of the '307 patent would have been obvious in view of the '295 Patent combined with Blum. F. 101-121, 141-145; C.92.

**b. The '295 Patent In View Of Blum And The '566 Patent Renders Claims 13 And 16 Of The '307 Patent Obvious**

The '566 Patent teaches that by optimizing the vehicle of a topical formulation to increase absorption, drug concentration could be reduced without a significant, if any, reduction in potency. F. 86; T. 336:5-13; DX-004 at 4:37-49, 8:20-17:56. The '566 Patent teaches that use of dicarboxylic acid esters, such as dibutyl adipate or dibutyl adipate and isopropyl myristate, "enhance and control the *epidermal, dermal*, and transdermal penetration of corticosteroids, allowing one to achieve the same level of efficacy with a lower overall concentration of the active ingredient."

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F. 86, 126; T. 336:17-337:6; DX-004 at 3:20-25, 4:37-49. Moreover, the '566 Patent discloses numerous examples of topical formulations that include HP and would have thus reinforced the POSA's motivation to combine Blum and the '295 Patent to achieve a reduced concentration HP formulation by dissolving the HP in a liquid oil component comprising a dicarboxylic acid ester. F. 89, 128-129; T. 338:5-12, 342:10-343:10; DX-004 at 8:19-14:58. Accordingly, claims 13 and 16 of the '307 patent would have been obvious in view of the '295 Patent combined with Blum and the '566 Patent. F. 122-130, 146-150; C.93.

**c. The '295 Patent In View Of Blum And JP '228 Renders Claims 13 And 16 Of The '307 Patent Obvious**

JP '228 discloses topical corticosteroid compositions at concentrations of 0.01 to 0.5% containing a liquid oil component of diethyl sebacate that completely dissolves the steroid. F. 90, 92, 134, 137; T. 339:18-340:12, 605:20-606:15; DX-005 at 10-11, Example 3. JP '228 teaches that the formulations of the invention exhibit “extremely good vasoconstriction action” and have “good drug release behavior and transdermal absorption, and hence ha[ve] a significant pharmacological effect.” F. 93, 135; T. 340:14-341:23; DX-005 at 13-15.

Given these teachings, JP '228 would have reinforced the POSA's motivation to combine Blum and the '295 Patent to achieve a reduced concentration HP formulation by dissolving the HP in a liquid oil component comprising diethyl sebacate. F. 138-139; T. 342:10-343:10. Accordingly, claims 13 and 16 of the '307

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patent would have been obvious in view of the '295 Patent combined with Blum and JP '228. F. 131-140, 151-155; C.94.

d. **Padagis's Prior Art Does Not Focus On Transdermal Delivery Through The Skin**

Contrary to Dr. Lane's unsupported testimony, Padagis's prior art, including the '566 Patent, *does not* focus only on delivery of drugs through the skin into systemic circulation, nor was it the goal of formulators in the 1980's and 1990's to deliver as much corticosteroid into systemic circulation as possible. T. 491:8-21, 503:8-15. Rather, consistent with common understanding at the time, the '566 Patent teaches that "[f]or the proper treatment of skin disorders or skin diseases, it is important that the pharmacologically active agent penetrate the stratum corneum and be made available at appropriate concentrations at the site of action, which can be the stratum corneum, the viable epidermis, the epidermis junction, the dermis itself, or all of the aforementioned layers of skin, depending upon the type of disorder or disease condition." F. 88; T. 604:1-11; DX-004 at 1:62-2:2. The stratum corneum, the viable epidermis, the epidermis junction, and the dermis are all layers within the skin. F. 88; T. 337:7-23. This teaching of the '566 Patent is consistent with Dr. Lane's admission that, prior to 2010, it was known that a corticosteroid must penetrate *into the skin* to exert its therapeutic effects and that systemic absorption of corticosteroids was known to cause serious side effects. F. 88; T. 206:25-207:6, 604:15-21. Dr. Lane's unsupported testimony that a POSA would have sought to

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push as much corticosteroid into systemic circulation as possible is directly contradicted by the prior art and should be disregarded. *See, e.g., Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372, 1378–79 (Fed. Cir. 2017); C.53.

**4. Adding Light Mineral Oil To The Liquid Oil Component Would Have Been Obvious ('307 Patent Claim 20)**

Claim 20 of the '307 patent requires that the liquid oil component further comprise light mineral oil. App'x A at I.A.3.3-4 (Limitations 20.3 & 20.4). The use of light mineral oil in topical pharmaceutical formulations was well-established prior to 2010 and would have been obvious. F. 157, 160, 163; T. 347:22-25. A POSA would have known that light mineral oil could function as an emollient (skin softener), solvent, oleaginous vehicle, and/or penetration enhancer, as well as providing occlusivity to the site of application for topical formulations, and a POSA would have been motivated to add it to the formulation to achieve those benefits. F. 157, 160, 163; T. 347:22-350:1; DX-201 at 12. Thus, claim 20 of the '307 patent would have been obvious in view of the '295 Patent combined with Blum or the '295 Patent combined with Blum and the '566 Patent. F. 156-158, 159-161; T. 347:5-350:1, 352:2-16; C.92-93.

Moreover, JP '228 disclosed topical corticosteroid compositions in which the steroid is dissolved in a liquid oil phase that comprises both light mineral oil and diethyl sebacate, further motivating a POSA to use light mineral oil as part of the

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liquid oil component. F. 91, 163; T. 339:18-340:8; DX-005 at 10-12. Thus, claim 20 of the '307 patent would also have been obvious in view of the '295 Patent in combination with Blum and JP '228. F. 162-164; T. 347:5-350:1, 352:2-16; C.94.

**5. Compositions Free Of White Petrolatum Would Have Been Obvious ('502 patent claim 4)**

Claim 4 of the '502 patent recites that the composition is free of white petrolatum. App'x A at I.B.1.3 (Limitation 4.3).<sup>7</sup> Prior to 2010, petrolatum-based formulations were known to be greasy and undesirable, and a POSA would have been motivated to exclude white petrolatum from the lower concentration HP formulation. F. 166, 179, 183; T. 351:6-10. The '295 Patent disclosed multiple example formulations that do not include white petrolatum, and JP '228 similarly does not teach the use of white petrolatum in its formulations. F. 166, 179, 183; T. 351:11-12, 351:15-16, 601:13-16. Thus, claim 4 of the '502 patent would have been obvious in view of the '295 Patent combined with Blum or the '295 Patent combined with Blum and JP '228. F. 165-177, 182-185; T. 350:2-351:25, 352:2-16; C.92, 94.

The '566 Patent teaches the advantages of excluding petrolatum, explaining that petrolatum-based ointments are greasy, and it may be desirable to have

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<sup>7</sup> Claim 4 of the '502 Patent also requires an "aqueous component comprising water," which is disclosed by the '295 Patent. App'x A (Limitation 4.2); F. 165, 178, 182; T. 326:18-327:10; DX-003 at 2:22-26, 3:68-4:10. The remaining limitations of claim 4, including 0.01% or less HP of, are addressed in §§ II.D.2-3; App'x A at (Limitation 4.4).

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cosmetically elegant (less greasy) topical products, such as creams, lotions, gels, and solutions. F. 179; T. 338:5-339:7; DX-004 at 11:23-27. Thus, claim 4 of the '502 patent would have also been obvious in view of the '295 Patent combined with Blum and the '566 Patent. F. 178-181; T. 350:2-351:25, 352:2-16; C.93.

**6. Applying The Lower Concentration HP Composition For Longer Than 2 Weeks Would Have Been Obvious**

Claim 16 of the '502 patent recites a method of applying certain corticosteroid compositions to treat skin disorders in an amount effective in ameliorating the signs or symptoms of the disorders over periods of treatment longer than two weeks.<sup>8</sup> App'x A at I.B.2.5 (Limitations 16.4 & 16.5). The parties agree that treating psoriasis takes longer than two weeks for most patients and that a POSA would have known that the risk of systemic side effects with topical corticosteroids is reduced when the steroid concentration is reduced. F. 64, 76, 107; 167; 187, 190, 193; T. 38:19-39:14, 50:15-18, 123:7-14, 162:5-7, 165:20-24, 166:9-167:10, 673:13-674:6; 794:20-795:4. Given this knowledge, a POSA would have been motivated to use the 0.01% HP composition to treat psoriasis for longer than two weeks and would have reasonably expected success in doing so. F. 187, 190, 193; T. 165:25-167:10.

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<sup>8</sup> Claim 16 of the '502 patent also requires an "aqueous component comprising water" and that the formulation be free of white petrolatum. App'x A (Limitations 16.2-16.3). Those limitations are addressed in § II.D.5. The remaining limitations of claim 16, including the concentration of the corticosteroid at less than 0.05%, are addressed in § II.D.2-3. See App'x A at I.B.2.

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Moreover, Blum disclosed successfully treating psoriasis with 0.02% HP for approximately 21 days, and was thus an amount effective in ameliorating the signs or symptoms of psoriasis. F. 187, 190, 193; T. 163:10-164:21, 324:11-325:15, 346:25-347:3, 353:6-9, 594:14-18; DX-002 at 4-6. Thus, claim 16 of the '502 patent would have been obvious in view of the '295 Patent in combination with Blum or the '295 Patent in combination with Blum and the '566 Patent. F. 186-188, 189-191; T. 352:18-353:17; C.92-93.

Additionally, the Temovate E label disclosed a formulation of the super-potent corticosteroid clobetasol propionate at 0.05% and teaches that this formulation could be used for up to four consecutive weeks when application was limited to less than 10% of body surface area. F. 194; T. 165:25-167:10, 353:18-354:24, 607:2-14; DX-006 (Temovate E Label) at 2. Thus, the Temovate E® Label would have reinforced the POSA's expectation that a topical composition comprising HP at less than 0.05% could be safely and effectively applied for periods longer than two consecutive weeks, especially when application is limited to 10% or less of the patient's body. F. 195; T. 166:25-167:10. Thus, claim 16 of the '502 patent would have been obvious in view of the '295 Patent in combination with Blum and the Temovate E Label. F. 192-196; T. 352:18-354:24; C.95.

**7. Bausch Cannot Prove That Secondary Considerations Overcome The Strong *Prima Facie* Case Of Obviousness**

The patentee bears the burden of producing evidence to establish the existence

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of secondary considerations of non-obviousness. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1353 (Fed. Cir. 2013); C.58-60. “[S]econdary considerations may presumptively be attributed to the patented invention only where the marketed product embodies the claimed features, and is coextensive with them.” *Muniauction, Inc. v. Thomason Corp.*, 532 F.3d 1318, 1328 (Fed. Cir. 2008) (internal quotation marks and citations omitted). Although evidence of secondary considerations must be considered, secondary considerations will not overcome a strong showing that the claimed invention was *prima facie* obvious. *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008); C.57. Bausch cannot overcome the strong *prima facie* case of obviousness for the HP Patents. C.91.

**a. No Commercial Success**

Bausch has not proven that Duobrii’s commercial performance supports the nonobviousness of the HP Patents for at least two reasons. First, Bausch has not proven a nexus between Duobrii’s commercial performance and the asserted claims of the HP Patents. F. 389-390. Bausch has not proven that Duobrii is coextensive with the claims of the HP Patents or that Duobrii’s commercial performance results from the allegedly novel features of the HP Patents. F. 386-390. Unlike Bryhali, Duobrii includes a combination of two active ingredients, one of which, tazarotene, is not mentioned in the HP Patents or the asserted claims. Notably, Bausch has not even asserted that Bryhali, which is also an embodiment of the HP Patents, is

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commercially successful. F. 385; T. 743:19-22.

Second, the evidence demonstrates that Duobrii is not a commercial success.

Over the period for which Bausch offered commercial data, Duobrii has: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] F. 392-404, 410; T. 748:23-749:3, 765:18-766:12, 775:4-24.

**b. No Unexpected Results**

Bausch has not proven that the HP Patents are non-obvious due to unexpected results. The only allegedly unexpected result Bausch has identified is maintaining similar efficacy and/or potency as Ultravate (0.05% HP) with a lower concentration of HP. Bausch solely relies on Bryhali and Duobrii, both of which contain HP at 0.01%, as evidence of compositions with this allegedly unexpected result. F. 202; T. 45:2-6, 46:8-12, 54:1-12, 709:16-710:9. But the asserted claims of the HP Patents encompass compositions with HP concentrations below 0.01%, and Bausch has not offered *any* evidence that compositions with less than 0.01% HP, or any 0.01% HP composition other than Bryhali or Duobrii, exhibits comparable potency and/or efficacy as Ultravate. F. 198, 201; T. 54:1-12, 671:3-10, 672:1-10, 709:16-710:9. Bausch's evidence of unexpected results is not reasonably commensurate in scope

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with the asserted claims and is entitled to little, if any, weight. *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008); F. 203.

Bausch has not proven that the HP Patents unexpectedly provide preferential delivery of the corticosteroid into the skin, rather than transdermal delivery through the skin and into systemic circulation. The HP Patents merely describe such preferential delivery as a “hypothesis,” and there is no disclosure in the patents proving that hypothesis. F. 204-208; T. 315:11-316:3. Bausch’s expert, Dr. Lane, admitted that the patents do not even measure systemic absorption for any of the formulations, which would be necessary to assess “preferential delivery.” F.50, 206; T. 608:22-609:2, 618:2-6. Dr. Lane attempted to point to the VCA testing in the patents to support this hypothesis, but she admitted that VCA testing measures local activity of the steroid in the skin, not systemic absorption through the skin. F. 207; T. 617:18-618:1.

**c. No Long-Felt But Unmet Need**

Bausch has not proven that the HP patents are nonobvious because they satisfied a long felt but unmet need for a super-potent corticosteroid that could safely be administered for longer than two weeks. Bausch has not offered any evidence that any of the compositions with less than 0.01% HP encompassed by the asserted claims of the HP Patents would be super-potent. F. 214; T. 54:1-12, 672:1-10, 709:16-710:9. The asserted claims of the ’502 patent encompass compositions with

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steroids other than HP, such as fluocinonide at a concentration of less than 0.05%. F. 215; T. 586:17-20. Fluocinonide formulations classified as potent and upper-mid potent were known prior to 2010. F. 215; T. 587:1-4. The '502 patent does not disclose any data demonstrating that a fluocinonide composition within the scope of the claims of the '502 patent would be super-potent. F. 215; T. 587:5-588:11. Thus, Bausch's evidence of a long-felt but unmet need is not reasonably commensurate in scope with the asserted claims and is entitled to little, if any, weight. *Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1325, 1336 (Fed. Cir. 2010); F. 217; C.66.

[REDACTED]  
[REDACTED], and Bausch did not even assert that Bryhali has been commercially successful. *Supra* § II.D.7.a. [REDACTED] is inconsistent with the innovative breakthrough Bausch claims to have achieved. Indeed, contrary to its litigation positions, [REDACTED]  
[REDACTED]

[REDACTED] F. 218-219; T. 756:21-24; DX-527 at 23. Thus, the real-world evidence reveals that neither Duobrii nor Bryhali solved any long-felt but unmet need in the field of psoriasis treatments.

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**III. THE ASSERTED CLAIMS OF THE COMBINATION  
PATENTS ARE INVALID**

**A. The Asserted Claims Of The Combination Patents**

Bausch asserts claims 3 and 6 of the '895 patent and claims 4, 5, and 7 of the '787 patent against Padagis's Combination ANDA Product.<sup>9</sup>

**B. The Asserted Claims Of The Combination Patents Would Have Been  
Obvious In View Of The Prior Art**

The Combination Patents merely add 0.045% tazarotene, a slight reduction from a known commercial product, to a known 0.01% HP formulation. This combination would have been obvious given that the prior art encouraged the combination of tazarotene with topical corticosteroids like HP because it would improve efficacy and reduce side effects. Moreover, the prior art IPD-118 Study disclosed a lotion for treating psoriasis that combined HP and tazarotene at the *exact concentrations* claimed in the Combination Patents. As Bausch repeatedly admitted to FDA, the prior art also disclosed that combining tazarotene with a topical corticosteroid would likely provide synergistic effects due to the complementary mechanisms of action of the two drugs. The asserted claims of the Combination Patents would have been obvious in view of the following prior art combinations before the June 2015 critical date: (1) Gollnick, U.S. Pub. No. US2012/0129824

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<sup>9</sup> For the Combination Patents, a POSA in June 2015 would have had the same qualifications as those described in § II.B for the HP Patents. F. 238-240; T. 170:18-171:6, 314:7-9, 365:5-10.

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(“’824 Publication”), and the IDP-118 Study; (2) Gollnick, the ’824 Publication, and the Tazorac Label; and (3) Gollnick, the ’824 Publication, and Gandhi. F. 25-28, 31-38, 312, 328, 344, 351, 361, 368; C.96-100.

**1. The Prior Art Encouraged The Combination Of Tazarotene With HP To Treat Psoriasis**

Combination topical therapy was the standard of care for treating psoriasis prior to 2015. F. 246; T. 52:6-15, 624:8-10. As Bausch’s expert, Dr. Stein Gold, wrote in her psoriasis therapy article, “fixed combinations are commonplace in dermatology, providing significant efficacy and tolerability benefits.” F. 247; T. 683:24-686:4; PTX-44 at Abstract. The choice to use tazarotene in combination with a corticosteroid was not novel. As described by Bausch, “tazarotene was an automatic choice because it was the only retinoid approved at that point.” T. 69:1-2. Moreover, the “efficacy and tolerability benefits” provided by the combination of tazarotene and topical corticosteroids were recognized in the prior art. F.248; T. 111:6-19, 686:16-687:21; PTX-380 at 1162. As Bausch repeatedly explained to FDA, combining tazarotene with a topical corticosteroid was known to improve efficacy, reduce irritation associated with tazarotene, and provide longer remission of psoriasis symptoms. F. 262-265, 269, 273-274; T. 110:3-8, 111:10-17, 111:20-112:1, 114:22-115:2, 122:6-16, 701:16-22, 702:16-703:14, 703:19-704:11; JTX-009-3 at BAU00002788-2789, 2811; JTX-009-5 at BAU00013661.

Gollnick also found, in two double-blind psoriasis clinical studies, that

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combining tazarotene with a high potency topical corticosteroid significantly improved efficacy and reduced local skin effects compared to tazarotene plus placebo cream. F. 249-251, 274-275; T. 178:10-22; DX-140 at 1, 5. Gollnick's conclusions would have motivated a POSA to combine tazarotene with HP, an even more potent steroid than those used in Gollnick. F. 278; T. 178:24-179:2. A POSA would have been motivated to combine HP and tazarotene in a single vehicle, as was commonplace in dermatology, because they would have known that doing so would improve convenience and patient adherence, and avoid issues with layering the two drugs in separate vehicles. F. 279; T. 179:3-14, 681:15-23.

A POSA would have also known that tazarotene had already been combined with HP in lotions for treating psoriasis. For example, Gandhi taught that combination in 2012 and explained that HP and tazarotene “have entirely different modes of action and when combined in a single formulation, have synergistic effects which lead to more rapid clearing and are notably effective for types of psoriasis which have not responded to corticosteroids or retinoids alone.” F. 252-253, 330, 336; T. 179:19-180:4, 185:2-16, 695:25-696:5; DX-141 at 7.

In January 2014, the IDP-118 Study disclosed a lotion for treating psoriasis that included the combination of 0.01% HP and 0.045% tazarotene—the identical concentrations of HP and tazarotene recited in the claims of the Combination

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Patents. F. 254-255, 280; T. 180:5-22; DX-064 at 1-2.<sup>10</sup> Thus, the IDP-118 Study not only would have reinforced the POSA's motivation to combine HP and tazarotene in a single vehicle, it would have directed the POSA to the exact concentrations claimed in the Combination Patents. F. 280.

**2. The '824 Publication Disclosed Every Limitation Of The Combination Patents Except 0.045% Tazarotene And The Synergy Limitations**

Having been motivated to combine 0.01% HP and 0.045% tazarotene by Gollnick, the IDP-118 Study, and/or Gandhi, a POSA would have then looked for an appropriate vehicle for the composition and would have been drawn to the '824 Publication, the *only* prior art reference disclosing a vehicle for a composition with 0.01% HP. F. 293, 303, 307; T. 299:1-6, 667:23-668:13. The '824 Publication disclosed vehicles that enabled lower concentrations of HP to achieve similar

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<sup>10</sup> As Padagis explained in its Opposition to Bausch's Motion *in Limine* No. 2, Bausch's experimental use argument regarding the IDP-118 Study is incorrect. D.I. 190; C.22-37. Experimental use is a judge-made doctrine that may negate the "public use" or "on sale" statutory bars under AIA 35 U.S.C. §102(a)(1). *Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1328 (Fed. Cir. 2019); C.28. Bausch has not identified a single instance where the experimental use exception was applied to a ***printed publication*** like the IDP-118 Study, and Bausch fails to provide any justification for its dramatic expansion of the experimental use doctrine. Such an expansion is particularly unwarranted here because Bausch had no obligation to include the concentration of the active ingredients in its submission to ClinicalTrials.gov, information that Bausch refers to as "proprietary," and Bausch had no expectation of privacy for that information once it was submitted to ClinicalTrials.gov. F. 34-38; T. 133:21-136:6, 443:20-444:1, 452:5-453:21; C.22-37.

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potency and efficacy as Ultravate, while reducing adverse events and allowing for longer durations of treatment. F. 257, 294, 350, 357; T. 181:3-14; DX-142 at [0035]. Formulation 4A disclosed every ingredient of IDP-118, the preferred embodiment of the Combination Patents, and their concentrations, except for 0.045% tazarotene. F. 259, 290, 322, 334; T. 139:3-12, 610:25-611:17; DX-142 at Table 4; JTX-002 at Table 4; JTX-003 at Table 4; *see also* App'x A at Limitations 3.1, 3.3, 3.5-6, 6.1, 6.3, 6.5-6, 4.1, 4.3, 4.6, 4.7, 5.1, 5.3, 5.6, 5.7, 7.1, 7.3.

A POSA would have been motivated to select a formulation with 0.01% HP by the IDP-118 Study, which disclosed that exact HP concentration, and/or by the knowledge that lowering the concentration of HP would reduce the risk of systemic side effects. F. 293, 349, 356; T. 123:7-14, 166:9-167:10, 298:4-25, 673:13-674:6; 794:24-795:4. Formulation 4A is one of only two formulations disclosed in the '824 Publication that includes 0.01% HP, and the '824 Publication teaches a method for making Formulation 4A. F. 293, 349, 356; T. 298:4-299:6, 367:16-370:24, 670:9-20; DX-142 at Tables 1 & 4. The '824 Publication also teaches that formulations with 0.01% HP provided similar potency and efficacy as formulations with higher HP concentrations, including Ultravate. F. 294, 350, 357; T. 181:3-14; DX-142 at Tables 1 & 3. These teachings would have motivated a POSA to use at least Formulation 4A as the vehicle for the 0.01% HP/0.045% tazarotene combination. F. 293-294, 349-350, 356-357; T. 180:23-181:14.

**ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER****3. Adding 0.045% Tazarotene To The 0.01% HP Lotion Disclosed In The '824 Publication Would Have Been Obvious**

Bausch's selection of 0.045% tazarotene for the combination with HP was not novel. *See* App'x A at Limitations 3.2, 6.2, 4.2, 5.2, 7.2. The IDP-118 Study expressly disclosed the combination of 0.045% tazarotene with 0.01% HP for treating psoriasis. F. 255, 287; T. 180:9-22, 666:16-667:14; DX-064 at 1-2. Moreover, selection of 0.045% tazarotene would have been an obvious result of routine experimentation in view of the 0.05% tazarotene product that was FDA approved and commercially available for treating psoriasis. F. 288, 320, 333; T. 377:1-9. Bausch did not optimize the concentration of tazarotene in Duobrii, but rather justified the 0.045% concentration to FDA by asserting that it was "comparable" to the 0.05% tazarotene that was already FDA approved and would "provide the potential for efficacy in the treatment of psoriasis similar to that of Tazorac® Cream 0.05%" because it was "close enough" to 0.05%. F. 268, 272; T. 87:10-20, 120:8-14, 121:20-122:5, 700:10-21, 796:17-797:1; JTX-009-3 at BAU00002791; JTX-009-5 at BAU00013662.

The Tazorac Label also would have motivated a POSA to select a tazarotene concentration of 0.045%. F. 315-319; T. 181:15-182:20. Local skin irritation was a well-known problem with tazarotene treatment, and the Tazorac Label teaches that the 0.05% tazarotene caused less skin irritation than the 0.1% dose but provided a similar level of efficacy. F. 243-245, 316-317, 319; T. 182:1-20; DX-010 at 3-4, 9.

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Given this knowledge, a skilled artisan would have been motivated to reduce the tazarotene concentration from 0.05% to 0.045% to achieve an even further reduction in irritation without any substantial impact on efficacy. F. 318-319; T. 182:6-20.

**4. The Synergy Limitations Should Not Be Given Patentable Weight**

An obvious drug formulation cannot become nonobvious simply by administering it to a patient and claiming the resulting effects. *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012) (citing *In re Kao*, 639 F.3d 1057, 1070 (Fed. Cir. 2011)); C.51. IDP-118 is an obvious drug formulation—it merely adds 0.045% tazarotene to a known formulation of 0.01% HP. That obvious combination does not become nonobvious simply because Bausch tested it on psoriasis patients and claimed the resulting inherent effects.

In the obviousness context, a claim limitation is inherently disclosed if “the limitation at issue [is] necessarily . . . present, or the natural result of the combination of elements explicitly disclosed by the prior art.” *Par Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014); C.51. The efficacy and adverse events produced by IDP-118 are the natural results of applying IDP-118 lotion to psoriatic skin. F. 295; T. 185:17-186:2. Thus, the synergies provided by IDP-118<sup>11</sup> are the

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<sup>11</sup> The parties stipulated that IDP-118 is an embodiment of the '895 and '787 Patents, and therefore, there is no dispute that IDP-118 exhibits the claimed synergies as construed by this Court, though Padagis reserves its right to appeal this Court's construction. D.I. 199 at ¶¶5, 7.

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natural result of the formulation, which is an obvious combination of elements explicitly disclosed in the prior art and adds “nothing of patentable consequence” to the claims. *In re Kao*, 639 F.3d at 1070; *Santarus, Inc.*, 694 F.3d at 1354; F. 295; T. 185:17-186:2; C.51; *see* App’x A at Limitations 3.4, 6.4, 4.4, 5.4, 7.4.

**5. A POSA Would Have Reasonably Expected The HP/Tazarotene Combination To Provide Synergy**

Even if this Court were to accord patentable weight to the Synergy Limitations (which it should not), a POSA would have reasonably expected the claimed synergies. Gollnick expressly stated that “[c]ombination therapy with tazarotene and a topical corticosteroid appears logical because these agents have some different (as well as some common) mechanisms of action and thus are *likely to have additive or synergistic effects*.” F. 296; DX-140 at 2; T. 178:10-22, 183:3-10, 184:20-185:8, 294:7-295:1, 695:25-696:5. Gandhi stated that HP and tazarotene “have entirely different modes of action and when combined in a single formulation, *have synergistic effects* which lead to more rapid clearing and are notably effective for types of psoriasis which have not responded to corticosteroids or retinoids alone.” F. 336; DX-141 at 7; T. 179:19-180:4, 184:20-185:16, 695:25-696:5. Given these teachings and a POSA’s knowledge regarding the mechanisms of action of HP and tazarotene, a POSA would have reasonably expected that the combination of 0.01% HP and 0.045% tazarotene would be capable of providing the claimed synergistic efficacy and a synergistic reduction of an adverse event. F. 296, 336; T. 184:20-

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185:16, 294:7-295:1.

Bausch repeatedly admitted and emphasized the expectation of synergy for the tazarotene/HP combination in its FDA submissions for Duobrii. In 2011, Bausch told FDA that when tazarotene is combined with a topical corticosteroid, “the irritation is reduced and a synergistic effect allows for longer duration of treatment and remission,” citing to a 2011 article. F. 264; JTX-009-3 at BAU00002788; T. 111:20-112:1. Bausch also told FDA in 2011 that the concept for combining tazarotene with HP was based on the “the potential for additive or synergistic effects due to different mechanisms of action.” F. 271; JTX-009-2 at BAU00002589; T. 693:17-24, 694:17-22. Bausch even told FDA “[s]ynergy between selected APIs *is expected* as the corticosteroid has shown to suppress epidermal irritation related to tazarotene and the retinoid pro-drug is anticipated to minimize skin atrophy associated with halobetasol propionate.” F. 270; JTX-011-3 at BAU00054957; T. 125:2-8.

Bausch’s only response to the explicit references to synergy in the prior art and its FDA submissions is that the word “synergy” did not actually mean “synergy” (i.e., greater than additive effects), but rather was just a synonym for “additive” or “complimentary” effects. The Court should readily dismiss Bausch’s litigation-inspired argument for several reasons. First, Bausch’s new position is alarmingly inconsistent with Bausch’s arguments during claim construction. Bausch told this

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Court that “synergy” as “used and understood in the field of the invention” of the Combination Patents had a well-established, plain and ordinary meaning – “when a combination product demonstrates an effect greater than what would be expected from administering the constituent components individually.” D.I. 59 at 12-13; *id.* at 29; D.I. 69 at 31, 35. Nowhere did Bausch suggest, as it does now, that the Combination Patents adopted a “nuanced” definition of synergy that departs from the common usage in the field. Moreover, Bausch never explained to FDA that it really meant “complimentary” or “additive” every time it used the word “synergy.” Second, Bausch’s new position requires unreasonable readings of both the prior art and Bausch’s FDA submissions. Both Gollnick and Bausch’s FDA submissions state that the combination of tazarotene and a topical corticosteroid is likely to provide “additive *or* synergistic effects.” DX-140 at 2; JTX-009-2 at BAU00002589. Under Bausch’s reading, even though these phrases distinguish between “additive” and “synergistic” effects in the alternative, a skilled artisan would read them to mean that the combination would likely provide “additive or additive” effects. T. 695:1-695:16. Such an interpretation defies both basic grammar and common sense.

Bausch’s evidence for its new understanding of “synergy,” Kircik, also directly rebuts Bausch’s argument. Kircik expressly teaches that “synergy” has a “clearly defined” meaning in pharmacological discourse that means “not only that agents are compatible, but that the product of their combined action is greater than

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the sum of the efficacy of the constituent parts.” F. 298; PTX-043 at 1; T. 697:8-698:2. When confronted with this evidence, Dr. Stein Gold took the extreme and unreasonable position that no document in this case, including Bausch’s FDA submissions, is “pharmacological discourse,” except Bausch’s post-patent filing statements regarding Duobrii. T. 698:11-699:4. Dr. Stein Gold’s assertion not only undermines her credibility, but also illustrates the absurdity of Bausch’s new position that “synergy” only means “synergy” when it suits Bausch’s interests.

The expectation of synergy recognized in the prior art and Bausch’s FDA submissions is particularly strong in view of this Court’s decision that no level of statistical significance is required to satisfy the Synergy Limitations and that a drug combination need not actually provide synergy, it need only be “capable of” providing synergy. *See* D.I. 196 at 3-5. Bausch cannot show that synergy is “rare” or “unexpected” under such an understanding. Dr. Stein Gold testified that there are only three FDA approved fixed-dose combination products for psoriasis, two of which demonstrate synergy under this Court’s construction and a third that was not tested for synergy. F. 301, 372; T. 692:18-22. Thus, synergy is not rare or unexpected in this context, despite Bausch’s repeated protests to the contrary.

**6. A POSA Would Have Been Motivated To Combine The Prior Art**

**a. The ’824 Publication, Gollnick, And The IDP-118 Study**

Gollnick teaches a POSA that combining tazarotene with a corticosteroid

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improves efficacy and reduces irritation and will likely provide synergistic effects when treating psoriasis; the IDP-118 Study informs them of a lotion with the combination of 0.01% HP and 0.045% tazarotene in a phase 2 study for treating psoriasis; and the '824 Publication provides them with a vehicle for a 0.01% HP lotion. F. 311; T. 193:21-16. These teachings would have led a POSA to the IDP-118 formulation disclosed in the Combination Patents, and a POSA would have been motivated to combine them given that all three references deal with treating psoriasis with tazarotene and/or HP, and the fact that the '824 Publication is the only prior art reference that disclosed a vehicle with 0.01% HP, the concentration of HP disclosed in the IDP-118 Study. F. 309; T. 182:21-183:25, 184:6-19. It would have been obvious to apply the composition of Claim 4 of the '787 patent once or more times per day for a period of time sufficient to treat the patient's psoriasis, as that was standard practice in the field of dermatology and disclosed by Gollnick (combination of taz and corticosteroid once per day was effective at 8 and 12 weeks). F. 358 (Limitations 4.1, 4.5); T. 188:22-189:4; DX-140 at 2-3. Accordingly, claims 3 and 6 of the '895 Patent and claims 4 and 5 of the '787 patent would have been obvious in view of the '824 Publication, Gollnick, and the IDP-118 Study. F. 276-312, 345-351, 352-361; T. 186:3-187:17, 187:18-190:7; 194:14-16; C.99.

**b. The '824 Publication, Gollnick, And The Tazorac Label**

Gollnick motivated a POSA to combine tazarotene and a corticosteroid; the

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'824 Publication provided them a vehicle for a super-potent 0.01% HP lotion; and the Tazorac Label would have motivated them to use 0.045% tazarotene in the combination to reduce irritation without a meaningful loss in efficacy. *Supra* §§III.B.3, 6.a. These teachings would have led a POSA to the IDP-118 formulation disclosed in the Combination Patents, as well as the claimed method of applying the composition recited in the '787 patent, and a POSA would have been motivated to combine them given that all three references deal with treating psoriasis with tazarotene and/or HP. F. 327, 358, 361; T. 182:21-183:25. Thus, claims 3 and 6 of the '895 Patent and claims 4 and 5 of the '787 patent would have been obvious in view of the '824 Publication, Gollnick, and the Tazorac Label. F. 313-328, 345-351, 352-361; T. 186:3-187:17, 187:18-190:7; 194:14-16; C.98.

**c. The '824 Publication, Gollnick, And Gandhi**

Gollnick motivated a POSA to combine tazarotene and a corticosteroid; the '824 Publication provided them a vehicle for a super-potent 0.01% HP lotion; and Gandhi disclosed formulations combining HP and tazarotene with synergistic effects and tazarotene at 0.05%. *Supra* §§III.B.5, 6.a. These teachings would have led a POSA to the IDP-118 formulation disclosed in the Combination Patents, as well as the claimed method of applying the composition recited in the '787 patent, and a POSA would have been motivated to combine them given that all three references deal with treating psoriasis with tazarotene and/or HP. F. 343, 358, 361; T. 182:21-

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183:25. Thus, claims 3 and 6 of the '895 Patent and claims 4 and 5 of the '787 patent would have been obvious in view of the '824 Publication, Gollnick, and Gandhi. F. 329-344, 345-351, 352-361; T. 186:3-187:17, 187:18-190:7; 194:14-16; C.100.

**7. A POSA Would Have Found It Obvious To Apply The Combination For 8 Weeks And Would Have Expected It To Provide Sustained Relief For Psoriasis**

The eight-week treatment period required by claim 7 of the '787 patent would have been obvious. App'x A at Limitation 7.6.<sup>12</sup> Gollnick's Figure 1 teaches that the efficacy rates for the tazarotene plus high potency corticosteroid combination were roughly equivalent at weeks 8 and 12, providing a POSA with a motivation and reasonable expectation of success for an 8-week treatment period. F. 364; T. 190:10-21; DX-140 at Fig. 1. A POSA also would have reasonably expected that a combination product with 0.01% HP could be safely administered for up to 8 consecutive weeks given the knowledge that reducing the concentration of HP likely reduces the risk of adverse events and the teaching in the '824 Publication that 0.01% HP allows for greater safety and longer treatment periods. F. 365; T. 190:22-191:8.

The sustained relief to psoriasis required by claim 7 of the '787 patent is directed to an inherent property of the IDP-118 formulation and would have been reasonably expected. App'x A at Limitation 7.7. The length of relief of psoriasis

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<sup>12</sup> Limitations 7.1-7.5 of claim 7 are addressed in § III.B.6.

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symptoms is the result of the natural reactions of the patient's disease to the IDP-118 formulation and is therefore an inherent property of the formulation. F. 366; T. 192:3-18. Moreover, the parties agree that, prior to 2015, tazarotene was known to provide a maintenance effect after cessation of therapy that could last up to four weeks. F. 365; T. 192:13-21, 704:22-705:9; DX-151 at 293; DX-010 at 9. Gollnick teaches that tazarotene provided this maintenance effect when combined with a highly potent topical corticosteroid – Figure 1 shows little loss in efficacy between the cessation of therapy and the 4-week follow up at week 16. F. 367; T. 191:17-192:4; DX-140 at Fig. 1. A POSA would have therefore reasonably expected the combination of 0.045% tazarotene and 0.01% HP to continue to provide relief to psoriasis for four weeks after cessation of therapy. F. 367; T. 191:9-192:2. Accordingly, claim 7 of the '787 patent would have been obvious in view of the '824 Publication and Gollnick in further combination with one of the IDP-118 Study, the Tazorac Label, and Gandhi. F. 362-368; T. 192:22-193:20, 194:14-16; C.96-100.

**8. Bausch Cannot Prove That Secondary Considerations Overcome The Strong *Prima Facie* Case Of Obviousness**

Bausch has not proven that any secondary considerations overcome the strong *prima facie* case of obviousness for the Combination Patents. Bausch has not proven any unexpected results. C.97. As explained above, any synergistic effects, length of treatment, and sustained relief provided by the IDP-118 formulation would have been reasonably expected by a POSA given the teachings of the prior art. *Supra* §§ III.B.5,

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7. Bausch also has not provided any objective evidence that anyone in the field of dermatology was skeptical of the 0.045% tazarotene/0.01% HP combination. F. 375. Bausch's only alleged evidence of skepticism is self-serving testimony from its own witnesses. *Id.* Bausch has not proven that Duobrii's commercial performance supports the nonobviousness of the Combination Patents. *Supra* § II.D.7.a.

Bausch has not proven that the Combination Patents solved any long-felt but unmet need for a super-potent corticosteroid that may be administered for a period of longer than two consecutive weeks. Prior to the Combination Patents, the '824 Publication disclosed a super-potent 0.01% HP formulation that could be administered for longer than two weeks. F. 377; T. 181:3-14; DX-142 at [0035]. Thus, if there was such a long-felt but unmet need, the prior art solved that need before the priority date of the Combination Patents. *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1305 (Fed. Cir. 2010); C.65. The real-world evidence, [REDACTED]

[REDACTED], also show that Duobrii did not solve a long-felt but unmet need. *Supra* § II.D.7.c.

**IV. CONCLUSION**

For the foregoing reasons, this Court should hold that the asserted claims of the HP and Combination Patents are invalid and enter judgment in favor of Padagis. C.101-123.

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Respectfully submitted,  
FOX & ROTHSCHILD, LLP

Dated: November 15, 2022

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**CERTIFICATE OF SERVICE**

I hereby certify that on November 15, 2022, a true and correct copy of the foregoing document was served on the following counsel of record at the addresses and in the manner indicated:

***VIA ELECTRONIC MAIL:***

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