

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

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

BAUSCH HEALTH	)	
IRELAND LIMITED, et al.,	)	
Plaintiffs,	)	
	)	Civil Action No. 20-5426 (SRC)
v.	)	(CLW) (CONSOLIDATED)
	)	
PADAGIS ISRAEL	)	FILED UNDER SEAL
PHARMACEUTICALS LTD et al.,	)	
	)	<i>Document Electronically Filed</i>
Defendants.	)	
	)	

DEFENDANTS PADAGIS ISRAEL PHARMACEUTICALS LTD
AND PADAGIS US LLC’S PROPOSED FINDINGS OF FACT
AND CONCLUSIONS OF LAW

TABLE OF CONTENTS

	Page No.
FINDINGS OF FACT.....	1
I. REMEDY	1
II. INVALIDITY	5
A. Prior Art.....	5
B. Findings of Fact Regarding the '307 and '502 patents	14
1. Person of Ordinary Skill in the Art.....	17
2. Background and Prior Art.....	18
a. Halobetasol Propionate Was a Well-Known Corticosteroid Useful for Treating Psoriasis Prior to 2010	18
b. Formulations with concentrations of HP below 0.05% were known to be effective in treating psoriasis before 2010	20
c. It Was Known in the Art That Lower Concentrations of Corticosteroids Were Associated With Reduced Side Effects and Increased Duration of Treatment.....	22
d. Use of Dicarboxylic Acid Esters to Solubilize Corticosteroids in Topical Formulations Was Known in the Art	23
i. The '295 Patent	24
ii. The '566 Patent	26
iii. JP '228.....	28

TABLE OF CONTENTS
(*cont'd*)

	Page No.
3. The Asserted Claims of the '307 Patent and the '502 Patent are Invalid as Obvious	29
a. Claim 13 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum.....	31
i. Blum Disclosed Topical Compositions Comprising Halobetasol Propionate (Limitation 13.1)	31
ii. The '295 Patent Disclosed Topical Corticosteroid Compositions Comprising a Liquid Oil Component Comprising Diethyl Sebacate, Wherein at Least 50% of the Corticosteroid Is Solubilized in the Liquid Oil Component at Room Temperature (22°C) (Limitations 13.2, 13.4).....	31
iii. The '295 Patent and Blum Disclosed Topical Corticosteroid Compositions, Including Halobetasol, at Concentrations Within the Claimed Range of “0.025% or Less” (Limitation 13.3).....	32
iv. A Skilled Artisan Would Have Been Motivated to Modify and Combine the '295 Patent and Blum with a Reasonable Expectation of Success in Arriving at the Subject Matter of Claim 13 of the '307 Patent.....	36
b. Claim 13 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with the '566 Patent.....	37

TABLE OF CONTENTS
(*cont'd*)

	Page No.
i. Blum and the '566 Patent Disclosed Topical Compositions Comprising Halobetasol Propionate (Limitation 13.1).....	37
ii. The '295 Patent and the '566 Patent Disclosed Topical Corticosteroid Compositions Comprising a Liquid Oil Component Comprising Dicarboxylic Acid Esters (Including Diethyl Sebacate), Wherein At Least 50% of the Corticosteroid Is Solubilized in the Liquid Oil Component at Room Temperature (22°C) (Limitations 13.2, 13.4).....	38
iii. The '295 Patent and Blum Disclosed Topical Corticosteroid Compositions, Including Halobetasol, At Concentrations Within the Claimed Range of “0.025% or Less” (Limitation 13.3).....	39
iv. A Skilled Artisan Would Have Been Motivated to Modify and Combine the '295 Patent, Blum, and the '566 Patent With A Reasonable Expectation of Success In Arriving At the Subject Matter of Claim 13 of the '307 Patent.	39
c. Claim 13 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with JP '228	40

TABLE OF CONTENTS
(*cont'd*)

	Page No.
i. Blum Disclosed Topical Compositions Comprising Halobetasol Propionate (Limitation 13.1)	40
ii. The '295 Patent and JP '228 Disclosed Topical Corticosteroid Compositions Comprising A Liquid Oil Component Comprising Diethyl Sebacate, Wherein At Least 50% of the Corticosteroid Is Solubilized in the Liquid Oil Component at Room Temperature (22°C) (Limitations 13.2, 13.4).....	41
iii. The '295 patent, Blum, and JP '228 Disclosed Topical Corticosteroid Compositions, including Halobetasol, At Concentrations Within the Claimed Range of “0.025% or Less” (Limitation 13.3).....	42
iv. A Skilled Artisan Would Have Been Motivated to Modify and Combine the '295 Patent, Blum, and JP '228 With A Reasonable Expectation of Success In Arriving at the Subject Matter of Claim 13 of the '307 Patent	42
d. Claim 16 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum.....	43
e. Claim 16 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with the '566 Patent.....	45

TABLE OF CONTENTS
(*cont'd*)

		Page No.
f.	Claim 16 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with JP '228	47
g.	Claim 20 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum	50
h.	Claim 20 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with the '566 Patent.....	51
i.	Claim 20 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with JP '228	52
j.	Claim 4 of the '502 Patent Would Have Been Obvious Over the '295 Patent In View of Blum	54
k.	Claim 4 of the '502 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with the '566 Patent.....	58
l.	Claim 4 of the '502 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with JP '228	60
m.	Claim 16 of the '502 Patent Would Have Been Obvious Over the '295 Patent In View of Blum	61
n.	Claim 16 of the '502 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with the '566 Patent.....	63
o.	Claim 16 of the '502 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with the Temovate Label	65

TABLE OF CONTENTS
(*cont'd*)

	Page No.
p. The Alleged Evidence Of Secondary Considerations Does Not Demonstrate Nonobviousness Of The '307 Or '502 Patents.....	67
i. No Unexpected Results	67
ii. No Reasonably Commensurate Long Felt Need	70
iii. No Failure of Others.....	73
iv. No Commercial Success.....	73
4. The Asserted Claims of the '307 and '502 Patents are Indefinite	74
C. Findings of Fact Regarding the '895 and '787 Patents.....	77
1. Person of Ordinary Skill in the Art.....	77
2. Background and Prior Art.....	78
a. Tazarotene Was A Well-known Retinoid Approved For Treating Psoriasis Prior To June 2015	78
b. Combining Taz With Topical Corticosteroids Was Recognized As A Desirable Combination Therapy For Psoriasis Prior To June 2015	80
i. Gollnick.....	81
ii. Gandhi	82
iii. IDP-118 Study.....	82
c. The '824 Publication Disclosed Topical Corticosteroid Compositions, and Methods of	

TABLE OF CONTENTS
(*cont'd*)

	Page No.
Using those Compositions, Including Halobetasol Formulations Prior to June 2015	83
d. Bausch's Representations to the FDA.....	85
3. The asserted claims of the '895 and '787 patents are invalid as obvious.....	89
a. Claim 3 Of The '895 Patent Would Have Been Obvious Over The '824 Publication In Combination With Gollnick And The IDP-118 Study	89
i. A POSA Would Have Been Motivated To Combine HP And Taz In A Single Formulation To Treat Psoriasis (Limitations 3.1, 3.2).....	90
ii. A POSA Would Have Been Motivated To Use 0.01% HP In The Combination Product (Limitation 3.1).....	92
iii. A POSA Would Have Been Motivated To Use 0.045% Taz In The Combination Product (Limitation 3.2).....	94
iv. The '824 Publication Disclosed The Claimed Dermatologically Acceptable Carrier (Limitation 3.3).....	95
v. Synergy Is An Inherent Property Of IDP-118 And Would Have Been Reasonably Expected (Limitation 3.4).....	97
vi. The '824 Publication Disclosed Lotion Emulsions (Limitation 3.6)	99

TABLE OF CONTENTS
(*cont'd*)

	Page No.
vii. A POSA Would Have Expected HP And Taz Would Be Dissolved In The Liquid Oil Component Of The '824 Publication (Limitation 3.5)	100
viii. A POSA Would Have Been Motivated To Combine The '824 Publication, Gollnick, And The IDP-118 Study With A Reasonable Expectation Of Success	102
b. Claim 3 Of The '895 Patent Would Have Been Obvious Over The '824 Publication In Combination With Gollnick And The Tazorac® Label	103
i. A POSA Would Have Been Motivated To Combine HP And Taz In A Single Formulation To Treat Psoriasis (Limitations 3.1, 3.2).....	103
ii. A POSA Would Have Been Motivated To Use 0.01% HP In The Combination Product (Limitation 3.1).....	103
iii. A POSA Would Have Been Motivated To Use 0.045% Taz In The Combination Product (Limitation 3.2).....	103
iv. The '824 Publication Disclosed The Claimed Dermatologically Acceptable Carrier (Limitation 3.3)	105
v. Synergy Is An Inherent Property Of IDP-118 And Would Have Been Reasonably Expected (Limitation 3.4).....	105

TABLE OF CONTENTS
(*cont'd*)

	Page No.
vi. The '824 Publication Disclosed Lotion Emulsions (Limitation 3.6)	106
vii. A POSA Would Have Expected HP And Taz Would Be Dissolved In The Liquid Oil Component Of The '824 Publication (Limitation 3.5)	106
viii. A POSA Would Have Been Motivated To Combine The '824 Publication, Gollnick, And The Tazorac® Label With A Reasonable Expectation Of Success	106
c. Claim 3 Of The '895 Patent Would Have Been Obvious Over The '824 Publication In Combination With Gollnick And Gandhi.....	107
i. A POSA Would Have Been Motivated To Combine HP And Taz In A Single Formulation To Treat Psoriasis (Limitations 3.1, 3.2).....	107
ii. A POSA Would Have Been Motivated To Use 0.01% HP In The Combination Product (Limitation 3.1).....	108
iii. A POSA Would Have Been Motivated To Use 0.045% Taz In The Combination Product (Limitation 3.2).....	108
iv. The '824 Publication Disclosed The Claimed Dermatologically Acceptable Carrier (Limitation 3.3)	109

TABLE OF CONTENTS
(*cont'd*)

	Page No.
v. Synergy Is An Inherent Property Of IDP-118 And Would Have Been Reasonably Expected (Limitation 3.4).....	109
vi. The '824 Publication Disclosed Lotion Emulsions (Limitation 3.6)	110
vii. A POSA Would Have Expected HP And Taz Would Be Dissolved In The Liquid Oil Component Of The '824 Publication (Limitation 3.5)	110
viii. A POSA Would Have Been Motivated To Combine The '824 Publication, Gollnick, And Gandhi With A Reasonable Expectation Of Success	110
d. Claim 6 Of The '895 Patent Would Have Been Obvious.....	111
e. Claim 4 Of The '787 Patent Would Have Been Obvious.....	114
f. Claim 5 of the '787 patent	118
g. Claim 7 of the '787 patent	119
i. It Would Have Been Obvious To Apply The Combination Of 0.01% HP And 0.045% Taz For A Period Of Eight Weeks (Limitation 7.6)	119
ii. The Continued Relief To Psoriasis Provided By The Claimed Method Is An Inherent Property Of IDP-118 And Would Have Been Expected (Limitation 7.7).....	120

TABLE OF CONTENTS
(*cont'd*)

	Page No.
4. The Alleged Evidence Of Secondary Considerations Does Not Demonstrate Nonobviousness Of The '895 Or '787 Patents.....	121
a. No unexpected results.....	122
b. No industry praise.....	122
c. No skepticism	122
d. No Long-Felt But Unmet Need	123
e. No Failure Of Others	124
D. Duobrii is not a commercial success that demonstrates non-obviousness	124
CONCLUSIONS OF LAW	132
I. DEFENDANTS HAVE SHOWN ALL ASSERTED CLAIMS ARE INVALID BY CLEAR AND CONVINCING EVIDENCE.....	132
A. The Claim Term “Liquid Oil Component” Renders All Asserted Claims of the '307 and '502 Patents Indefinite.....	133
B. The Asserted Claims Are Obvious Over the Prior Art	134
1. Level of Ordinary Skill In The Art	136
2. Scope and Content of the Prior Art.....	138
a. The IDP 118 Study is a Prior Art Printed Publication and Does not Qualify for the Experimental Use Exception	143
i. The IDP 118 Study Qualifies as a Printed Publication	143

TABLE OF CONTENTS
(*cont'd*)

	Page No.
ii. The IDP 118 Study Does Not Qualify for the Experimental Use Exception	144
3. Differences Between the Claimed Invention and the Prior Art	150
4. Any Purported Secondary Considerations of Nonobviousness Do Not Outweigh the <i>Prima Facie</i> Case of Obviousness for All Asserted Claims.....	161
i. Bausch Has Not Demonstrated Nexus to the Asserted Claims.....	162
ii. Bausch Has Not Shown that Bryhali or Duobrii Satisfied a Long-Felt, Unmet Need.....	164
iii. Bausch Has Not Shown Failure of Others	168
iv. Bausch Has Not Demonstrated Any Unexpected Results	170
v. Bausch Has Not Shown Industry Praise for Bryhali or Duobrii	173
vi. Duobrii is Not a Commercial Success and Bausch Did Not Assert Commercial Success for Bryhali.....	174
vii. Bausch Has Not Demonstrated Industry Skepticism	179
viii. Copying Is Not Probative of Nonobviousness in the Context of Generic Drugs.....	179

TABLE OF CONTENTS
(*cont'd*)

	Page No.
5. Obviousness Conclusions	180
II. REMEDY	182
A. Bausch is Not Entitled to Any Relief.....	182
B. Padagis is Entitled to a Judgment of Invalidity.....	186

TABLE OF AUTHORITIES

Page No(s).

<i>ABT Sys., LLC v. Emerson Elec. Co.</i> , 797 F.3d 1350 (Fed. Cir. 2015)	176
<i>Acorda Therapeutics, Inc. v. Roxane Labs., Inc.</i> , Civil Action No. 14–882–LPS, 2017 WL 1199767	160, 173
<i>Agrizap, Inc. v. Woodstream Corp.</i> , 520 F.3d 1337 (Fed. Cir. 2008)	162
<i>In re Aller</i> , 220 F.2d 454 (C.C.P.A. 1955)	158
<i>Allergan, Inc. v. Apotex Inc.</i> , 754 F.3d 952 (Fed. Cir. 2014)	154, 161
<i>Allergan, Inc. v. Sandoz Inc.</i> , 726 F.3d 1286 (Fed. Cir. 2013)	156
<i>Allergan, Inc. v. Watson Labs., Inc.-Fla.</i> , 869 F. Supp. 2d 456 (D. Del. 2012).....	180
<i>Amgen Inc. v. Hoechst Marion Roussel, Inc.</i> , 314 F.3d 1313 (Fed. Cir. 2003)	141
<i>Am. Hoist & Derrick Co. v. Sowa & Sons</i> , 725 F.2d 1350 (Fed. Cir. 1984)	136
<i>In re Antonie</i> , 559 F.2d 618 (CCPA 1977)	158
<i>Apple Inc. v. Samsung Elecs. Co., Ltd.</i> , 816 F.3d 788, 805-06 (Fed. Cir. 2016 (en banc), vacated in part on other grounds on reh’g en banc, 839 F.3d 1034 (Fed. Cir. 2016).....	180
<i>Application of Hill</i> , 284 F.2d 955 (C.C.P.A. 1960)	173

TABLE OF AUTHORITIES
(*cont'd*)

	Page No(s).
<i>In re Applied Materials, Inc.</i> , 692 F.3d 1289 (Fed. Cir. 2012)	158
<i>Arrow Int’l., Inc. v. Spire Biomedical, Inc.</i> , 635 F. Supp. 2d 46 (D. Mass. 2009)	149, 150
<i>AstraZeneca LP v. Breath Ltd.</i> , 542 F. App’x 971 (Fed. Cir. 2013)	159
<i>AstraZeneca LP v. Breath Ltd.</i> , 88 F. Supp. 2d 326 (D.N.J. 2015)	168
<i>Asyst Techs., Inc. v. Emtrak, Inc.</i> , 544 F.3d 1310 (Fed. Cir. 2008)	163
<i>Atlanta Attachment Co. v. Leggett & Platt, Inc.</i> , 516 F.3d 1361 (Fed. Cir. 2008)	146
<i>Auris Health, Inc. v. Intuitive Surgical Operations, Inc.</i> , 32 F.4th 1154 (Fed. Cir. 2022)	179
<i>Aventis Pharma S.A. v. Hospira, Inc.</i> , 743 F. Supp. 2d 305 (D. Del. 2010)	168, 171
<i>B. Braun Melsungen AG v. Terumo Med. Corp.</i> , 778 F. Supp. 2d 506 (D. Del. 2011)	167
<i>Barry v. Medtronic, Inc.</i> , 914 F.3d 1310 (Fed. Cir. 2019)	144
<i>Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc.</i> , 713 F.3d 1369 (Fed. Cir. 2013)	179
<i>Bayer Pharma AG v. Watson Labs., Inc.</i> , 874 F.3d 1316 (Fed. Cir. 2017)	157

TABLE OF AUTHORITIES
(cont'd)

	Page No(s).
<i>Bayer Schering Pharma AG v. Barr Labs., Inc.</i> , Civil Action No. 05–cv–2308 (PGS), 2008 WL 628592 (D. N.J. Mar. 3, 2008).....	146
<i>Belden Techs., Inc. v. Superior Essex Commc’ns LP</i> , 802 F. Supp. 2d 555 (D. Del. 2011).....	138
<i>In re Bigio</i> , 381 F.3d 1320 (Fed. Cir. 2004)	140
<i>Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.</i> , 246 F.3d 1368 (Fed. Cir. 2001)	159
<i>Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.</i> , 752 F.3d 967 (Fed. Cir. 2014)	170, 173
<i>Campbell Soup Co. v. Gamon Plus, Inc.</i> , 10 F.4th 1268 (Fed. Cir. 2021)	177
<i>Constant v. Advanced Micro-Devices, Inc.</i> , 848 F.2d 1560 (Fed. Cir. 1988)	141, 144
<i>Cubist Pharm., Inc. v. Hospira, Inc.</i> , 805 F.3d 1112 (Fed. Cir. 2015)	169
<i>In re Cuozzo Speed Techs., LLC</i> , 793 F.3d 1268 (Fed. Cir. 2015)	160
<i>In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.</i> , 676 F.3d 1063 (Fed. Cir. 2012)	169
<i>Daiichi Sankyo Co., Ltd. v. Apotex Inc.</i> , 501 F.3d 1254 (Fed. Cir. 2007)	137
<i>In re DeBlauwe</i> , 736 F.2d 699 (Fed. Cir. 1984)	170

TABLE OF AUTHORITIES
(*cont'd*)

	Page No(s).
<i>Demaco Corp. v. F. Von Langsdorff Licensing Ltd.</i> , 851 F.2d 1387 (Fed. Cir. 1988)	162
<i>In re Dill</i> , 604 F.2d 1356 (C.C.P.A. 1979)	163
<i>Dome Patent L.P. v. Lee</i> , 799 F.3d 1372 (Fed. Cir. 2015)	155
<i>Donner Tech., LLC v. Pro Stage Gear, LLC</i> , 979 F.3d 1353 (Fed. Cir. 2020)	140
<i>Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.</i> , 800 F.3d 1375 (Fed. Cir. 2015)	135
<i>DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.</i> , 464 F.3d 1356 (Fed. Cir. 2006)	153, 169
<i>E.I. DuPont de Nemours & Co. v. Synvina C.V.</i> , 904 F.3d 996 (Fed. Cir. 2018)	157, 158
<i>E.I. DuPont De Nemours and Co. v. Monsanto Co.</i> , 903 F. Supp. 680 (D. Del. 1995)	165
<i>Ecolab, Inc. v. FMC Corp.</i> , 569 F.3d 1335 (Fed. Cir. 2009)	152
<i>Ecolochem, Inc. v. S. Cal. Edison Co.</i> , 227 F.3d 1361 (Fed. Cir. 2000)	135, 169
<i>Eisai Co. Ltd. v. Dr. Reddy’s Labs., Ltd.</i> , 533 F.3d 1353 (Fed. Cir. 2008)	135
<i>Eli Lilly & Co. v. Barr Labs., Inc.</i> , 251 F.3d 955 (Fed. Cir. 2001)	158, 160

TABLE OF AUTHORITIES
(cont'd)

	Page No(s).
<i>Eli Lilly and Co. v. Zenith Goldline Pharm., Inc.</i> , 471 F.3d 1369 (Fed. Cir. 2006)	146, 148
<i>Endo Pharm. Sols. Inc. v. Custopharm, Inc.</i> , 234 F.Supp.3d 587 (D. Del. 2017).....	137
<i>Envtl. Designs, Ltd. v. Union Oil Co. of Cal.</i> , 713 F.2d 693 (Fed. Cir. 1983)	137
<i>Ericsson Inc. v. Intellectual Ventures I LLC</i> , 890 F.3d 1336 (Fed. Cir. 2018)	161
<i>Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.</i> , 533 F.3d 1353 (Fed. Cir. 2008).....	135
<i>EWP Corp. v. Reliance Universal Inc.</i> , 755 F.2d 898 (Fed. Cir. 1985)	152
<i>EZ Dock v. Schafer Sys., Inc.</i> , 276 F.3d 1347 (Fed. Cir. 2002)	146
<i>In re Fout</i> , 675 F.2d 297 (C.C.P.A. 1982)	141
<i>In re Fulton</i> , 391 F.3d 1195 (Fed. Cir. 2004)	155
<i>Galderma Labs., L.P. v. Tolmar, Inc.</i> , 737 F.3d 731 (Fed. Cir. 2013)	<i>passim</i>
<i>In re Gardner</i> , No. 2011-1310, 2011 WL 5516077 (Fed. Cir. Nov. 14, 2011)	165, 167
<i>In re Geisler</i> , 116 F.3d 1465 (Fed. Cir. 1997)	171
<i>Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC</i> , 618 F.3d 1294 (Fed. Cir. 2010)	167, 174

TABLE OF AUTHORITIES
(*cont'd*)

	Page No(s).
<i>In re Gershon</i> , 372 F.2d 535 (C.C.P.A. 1967)	165
<i>Gilead Sciences, Inc. v. Sigmapharm Labs., LLC</i> , Civil Action No. 10–4931 (SDW)(MCA), 2014 WL 1293309 (D. N.J. Mar. 31, 2015).....	145
<i>GlaxoSmithKline, LLC, v. Banner Pharmacaps, Inc., C.A. 11–046– RGA</i> , 2013 WL 4082232 (D. Del. Aug. 9, 2013).....	137
<i>In re GPAC</i> , 57 F.3d 1573 (Fed. Cir. 1995)	163
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966).....	162, 170
<i>In re Grasselli</i> , 713 F.2d 731 (Fed. Cir. 1983)	163, 164, 168
<i>Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.</i> , 340 U.S. 147 (1950).....	175
<i>In re Greenfield</i> , 571 F.2d 1185 (C.C.P.A. 1978).....	164
<i>In re Gurley</i> , 27 F.3d 551 (Fed. Cir. 1994)	155
<i>In re Hamilton</i> , 882 F.2d 1576 (Fed. Cir. 1989)	150
<i>Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.</i> , 855 F.3d 1356 (Fed. Cir. 2017)	146
<i>Homeland Housewares, LLC v. Whirlpool Corp.</i> , 865 F.3d 1372 (Fed. Cir. 2017)	161

TABLE OF AUTHORITIES
(*cont'd*)

Page No(s).

<i>Immunex Corp. v. Sandoz Inc.</i> , 395 F. Supp. 3d 366 (D.N.J. 2019)	180
<i>Interval Licensing LLC v. AOL, Inc.</i> , 766 F.3d 1364 (Fed. Cir. 2014) <i>cert. denied</i> , 136 S. Ct. 59 (2015)	133
<i>IPXL Holdings, LLC v. Amazon.com, Inc.</i> , 430 F.3d 1377 (Fed. Cir. 2005)	182
<i>Iron Grip Barbell Co. v. USA Sports, Inc.</i> , 392 F.3d 1317 (Fed. Cir. 2004)	169
<i>J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.</i> , 106 F.3d 1563 (Fed. Cir. 1997)	177
<i>Jazz Pharm., Inc. v. Amneal Pharm., LLC</i> , 895 F.3d 1347 (Fed. Cir. 2018)	143
<i>In re Kahn</i> , 441 F.3d 977 (Fed. Cir. 2006)	166
<i>In re Huai-Hung Kao</i> , 639 F.3d 1057 (Fed. Cir. 2011)	159, 163
<i>In re Katz</i> , 687 F.2d 450 (C.C.P.A. 1982)	139
<i>In re Klein</i> , 647 F.3d 1343	140
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	<i>passim</i>
<i>May v. Carriage, Inc.</i> , 688 F. Supp. 408 (N.D. Ind. 1988)	167
<i>McNeil-PPC, Inc. v. L. Perrigo Co.</i> , 337 F.3d 1362 (Fed. Cir. 2003)	172

TABLE OF AUTHORITIES
(cont'd)

	Page No(s).
<i>MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc.</i> , 731 F.3d 1258 (Fed. Cir. 2013)	164
<i>Media Rights Techs. v. Cap. One Fin. Corp.</i> , 800 F.3d 1366 (Fed. Cir. 2015)	133
<i>Medichem, S.A. v. Rolabo, S.L.</i> , 437 F.3d 1157 (Fed. Cir. 2006)	156
<i>Medtronic Inc. v. Edwards Lifesciences Corp.</i> , Case No. SACV 12-00327-JVS, 2013 WL 12113417 (C.D. Cal. Sept. 17, 2013)	168
<i>Medtronic Inc. v. Intermedics, Inc.</i> , 799 F.2d 734 (Fed. Cir. 1986)	165
<i>In re Merchant</i> , 575 F.2d 865 (C.C.P.A. 1978)	172
<i>Merck & Co., Inc. v. Biocraft Labs., Inc.</i> , 874 F.2d 804 (Fed. Cir. 1989)	152, 155
<i>Merck & Co., Inc. v. Teva Pharm. USA, Inc.</i> , 395 F.3d 1364 (Fed. Cir. 2005)	140, 175
<i>In re Merck</i> , 800 F.2d 1091 (Fed. Cir. 1986)	156
<i>Microsoft Corp. v. i4i Ltd. Partnership</i> , 564 U.S. 91 (2011)	132, 141
<i>Mitsubishi Chem. Corp. v. Barr Labs., Inc.</i> , 718 F. Supp. 2d 382	178
<i>Motorola, Inc. v. Interdigital Tech. Corp.</i> , 121 F.3d 1461 (Fed. Cir. 1997)	154

TABLE OF AUTHORITIES
(*cont'd*)

	Page No(s).
<i>In re Mouttet</i> , 686 F.3d 1322 (Fed. Cir. 2012)	155, 157
<i>Muniauction, Inc. v. Thomson Corp.</i> , 532 F.3d 1318 (Fed. Cir. 2008)	163, 174
<i>Nautilus, Inc. v. Biosig Instruments, Inc.</i> , 134 S. Ct. 2120 (2014).....	133
<i>Netscape Commcn's Corp. v. Konrad</i> , 295 F.3d 1315 (Fed. Cir. 2002)	148, 149
<i>Newell Co. v. Kenney Mfg. Co.</i> , 864 F.2d 757 (Fed. Cir. 1988)	166
<i>In re Nomiya</i> , 509 F.2d 566 (C.C.P.A. 1975)	141
<i>Novartis Pharm. Corp. v. West-Ward Pharm. Int'l, Ltd.</i> , 287 F. Supp. 3d 505 (D. Del. 2017).....	172
<i>Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.</i> , 719 F.3d 1346 (Fed. Cir. 2013)	161
<i>NXP B.V. v. Blackberry, Ltd.</i> , 58 F. Supp. 3d 1313 (M.D. Fla. 2014).....	183
<i>Ormco Corp. v. Align Tech., Inc.</i> , 463 F.3d 1299 (Fed.Cir.2006)	157, 169
<i>Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.</i> , No. 07-1000 (MLC), 2015 WL 5921035 (D.N.J. Oct. 9, 2015).....	183
<i>Par Pharm., Inc. v. TWi Pharm., Inc.</i> , 120 F. Supp. 3d 468 (D. Md. July 28, 2015), <i>aff'd</i> , 624 Fed. Appx. 756 (Fed. Cir. 2015).....	160

TABLE OF AUTHORITIES
(*cont'd*)

	Page No(s).
<i>Par Pharm. Inc. v. TWi Pharm., Inc.</i> , 773 F.3d 1186 (Fed. Cir. 2014)	155, 158
<i>In re Paulsen</i> , 30 F.3d 1475 (Fed. Cir. 1994)	163
<i>Pennwalt Corp. v. Akzona, Inc.</i> , 740 F.2d 1573 (Fed.Cir.1984)	148
<i>In re PepperBall Techs., Inc.</i> , 469 F. App'x 878 (Fed. Cir. 2012)	166
<i>Perfect Web Techs., Inc. v. InfoUSA, Inc.</i> , 587 F.3d 1324 (Fed. Cir. 2009)	165, 166
<i>Pernix Ireland Pain DAC v. Alvogen Malta Operations Ltd.</i> , 323 F. Supp. 3d 566 (D. Del. 2018).....	136
<i>In re Peterson</i> , 315 F.3d 1325 (Fed. Cir. 2003)	154, 157
<i>Pfizer, Inc. v. Apotex, Inc.</i> , 480 F.3d 1348 (Fed. Cir. 2007)	<i>passim</i>
<i>PharmaStem Therapeutics, Inc. v. ViaCell, Inc.</i> , 491 F.3d 1342 (Fed. Cir. 2007)	141, 142, 174
<i>Plexxikon Inc. v. Novartis Pharm. Corp.</i> , 525 F. Supp. 3d 1104 (N.D. Cal. Mar. 15, 2021)	132
<i>Power Oasis, Inv. v. T-Mobile USA, Inc.</i> , 522 F.3d 1299 (Fed. Cir. 2008)	136
<i>Prometheus Labs., Inc. v. Roxane Labs., Inc.</i> , 805 F.3d 1092 (Fed. Cir. 2015)	135

TABLE OF AUTHORITIES
(*cont'd*)

Page No(s).

<i>Purdue Pharm. Products L.P. v. Actavis Elizabeth LLC</i> , Civil Action No. 12–5311 (JLL)(JAD), 2015 WL 5032650 (D. N.J. Aug. 25, 2015).....	160
<i>Ritchie v. Vast Resources, Inc.</i> , 563 F.3d 1334 (Fed. Cir. 2009)	152, 176
<i>Riverwood Intern. Corp. v. R.A. Jones & Co.</i> 324 F.3d 1346 (Fed. Cir. 2003)	139
<i>Sanofi v. Glenmark Pharm. Inc.</i> , 204 F. Supp. 3d 665 (D. Del. 2016).....	145
<i>Sanofi-Aventis v. Sandoz, Inc.</i> , 272 F.R.D. 391 (D.N.J. 2011).....	144
<i>Santarus, Inc. v. Par Pharm., Inc.</i> , 694 F.3d 1344 (Fed. Cir. 2012)	159, 177, 178
<i>Santarus, Inc. v. Par Pharm., Inc.</i> , 720 F. Supp. 2d 427 (D. Del. 2010), <i>aff'd</i> in part, <i>rev'd</i> in part, 694 F.3d 1344 (Fed. Cir. 2012)	177, 178
<i>Schering Corp. v. Geneva Pharm.</i> , 339 F.3d 1373 (Fed. Cir. 2003)	159
<i>Sciele Pharma, Inc. v. Lupin Ltd.</i> , 684 F.3d 1253 (Fed. Cir. 2012)	142
<i>In re Sebela Patent Lit.</i> , Civil Action No.: 14-6414 (CCC) (MF), 2017 WL 3449054 (D. N.J. Aug. 11, 2017).....	165
<i>Senju Pharm. Co. v. Lupin Ltd.</i> , 780 F.3d 1337 (Fed. Cir. 2015)	173

TABLE OF AUTHORITIES
(*cont'd*)

	Page No(s).
<i>In re Sernaker</i> , 702 F.2d 989 (Fed. Cir. 1983)	136
<i>Shuffle Master, Inc. v. MP Games LLC</i> , 553 F. Supp. 2d 1202 (D. Nev. 2008).....	166
<i>Sjolund v. Musland</i> , 847 F.2d 1573 (Fed. Cir. 1988)	141, 176
<i>Small v. Nobel Biocare USA, LLC</i> , Nos. 05 Civ. 3225(NRB), 06 Civ. 683(NRB), 2013 WL 3972459	146
<i>SmithKline Beecham Corp. v. Apotex Corp.</i> , 286 F. Supp. 2d 925 (N.D. Ill. 2001).....	147, 148
<i>Solder Removal Co. v. U.S. Int’l Trade Comm’n</i> , 582 F.2d 628 (C.C.P.A. 1978)	136
<i>In re Soni</i> , 54 F.3d 746 (Fed. Cir. 1995)	170
<i>Sunoco Partners Marketing & Terminals L.P. v. U.S. Venture, Inc.</i> , 32 4th. 1161 (Fed. Cir. 2022)	147
<i>Surface Tech., Inc. v. U.S. Int’l Trade Comm’n</i> , 801 F.2d 1336 (Fed. Cir. 1986)	142
<i>Symbol Techs., Inc. v. Opticon, Inc.</i> , 935 F.2d 1569 (Fed. Cir. 1991)	141
<i>Syntex (U.S.A.) LLC v. Apotex, Inc.</i> , 407 F.3d 1371 (Fed. Cir. 2005)	175
<i>Tech. Licensing Corp. v. Videotek, Inc.</i> , 545 F.3d 1316 (Fed. Cir. 2008)	132, 135
<i>Texas Instruments Inc. v. U.S. Int’l Trade Comm’n</i> , 988 F.2d 1165 (Fed. Cir. 1993)	167

TABLE OF AUTHORITIES
(cont'd)

	Page No(s).
<i>Therasense, Inc. v. Becton, Dickenson & Co.</i> , 593 F.3d 1325 (Fed. Cir. 2010)	164, 168
<i>Tokai Corp. v. Easton Enters., Inc.</i> , 632 F.3d 1358 (Fed. Cir. 2011)	176, 177
<i>TP Labs., Inc. v. Prof'l Positioners, Inc.</i> , 724 F.2d 972 (Fed. Cir. 1984)	149
<i>Transocean Offshore Drilling, Inc. v. Maersk Contractors USA, Inc.</i> , 617 F.3d 1296 (Fed. Cir. 2010)	179
<i>Trs. of Columbia Univ. v. Illumina, Inc.</i> , No. 2014-1547, 2015 WL 4385761 (Fed. Cir. July 17, 2015)	172
<i>TVnGo Ltd. v. LG Elecs., Inc.</i> , No. 18-10238-RMB-KMW, 2020 WL 1899781 (D.N.J. Apr. 17, 2020), <i>aff'd</i> , No. 20-1837 (Fed. Cir. June 28, 2021)	134
<i>U.S. Surgical Corp. v. Ethicon, Inc.</i> , 103 F.3d 1554 (Fed. Cir. 1997)	137
<i>Union Carbide Corp. v. Am. Can Co.</i> , 724 F.2d 1567 (Fed. Cir. 1984)	136
<i>ViiV Healthcare UK Ltd. v. Lupin Ltd.</i> , 6. F. Supp. 3d 461 (D. Del. 2013)	179
<i>Voter Verified, Inc. v. Premiere Election Solutions</i> , 698 F.3d 1374 (Fed. Cir. 2012)	143
<i>Vulcan Eng'g Co. v. Fata Aluminium, Inc.</i> , 278 F.3d 1366 (Fed. Cir. 2002)	174
<i>Warner Chilcott Co., LLC v. Lupin Ltd.</i> , Civil Action Nos. 11–5048 (JAP), 12–2928(JAP), 2014 WL 202659 (D.N.J. Jan. 17, 2014)	137

TABLE OF AUTHORITIES (*cont'd*)

Page No(s).

<i>Warner Chilcott Co., LLC v. Teva Pharm. USA, Inc.</i> , 89 F. Supp. 3d 641 (D. N.J. 2015).....	171
<i>WBIP, LLC v. Kohler Co.</i> , 829 F.3d 1317 (Fed. Cir. 2016)	179
<i>Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC</i> , 683 F.3d 1356 (Fed. Cir. 2012)	171, 176
<i>WMS Gaming Inc. v. Int’l Game Tech.</i> , 184 F.3d 1339 (Fed. Cir. 1999)	161
<i>In re Wyer</i> , 655 F.2d 221 (CCPA 1981)	143

OTHER AUTHORITIES

35 U.S.C. §102.....	<i>passim</i>
35 U.S.C. § 103	<i>passim</i>
35 U.S.C. § 112.....	133, 134
35 U.S.C. § 271	<i>passim</i>
35 U.S.C. § 282	182
35 U.S.C. § 285.....	3, 4, 185, 186
Fed. R. Civ. P. 30	144
Fed. R. Civ. P. 54	3, 185
MPEP § 2128	143
MPEP § 2132	139

TABLE OF AUTHORITIES
(*cont'd*)

Page No(s).

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

FINDINGS OF FACT

Padagis proposes that this Court reach the following Findings of Fact based on the evidence presented at trial:¹

I. REMEDY

1. Bausch is not entitled to a judgment that Padagis's Halobetasol Propionate Lotion ANDA Product ("Padagis's HP ANDA Product") infringes any valid Asserted Claim of any of the U.S. Patent Nos. 8,809,307 (the "'307 patent") or 10,478,502 (the "'502 patent") patents.²

2. Bausch is not entitled to a judgment that Padagis's Halobetasol Propionate and Tazarotene Lotion ANDA Product ("Padagis's Combination ANDA Product") infringes any valid Asserted Claim of any of the '307 or '502 patents or U.S. Patent Nos. 10,426,787 (the "'787 patent") or 10,251,895 (the "'895 patent").³

3. Bausch is not entitled to an order under 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval for Padagis to commercially make, use,

¹ To the extent that any of the identified findings of fact are determined to constitute an issue of law, Padagis hereby incorporates such issues into Padagis's Proposed Conclusions of Law. To the extent that any issue identified in Padagis's Proposed Conclusions of Law is determined to constitute an issue of fact, Padagis hereby incorporates such issues into Padagis's Proposed Findings of Fact.

² Bausch has asserted claims 13, 16, and 20 of the '307 patent and claims 4 and 16 of the '502 patent against Padagis's HP ANDA Product.

³ Bausch has asserted claims 13, 16, and 20 of the '307 patent; claims 4 and 16 of the '502 patent; claims 4, 5, and 7 of the '787 patent; and claims 3 and 6 of the '895 patent against Padagis's Combination ANDA Product.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

or sell the drug product that is the subject of ANDA No. 214285 (“Padagis’s HP ANDA”) be not earlier than the latest of the expiration dates of the ’307 and ’502 patents.⁴

4. Bausch is not entitled to an order under 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval for Padagis to commercially make, use, or sell the drug product that is the subject of ANDA No. 214626 (“Padagis’s Combination ANDA”) be not earlier than the latest of the expiration dates of the ’307, ’502, ’787, and ’895 patents.⁵

5. Bausch is not entitled to an injunction under 35 U.S.C. § 271(a) enjoining Padagis from making, using, offering to sell, selling, or importing the drug product that is the subject of Padagis’s HP ANDA during the term of the ’307 and ’502 patents.

6. Bausch is not entitled to an injunction under 35 U.S.C. § 271(a) enjoining Padagis from making, using, offering to sell, selling, or importing the drug product that is the subject of Padagis’s Combination ANDA during the term of the ’307, ’502, ’787, and ’895 patents.

⁴ Padagis filed a Paragraph IV certification for the ’307 and ’502 patents as part of Padagis’s HP ANDA.

⁵ Padagis filed a Paragraph IV certification for the ’307, ’502, ’787, and ’895 patents as part of Padagis’s Combination ANDA.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

7. Bausch is not entitled to an injunction under 35 U.S.C. § 271(b) enjoining Padagis from making, using, offering to sell, selling, or importing the drug product that is the subject of Padagis's HP ANDA during the term of the '307 and '502 patents.

8. Bausch is not entitled to an injunction under 35 U.S.C. § 271(b) enjoining Padagis from making, using, offering to sell, selling, or importing the drug product that is the subject of Padagis's Combination ANDA during the term of the '307, '502, '787, and '895 patents.

9. Bausch is not entitled to an injunction under 35 U.S.C. § 271(c) enjoining Padagis from making, using, offering to sell, selling, or importing the drug product that is the subject of Padagis's HP ANDA during the term of the '307 and '502 patents.

10. Bausch is not entitled to an injunction under 35 U.S.C. § 271(c) enjoining Padagis from making, using, offering to sell, selling, or importing the drug product that is the subject of Padagis's Combination ANDA during the term of the '307, '502, '787, and '895 patents.

11. If Bausch proves infringement of any valid asserted claim, Bausch is not entitled to costs under Fed. R. Civ. P. 54(d)(1).

12. Bausch has not established that this case is an exceptional case meriting the award of attorney's fees to the prevailing party under 35 U.S.C. § 285. To the

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

extent Bausch failed to present factual evidence necessary to establish its entitlement to any remedy, such remedy should be denied.

13. Padagis is entitled to a judgment that the Asserted Claims of the '307 patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 103 and/or 112.

14. Padagis is entitled to a judgment that the Asserted Claims of the '502 patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 103 and/or 112.

15. Padagis is entitled to a judgment that the Asserted Claims of the '787 patent are invalid for failure to satisfy the requirements of 35 U.S.C. § 103.

16. Padagis is entitled to a judgment that the Asserted Claims of the '895 patent are invalid for failure to satisfy the requirements of 35 U.S.C. § 103.

17. Padagis is entitled to a judgment ordering that Bausch's Complaints⁶ be dismissed with prejudice and judgment be entered in favor of Padagis.

18. Padagis is entitled to a judgment declaring this case exceptional and awarding Padagis its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

⁶ "Complaints" refers collectively to Bausch's complaints filed in case Nos. 20-cv-5426 and 20-cv-11087, which were consolidated for all purposes in this matter. *See* Case No. 20-11087, D.I. 7.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

II. INVALIDITY

A. Prior Art

19. DX-002, Blum et al.. “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,” Chinese J. Dermaol. Vol. 19(3), 139-141 (1986) (“Blum”) was published in 1986. D.I. 166 (Final Pretrial Order) at ¶ 99 (stipulated fact). Therefore, Blum is available more than a year before the earliest priority date of the ’307 and ’502 patents under pre-AIA 35 U.S.C. § 102(b). D.I. 166 (Final Pretrial Order) at ¶ 99 (stipulated fact). Blum is therefore available more than a year before the earliest priority date of the ’895 and ’787 patents under AIA 35 U.S.C. §102(a). D.I. 166 (Final Pretrial Order) at ¶ 99. Blum therefore qualifies as prior art to the ’307, ’502, ’787, and ’895 patents. Blum was not before the USPTO during prosecution of the ’307, ’502, ’787, and ’895 patents. JTX-001 (’307 patent) at References Cited (item 56); JTX-004 (’502 patent) at References Cited (item 56); JTX-003 (’787 patent) at References Cited (item 56); JTX-002 (’895 patent) at References Cited (item 56).

20. DX-003, U.S. Patent No. 4,233,295 (“’295 patent”) was filed on May 31, 1979 and issued on November 11, 1980. D.I. 166 (Final Pretrial Order) at ¶ 90 (stipulated fact). The ’295 patent is therefore available more than a year before the earliest priority date of the ’307 and ’502 patents under pre-AIA 35 U.S.C. § 102(b).

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

D.I. 166 (Final Pretrial Order) at ¶ 90 (stipulated fact). The '295 patent is therefore available more than a year before the earliest priority date of the '895 and '787 patents under AIA 35 U.S.C. §102(a). D.I. 166 (Final Pretrial Order) at ¶ 90 (stipulated fact). The '295 Patent therefore qualifies as prior art to the '307, '502, '787, and '895 patents.

21. DX-004, U.S. Patent No. 5,326,566 (“’566 patent”) was filed on August 19, 1993 and issued on July 5, 1994. D.I. 166 (Final Pretrial Order) at ¶ 91 (stipulated fact); T. 336:8-9.⁷ The '566 patent is therefore available more than a year before the earliest priority date of the '307 and '502 patents under pre-AIA 35 U.S.C. § 102(b). D.I. 166 (Final Pretrial Order) at ¶ 91 (stipulated fact). The '566 patent is therefore available more than a year before the earliest priority date of the '895 and '787 patents under AIA 35 U.S.C. §102(a). D.I. 166 (Final Pretrial Order) at ¶ 91 (stipulated fact). The '566 Patent therefore qualifies as prior art to the '307, '502, '787, and '895 patents.

22. DX-005, Japanese Patent Application Publication No. S63-255228 (“JP '228”) published on October 21, 1988. D.I. 166 (Final Pretrial Order) at ¶ 95 (stipulated fact); T. 339:9-22. JP '228 is therefore available more than a year before the earliest priority date of the '307 and '502 patents under pre-AIA 35 U.S.C. §

⁷ Citations to the trial transcript are referred to herein as T. [page:line].

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

102(b). D.I. 166 (Final Pretrial Order) at ¶ 95 (stipulated fact). JP '228 is therefore available more than a year before the earliest priority date of the '895 and '787 patents under AIA 35 U.S.C. §102(a). D.I. 166 (Final Pretrial Order) at ¶ 95 (stipulated fact). JP '228 therefore qualifies as prior art to the '307, '502, '787, and '895 patents.

23. DX-006, Prescribing Information for Temovate E® (clobetasol propionate) Emollient, 0.05% ("Temovate E® Label") published in July 2000. D.I. 166 (Final Pretrial Order) at ¶ 89 (stipulated fact). The Temovate E® Label is therefore available more than a year before the earliest priority date of the '307 and '502 patents under pre-AIA 35 U.S.C. § 102(b). D.I. 166 (Final Pretrial Order) at ¶ 89 (stipulated fact). The Temovate E® Label is therefore available more than a year before the earliest priority date of the '895 and '787 patents under AIA 35 U.S.C. §102(a). D.I. 166 (Final Pretrial Order) at ¶ 89 (stipulated fact). The Temovate E® Label therefore qualifies as prior art to the '307, '502, '787, and '895 patents. The Temovate E® Label was not before the USPTO during prosecution of the '307, '502, '787, and '895 patents. JTX-001 ('307 patent) at References Cited (item 56); JTX-004 ('502 patent) at References Cited (item 56); JTX-003 ('787 patent) at References Cited (item 56); JTX-002 ('895 patent) at References Cited (item 56).

24. DX-009, Prescribing Information for Ultravate® (halobetasol propionate) Cream, 0.05% (April 2003) ("Ultravate® Cream Label") published in

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

April 2003. D.I. 166 (Final Pretrial Order) at ¶ 87 (stipulated fact). The Ultravate® Cream Label is therefore available more than a year before the earliest priority date of the '307 and '502 patents under pre-AIA 35 U.S.C. § 102(b). D.I. 166 (Final Pretrial Order) at ¶ 87 (stipulated fact). The Ultravate® Cream Label is available more than a year before the earliest priority date of the '895 and '787 patents under AIA 35 U.S.C. §102(a). D.I. 166 at ¶ 87 (stipulated fact). The Ultravate® Cream Label therefore qualifies as prior art to the '307, '502, '787, and '895 patents. The Ultravate® Cream Label was not before the USPTO during prosecution of the '307, '502, '787, and '895 patents. JTX-001 ('307 patent) at References Cited (item 56); JTX-004 ('502 patent) at References Cited (item 56); JTX-003 ('787 patent) at References Cited (item 56); JTX-002 ('895 patent) at References Cited (item 56).

25. DX-010, Prescribing Information for Tazorac® (tazarotene) Cream, 0.05% and 0.1% (December 2013) (“Tazorac® Label”) published in December 2013. D.I. 166 (Final Pretrial Order) at ¶ 88 (stipulated fact). The, Tazorac® Label is therefore available more than a year before the earliest priority date of the '895 and '787 patents under AIA 35 U.S.C. § 102(a). D.I. 166 (Final Pretrial Order) at ¶ 88 (stipulated fact). The Tazorac® Label therefore qualifies as prior art to the '787, and '895 patents.

26. DX-140, Gollnick et al., “Combination Therapy with tazarotene plus a topical corticosteroid for the treatment of plaque psoriasis,” British Journal of

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

Dermatology 1999: 140 (Suppl. 54): 18-23 (“Gollnick”) was published in 1999, and therefore is available more than a year before the earliest priority date of the ’895 and ’787 patents under AIA 35 U.S.C. §102(a). D.I. 166 (Final Pretrial Order) at ¶ 98 (stipulated fact). Gollnick therefore qualifies as prior art to the ’787 and ’895 patents. Gollnick was not before the U.S.P.T.O during prosecution of the ’787 and ’895 patents. JTX-003 (’787 patent) at References Cited (item 56); JTX-002 (’895 patent) at References Cited (item 56).

27. DX-141, Indian Patent Application IN 2461/MUM/2009 (“Gandhi”) published on March 30, 2012, and therefore is available more than a year before the earliest priority date of the ’895 and ’787 patents under AIA 35 U.S.C. §102(a). D.I. 166 (Final Pretrial Order) at ¶ 96 (stipulated fact); T. 169:22-170:3. Gandhi therefore qualifies as prior art to the ’787 and ’895 patents.

28. DX-142, U.S. Patent Application Publication No. US 2012/0129824 (“’824 Publication”) published on May 24, 2012, and therefore is available more than a year before the earliest priority date of the ’895 and ’787 patents under AIA 35 U.S.C. §102(a). D.I. 166 (Final Pretrial Order) at ¶ 94 (stipulated fact). The ’824 Publication therefore qualifies as prior art to the ’787 and ’895 patents.

29. DX-203, U.S. Patent No. 8,808,716 (“’716 Patent”) was filed on July 20, 2012 and issued on August 19, 2014. D.I. 166 (Final Pretrial Order) at ¶ 93 (stipulated fact). The ’716 patent is therefore available more than a year before the

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

earliest priority date of the '895 and '787 patents under AIA 35 U.S.C. §102(a). D.I. 166 (Final Pretrial Order) at ¶ 93 (stipulated fact). The '716 Patent therefore qualifies as prior art to the '787 and '895 patents.

30. DX-196, Gao et al., “Topical formulations of fluocinolone acetonide,” *Eur J of Clin Pharmacol* 46:71-75 (1994) (“Gao”) was published in 1994. T. 321:7-23; *see also* DX-196 at 1. Therefore, Gao was publicly available more than a year before the earliest priority date of the '307 and '502 patents under pre-AIA 35 U.S.C. § 102(b). Gao was also publicly available more than a year before the earliest priority date of the '895 and '787 patents under AIA 35 U.S.C. §102(a). Gao therefore qualifies as prior art to the '307/'502 and '895/'787 patents. Gao was not before the U.S.P.T.O during prosecution of the '307, '502, '787, and '895 patents. JTX-001 ('307 patent) at References Cited (item 56); JTX-004 ('502 patent) at References Cited (item 56); JTX-003 ('787 patent) at References Cited (item 56); JTX-002 ('895 patent) at References Cited (item 56).

31. DX-064, Version 1 of the Study Record for Study No. NCT02045277 (the “IDP-118 Study”) that was submitted to ClinicalTrials.gov on January 22, 2014. T. at 135:25-136:6, 447:20-448:3 (Dr. Binu Alexander testifying that DX-064 depicts version 1 of the study record for Study No. NCT 02045277 that was submitted to ClinicalTrials.gov on January 22, 2014); *see also* DX-064. Bausch designated Dr. Binu Alexander as Bausch’s Rule 30(b)(6) witness to testify

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

regarding Bausch's general practices and procedures regarding the submission, updating, or removal of information from or to ClinicalTrials.gov. T. 438:10-439:23. Dr. Alexander was responsible for providing information to ClinicalTrials.gov regarding Bausch's clinical trials for Duobrii. T. 441:9-13.

32. DX-064 was first posted publicly on ClinicalTrials.gov's website on or around January 24, 2014. T. at 136:4-6, 180:9-16, 444:8-15, 448:14-25, 666:24-667:11; *see also* DX-064 at Study Status; *see also* T. 444:13-14 (Dr. Binu Alexander testifying that the first posted date on a ClinicalTrials.gov study record is "when the CT.gov listing is first made public"). DX-064 was therefore publicly available more than a year before the earliest priority date of the '895 and '787 patents under AIA 35 U.S.C. §102(a). T. at 136:4-6, 180:9-16, 444:8-15, 448:14-25, 666:24-667:11; *see also* DX-064 at Study Status. DX-064 ("The IDP-118 Study") disclosed the identities and concentrations of the active ingredients in IDP-118 Lotion as halobetasol propionate at 0.01% and tazarotene at 0.045% when it was first posted on ClinicalTrials.gov on or around January 24, 2014. T. at 134:22-136:6, 169:14-21, 445:11-21 (Dr. Binu Alexander testifying that when the study information for Study No. NCT 02045277 was first posted on ClinicalTrials.gov, the Arms and Interventions section identified the concentrations of the active ingredients in IDP-118 lotion), 449:21-25; *see also* DX-064 at Arms and Interventions.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

33. ClinicalTrials.gov is a public repository of clinical trials that are being or have been conducted in the United States. T. at 439:24-440:1 (Dr. Binu Alexander testifying that ClinicalTrials.gov is “a public repository of clinical trials that are being conducted”). ClinicalTrials.gov is a way for the public to understand if there are clinical trials going on which may pertain to their health issues. T. 440:11-16 (Dr. Binu Alexander testifying that trial information on ClinicalTrials.gov is “a way for the public to understand if there are clinical trials going on, which may pertain, to help them with their health issues”).

34. Bausch was required to submit information to ClinicalTrials.gov regarding its clinical trials, including information such as the trial title, what phase the trial is, and what proposed criteria are within the protocol of the trial. T. 440:2-16. Bausch was not required to submit the identities and concentrations of the active ingredients included in IDP-118 Lotion to ClinicalTrials.gov for Study No. NCT02045277. T. at 443:20-444:1, 452:5-453:20. Bausch considered the identities and concentrations of the active ingredients in IDP-118 Lotion to be Bausch’s proprietary information that did not need to be disclosed on a public website. T. at 135:21-24, 452:5-453:21 (Dr. Binu Alexander testifying that the concentrations of the active ingredients in IDP-118 lotion were “proprietary information that did not need to be disclosed in a public site”).

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

35. Bausch updated the study record for Study No. NCT02045277 on August 15, 2016, removing the concentrations of the active ingredients for IDP-118 Lotion. T. 450:21-451:1; 451:18-452:4; *see also* DX-066 at Arms and Interventions.

36. Bausch expected that the information Bausch submitted to ClinicalTrials.gov regarding Study No. NCT02045277 would be published on the ClinicalTrials.gov website. T. 134:4-17 (Dr. Radhakrishnan Pillai testifying that when Bausch submitted information to ClinicalTrials.gov “we would expect that ClinicalTrials.gov would publish it”). Bausch did not have any expectation of confidentiality with respect to the information it submitted to ClinicalTrials.gov regarding Study No. NCT02045277. T. 134:18-21.

37. Information is never removed from ClinicalTrials.gov; it is always present within the audit history for the clinical trial. T. 452:13-15. Therefore, the active ingredients and their concentrations in IDP-118 Lotion that were disclosed in Version 1 of the study Record for Study No. NCT02045277 remain publicly available in the audit history on ClinicalTrials.gov for Study No. NCT02045277.

38. DX-064 (“The IDP-118 Study”) is a printed publication and is prior art to the ’895 and ’787 patents. DX-064 (“The IDP-118 Study”) does not constitute an experimental use. DX-064 (The IDP-118 Study) was not before the U.S.P.T.O during prosecution of the ’787 and ’895 patents. JTX-003 (’787 patent) at References Cited (item 56); JTX-002 (’895 patent) at References Cited (item 56).

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

B. Findings of Fact Regarding the '307 and '502 patents

39. The earliest priority date of the alleged invention of the claims of the '307 and '502 patents is November 22, 2010. T. 156:10-15, 313:11-13, 472:4-14.

40. The '307 and '502 patents have substantively identical specifications. T. 158:1-3, 472:15-18.

41. The '307 and '502 patents disclose examples of several formulations labeled A through E in Table 1 that include various concentrations of halobetasol propionate ("HP"), ranging from 0.01% to 0.035%. T. 310:12-24; *see also* JTX-001 ('307 patent) at Table 1. Table 3 of the '307 and '502 patents disclose vasoconstrictor assay ("VCA") testing of formulations A through E from Table 1 as well as Ultravate® and discloses that formulations A through D of Table 1 exhibited similar VCA scores as Ultravate®. T. 311:4-312:9; *see also* JTX-001 ('307 patent) at Table 3.

42. The '307 and '502 patents disclose a total of 7 example formulations that are described to fall within the scope of the invention that include a concentration of HP less than 0.05%. JTX-001 ('307 patent) at Tables 1, 4, and 5; JTX-004 ('502 patent) at Tables 1, 4, and 5.

43. Formulation C in Table 1 and Formulation 4A in Table 4 include a concentration of 0.01% HP. JTX-001 ('307 patent) at Tables 1 and 4; JTX-004 ('502 patent) at Tables 1 and 4.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

44. Formulation B in Table 1, Formulation 4B in Table 4, and the formulation in Table 5 each include a concentration of 0.025% HP. JTX-001 ('307 patent) at Tables 1, 4, and 5; JTX-004 ('502 patent) at Tables 1, 4, and 5.

45. Formulations A and D in Table 1 include a concentration of 0.035% HP. JTX-001 ('307 patent) at Table 1; JTX-004 ('502 patent) at Tables 1.

46. Example 4 of the '307 and '502 patents discloses a method for making the formulations listed in Table 4. JTX-001 ('307 patent) at Example 4; T. 368:21-370:24.

47. The '307 and '502 patents do not disclose examples of any formulation with a concentration of halobetasol propionate less than 0.01%. T. 672:7-10. The '307 and '502 patents do not disclose any VCA testing of any formulation with a concentration of halobetasol propionate less than 0.01%. T. 672:4-6.

48. The '307 and '502 patents do not disclose examples of any formulation with a corticosteroid other than halobetasol propionate. T. 590:4-14.

49. The '307 and '502 patents do not disclose any clinical data for any of the formulations disclosed in the patents. T. 571:2-3, 588:24-589:2. The '307 and '502 patents do not disclose any clinical data regarding treatment for longer than two consecutive weeks with the claimed formulations. T. 589:3-13.

50. The '307 and '502 patents do not disclose any data regarding the systemic absorption of halobetasol propionate for any of the disclosed formulations.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

T. 608:22-609:2, 618:2-6. VCA testing does not measure the amount of systemic absorption of a corticosteroid. T. 617:18-618:1.

51. In the Background of the Invention, the '307 and '502 patents disclose that “because of the high potency of Class 1 corticosteroids, which correlates with a high incidence and severity of systemic side effects, including hypothalamic-pituitary-adrenal HPA axis suppression, topical treatment with superpotent corticosteroids is generally limited in duration to 2 weeks.” JTX-001 ('307 patent) at 2:36-41; T. 331:25-332:11.

52. In the Background of the Invention, the '307 and '502 patents disclose that “Chronic skin conditions, such as psoriasis, however often require long periods of treatment, greater than 2 weeks to manage such conditions. Therefore, it would be desirable to have a superpotent corticosteroid formulation with a reduced incidence and/or severity of systemic side effects so that therapy could be continued for durations longer than two weeks.” JTX-001 ('307 patent) at 2:46-51; T. 332:18-22.

53. The '307 and '502 patents do not disclose any example of a formulation with any corticosteroid other than HP. JTX-001 ('307 patent) Examples 1-5; JTX-004 ('502 patent) Examples 1-5; T. 590:4-14.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

1. Person of Ordinary Skill in the Art

54. A person of ordinary skill in the art related to the '307 and '502 patents 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. T. 156:16-157:7, 313:6-314:2. A person of ordinary skill in the art should not be limited to a person who speaks English. T. 593:2-7. A person of ordinary skill in the art is presumed to be aware of all of the relevant scientific field and literature. T. 593:8-13.

55. Dr. Stern met the qualifications for a person of ordinary skill in the art as of November 2010. T. 157:8-10; DX-208 (Stern CV). Dr. Stern testified that his opinions would not change under Plaintiffs' definition of a person of ordinary skill in the art. T. 157:11-17.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

56. Dr. Michniak-Kohn met the qualifications for a person of ordinary skill in the art as of November 2010. T. 314:4-6; DX-184 (Michniak-Kohn CV). Dr. Michniak-Kohn testified that her opinions would not change under Plaintiffs' definition of a person of ordinary skill in the art. T. 314:10-15.

2. Background and Prior Art

a. Halobetasol Propionate Was a Well-Known Corticosteroid Useful for Treating Psoriasis Prior to 2010

57. Psoriasis is a common inflammatory disorder of the skin and is a chronic disease that has no cure. T. 38:19-39:14, 162:3-4. There are three main categories of topical therapies for psoriasis: topical corticosteroids, vitamin A analogs, and vitamin D analogs. T. 41:3-11.

58. Topical corticosteroids are the mainstay of topical therapies prescribed for treating psoriasis. T. 41:6-8. Topical corticosteroids may be categorized by their potency, which has commonly been measured by their ability to induce vasoconstriction (narrowing or constriction of the blood vessels) as measured by a test known as the Vasoconstrictor Assay ("VCA"). T. 42:17-43:2, 78:7-18, 311:6-312:4, 617:18-618:1.

59. Prior to 2010, the use of topical corticosteroids was known to carry a risk of side effects. T. 41:18-25, 161:14-22. The risk of side effects was known to

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

generally increase with the potency of the corticosteroid and the amount of the steroid applied to the skin. T. 41:18-25, 161:23-162:2, 162:8-14.

60. Halobetasol propionate (“HP”) is a well-known synthetic corticosteroid that has been commercially available for decades before the priority date of the HP Patents and is very commonly used to treat psoriasis. T. 43:14-17, 160:22-161:6. HP was known to have both anti-inflammatory and antipruritic (i.e., anti-itching) effects when topically applied. T. 49:9-13, 160:24-161:1; *see also* DX-009 (Ultravate® Cream Label) at Description.

61. The commercial product, known as Ultravate®, comprises HP at a concentration of 0.05% and was first approved by the FDA for use in the United States in 1990. T. 43:18-44:1, 482:21-483:5; *see also* DX-009 (Ultravate® Cream Label) at Description. Ultravate® was known to be useful for treating psoriasis before 2010. T. 49:23-25. HP at 0.05% in Ultravate is classified as a super-potent corticosteroid. T. 161:4-6; *see also* DX-009 (Ultravate® Label) at Indications and Usage.

62. Plaintiffs have not offered any evidence that the concentration of HP in Ultravate® was “optimized” by Bristol-Myers Squibb or any other person or company. T. 709:5-12; 729:20-23.

63. Due to the risk of systemic side effects such as HPA axis suppression, since at least 1995, the FDA has warned that treatment with Ultravate® Cream

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

should be limited to two consecutive weeks at no more than 50 g/week. T. 50:6-14, 108:14-24, 161:14-22, 319:13-19; *see also* DX-009 (Ultravate® Label) at Dosage and Administration; DX-212 (Ultravate® Label 1995) at Dosage and Administration.

64. Two weeks of treatment is not a sufficient period of time to adequately treat psoriasis for the majority of patients. T. 50:15-18, 162:5-7, 165:20-24.

b. Formulations with concentrations of HP below 0.05% were known to be effective in treating psoriasis before 2010

65. DX-002 (Blum), a medical journal article published in 1986, reports a study of the treatment of psoriasis with HP (referred to in Blum by its synonym CGP 14458) at concentrations of 0.02% and 0.05% compared against treatment with another super-potent corticosteroid, Dermovate (Clobetasol 17-propionate). T. 163:10-20, 323:15-324:9; *see also* DX-002 (Blum) at 4. At least the abstract of the Blum article was originally published in English. T. 209:3-5, 596:23-597:12. Blum's teachings were also cited in a textbook on topical corticosteroids that was published in 1992. T. 597:20-599:5; *see also* DX-156 (Loder) at 11 (Table 3), 15 n. 4.

66. Blum disclosed that HP at 0.02% produced clinical success in over 80% of psoriasis patients treated after 3 weeks. T. 163:21-164:10, 324:14-325:15, 594:14-18; *see also* DX-002 (Blum) at 5, Table 1.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

67. Blum disclosed that Dermovate (0.05% clobetasol propionate) produced clinical success in 86.4% of psoriasis patients treated after 3 weeks. T. 164:6-10, 594:9-13; *see also* DX-002 (Blum) at 5, Table 1. Blum teaches that Dermovate was recognized as the most effective topical corticosteroid for psoriasis on the market at the time of the study. T. 164:6-10; *see also* DX-002 (Blum) at 5.

68. Blum also disclosed that 0.02% HP was similarly as efficacious as the branded product Dermovate (81% “cured” or “significant improvement” vs. 86% “cured” or “significant improvement”), which was recognized as the most effective topical corticosteroid on the market at the time. T. 163:23-164:10, 324:14-325:15; *see also* DX-002 (Blum) at 5, Table 1.

69. Blum also disclosed that the 0.02% HP ointment provided only 9% less treatment success than the 0.05% HP ointment, and therefore a 60% reduction in HP concentration resulted in only a 9% difference in efficacy. T. 163:23-164:10, 324:14-325:15, 594:14-22; *see also* DX-002 (Blum) at 5, Table 1.

70. Blum performed a statistical analysis on the efficacy data and concluded that “the difference among the [efficacy for] the 3 groups was not statistically significant.” T. 164:11-21, 325:20-326:9, 595:8-596:4, 675:14-16; *see also* DX-002 (Blum) at 6.

71. Blum teaches that “just like finding the dose for a systemic medication in order to develop a dermatological preparation it is most important to conduct

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

double blind trials to find the right concentration in the treatment of patients with chronic plaque psoriasis.” DX-002 (Blum) at 6; *see also* T. 596:5-22.

72. Prior to November 2010, a person of ordinary skill in the art would have known that different concentrations of the same corticosteroid may exhibit a similar pharmacodynamic response. T. 320:19-22.

73. Gao discloses a study of concentration dilutions of the corticosteroid fluocinolone acetonide in a cream at concentrations of 0.025%, 0.0065%, and 0.0025%. T. 321:22-322:7; *see also* DX-196 (Gao) at 3. Gao disclosed VCA testing of each dilution concentration and teaches that “although there was a trend towards less activity at lower concentrations, there was no significant difference in the activities of the three dilutions of the cream.” T. 322:8-22; *see also* DX-196 (Gao) at 3. Based on the VCA findings, Gao teaches that “perhaps even at the 0.0025 percent level, sufficient steroid is present to saturate receptors in the skin so that an increase in concentration would not produce any enhancement in activity.” T. 322:17-22; *see also* DX-196 (Gao) at 4.

c. It Was Known in the Art That Lower Concentrations of Corticosteroids Were Associated With Reduced Side Effects and Increased Duration of Treatment

74. In view of the known risk of systemic side effects associated with 0.05% HP, a skilled artisan prior to 2010 would have been motivated to treat psoriasis with a concentration of HP lower than 0.05% to minimize the risk of

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

adverse effects and achieve a safe treatment period of longer than two consecutive weeks. T. 162:15-163:9, 165:11-19, 212:4-21.

75. It was known prior to 2010 that the super-potent corticosteroid clobetasol propionate 0.05%, marketed as Temovate E®, could be safely applied for a period longer than two consecutive weeks when application of the composition was limited to less than 10% of the patient's total body surface area. T. 165:25 - 167:10, 354:3-24, 607:2-14; *see also* DX-006 (Temovate E® Label) at Dosage and Administration.

76. A skilled artisan prior to 2010 would have known that the risk of systemic side effects associated with topical corticosteroids is reduced when the concentration of the steroid is reduced. T. 123:7-14, 166:11-167:10, 673:13-674:6; 794:24-795:1.

77. Prior to 2010 a person of ordinary skill in the art would have had a reasonable expectation that a topical pharmaceutical composition with a concentration of HP below 0.05% could be safely used to treat psoriasis for a period longer than two consecutive weeks. T. 165:25-167:10.

**d. Use of Dicarboxylic Acid Esters to Solubilize
Corticosteroids in Topical Formulations Was Known in the
Art**

78. It was known prior to 2010 that the active drug in a topical pharmaceutical composition must be dissolved in the formulation in order for the

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

drug to be absorbed by the skin and exert its therapeutic effect. T. 72:6-16, 343:2-6; *see also* DX-003 ('295 patent) at 1:10-16. HP was known to be a lipophilic compound and therefore soluble in oily solvents. T. 316:21-317:2. HP was also known to be insoluble in water or aqueous environments. T. 316:21-317:2, 318:24-319:12; *see also* DX-009 (Ultravate® Label) at Description.

79. Prior to 2010, the use of a liquid oil to solubilize an active ingredient was a well-established approach to formulating lipophilic drugs, such as corticosteroids, for topical administration. T. 319:20-320:18. Dicarboxylic acid esters are liquid oils, which were commonly used in dermatological formulations prior to 2010 to dissolve lipophilic active ingredients. T. 319:20-320:18.

80. Dialkyl sebacates are a subset of the class of compounds known as dicarboxylic acid esters and were known prior to 2010 to act as both solvents and chemical penetration enhancers for topical formulations. T. 320:23-321:4. Diethyl sebacate is a dialkyl sebacate with two carbons. T. 321:5-6, 328:11-329:2.

81. Chemical penetration enhancers are compounds that when included in a topical drug formulation, affect the top-most layer of the skin, allowing more of the drug to pass through the topmost layer of the skin, which is known as the stratum corneum, and into the other layers of the skin such as the epidermis and dermis. T. 333:10-335:20, 337:7-338:2.

i. The '295 Patent

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

82. The '295 patent discloses various corticosteroid lotion formulations comprising both a liquid oil phase and an aqueous phase and discloses that the corticosteroid is entirely dissolved at room temperature (22°C) in the liquid oil phase. T. 326:13-327:10; *see also* DX-003 ('295 Patent) at 2:22-26, 3:68-4:10.

83. The '295 Patent teaches that its disclosures are applicable to any topically active anti-inflammatory steroid. T. 329:23-330:2; *see also* DX-003 ('295 Patent) at 2:6-10. Halobetasol propionate is in the same class of steroids as those disclosed in the examples of the '295 Patent. T. 330:5-8; *see also* DX-003 ('295 Patent) at 6:60-10:68. The '295 Patent discloses a range of concentrations for the corticosteroids, preferably from about 0.025% to about 0.2% by weight. T. 327:12-328:9; *see also* DX-003 ('295 Patent) at 1:45-51. The '295 Patent also discloses that for lotion formulations where the steroid is completely dissolved, the concentration of the steroid can range from 0.005% to about 0.6% by weight and are preferably between 0.02% and 0.05% by weight. T. 328:6-9; *see also* DX-003 ('295 Patent) at 2:61-3:2.

84. The '295 Patent teaches the use of sebacates, such as dialkyl sebacate, in topical corticosteroid formulations. T. 328:15-16; *see also* DX-003 ('295 Patent) at 1:40-44. The '295 Patent teaches that dialkyl sebacates, wherein the alkyl contains 1 to 10 carbons are excellent vehicles for corticosteroids. T. 328:15-25, 599:6-

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

600:1; DX-003 ('295 Patent) at 1:40-44. Diethyl sebacate is a dialkyl sebacate with two carbons. T. 328:20-329:2, 600:6-8.

85. Selection of diethyl sebacate from the list of dialkyl sebacates disclosed in the '295 Patent would have been a matter of routine optimization for a person of ordinary skill in the art. T. 329:9-19.

ii. The '566 Patent

86. The '566 Patent teaches that by optimizing the vehicle of a topical formulation, the concentration of a drug could be reduced without a significant, if any, reduction in potency. T. 336:10-15; *see also* DX-004 ('566 Patent) at 4:37-49, 8:20-17:56. The '566 Patent teaches that the 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. T. 336:17-337:6; *see also* DX-004 ('566 Patent) at 3:20-25, 4:37-49.

87. The teachings of the '566 Patent are not limited to enhancing transdermal penetration of corticosteroids. T. 501:17-502:3, 602:11-603:5; *see also see also* DX-004 ('566 Patent) at 3:20-25. The '566 Patent teaches enhancement of epidermal and dermal penetration of corticosteroids. T. 501:17-502:3, 602:11-603:5; *see also see also* DX-004 ('566 Patent) at 3:20-25.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

88. 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.” T. 604:1-11; *see also* DX-004 ('566 Patent) at 1:62-2:2. The stratum corneum, the viable epidermis, the epidermis junction, and the dermis are all layers within the skin. T. 337:7-338:2. Prior to 2010, a person of ordinary skill in the art would have known that in order to treat psoriasis, a corticosteroid needs to penetrate into the patient’s skin. T. 604:15-21.

89. The '566 Patent discloses numerous examples of topical formulations that include HP as the active ingredient. T. 338:8-12; *see also* DX-004 ('566 Patent) at 8:19-14:58. The '566 Patent also teaches topical corticosteroid formulations that are oil-in-water emulsions. T. 338:13-14; *see also* DX-004 ('566 Patent) at 4:56-5:6, 5:16-20, 5:26-38; 6:44-66, 8:19-14:58. The '566 Patent teaches that the corticosteroids are dissolved in a liquid oil phase containing dibutyl adipate (a dicarboxylic acid ester) or dibutyl adipate and isopropyl myristate (a monocarboxylic acid ester). T. 337:4-6, 338:15-24; JTX-001 ('307 patent) at 5:56-58.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

iii. JP '228

90. JP '228 discloses topical oil-in-water cream emulsion corticosteroid formulations where the steroid is completely dissolved in an oil phase by one or more solvents, including the solvents diethyl sebacate, diisopropyl adipate, and triacetin. T. 339:23-340:12, 605:20-606:15; *see also* DX-005 (JP '228) at 10-11, Example 3.

91. JP '228 teaches the use of light mineral oil as part of the oil phase of the topical corticosteroid formulations. T. 340:4-8; DX-005 (JP '228) at 10-12.

92. JP '228 teaches that the concentration of the corticosteroid in the topical formulations can range from 0.01% to 0.5% by weight. T. 605:1-15; *see also* DX-005 (JP '228) at 10.

93. JP '228 discloses VCA testing of the formulations of the invention and teaches that the formulations of the invention exhibit “extremely good vasoconstriction action” and have “good drug release behavior and transdermal absorption, and hence has a significant pharmacological effect.” T. 340:18-341:7; DX-005 (JP '228) at 13-15. A person of ordinary skill in the art would understand that the term “transdermal absorption” as used in JP '228 refers to absorption of the corticosteroid into the dermal layer of the skin. T. 341:8-23, 617:18-618:1.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

3. The Asserted Claims of the '307 Patent and the '502 Patent are Invalid as Obvious

94. Claims 13, 16, and 20 of the '307 patent and claim 4 of the '502 patent are invalid as obvious under 35 U.S.C. § 103.⁸ Each of these claims would have been obvious to a skilled artisan prior to 2010 over the following combinations of prior art: (1) the '295 patent in view of Blum; (2) the '295 patent in view of Blum and the '566 patent; and (3) the '295 patent in view of Blum and JP '228. T. 322:24-323:14.

95. Claim 16 of the '502 patent is invalid as obvious under 35 U.S.C. § 103. Claim 16 would have been obvious to a skilled artisan prior to 2010 over the following combinations of prior art: (1) the '295 patent in view of Blum; (2) the '295 patent in view of Blum and the '566 patent; and (3) the '295 patent in view of Blum in combination with the Temovate® Label. T. 322:24-323:14.

96. The asserted claims of the '307 and '502 patents do not recite or otherwise require that the claimed formulation provide the same or similar potency as formulations containing HP at 0.05%. App'x A at I.A-B; T. 584:4-20, 592:4-15, 670:21-671:2; JTX-001 ('307 patent) at claims 1, 13, 16, 20; JTX-004 ('502 patent) at claims 1, 4, 16.

⁸ The pre-AIA version of 35 U.S.C. § 103 applies to the '307 and '502 patents.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

97. The asserted claims of the '307 and '502 patents do not recite or otherwise require that the claimed formulation provides the same or similar efficacy as formulations containing HP at 0.05%. App'x A at I.A-B; T. 584:4-20, 592:4-15, 670:21-671:2; JTX-001 ('307 patent) at claims 1, 13, 16, 20; JTX-004 ('502 patent) at claims 1, 4, 16.

98. The asserted claims of the '307 and '502 patents do not recite or otherwise require that the claimed formulation is classified as a super-potent corticosteroid. App'x A at I.A-B; JTX-001 ('307 patent) at claims 1, 13, 16, 20; JTX-004 ('502 patent) at claims 1, 4, 16.

99. The asserted claims of the '307 and '502 patents do not recite or otherwise require that the claimed formulation provides preferential delivery of HP into the skin rather than through the skin. App'x A at I.A-B; T. 607:18-608:4; JTX-001 ('307 patent) at claims 1, 13, 16, 20; JTX-004 ('502 patent) at claims 1, 4, 16.

100. The asserted claims of the '307 and '502 patents encompass compositions with HP at concentrations less than 0.01%. App'x A at I.A-B; T. 671:3-6; JTX-001 ('307 patent) at claims 1, 13, 16, 20; JTX-004 ('502 patent) at claims 1, 4, 16. The asserted claims of the '307 and '502 patents do not recite a lower limit for the concentration of HP. App'x A at I.A-B; T. 671:7-10; JTX-001 ('307 patent) at claims 1, 13, 16, 20; JTX-004 ('502 patent) at claims 1, 4, 16.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

a. Claim 13 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum

i. Blum Disclosed Topical Compositions Comprising Halobetasol Propionate (Limitation 13.1)⁹

101. As discussed above, Blum discloses topical compositions comprising HP at concentrations of 0.02% and 0.05% that were effective in treating psoriasis. T. 163:12-164:21, 323:15-325:15; *see also* DX-002 (Blum) at 4.

102. Additionally, prior to 2010, HP was commercially available in topical ointment and cream formulations at a concentration of 0.05%. T. 43:18-44:1, 49:23-50:2, 482:21-483:5; *see also* DX-009 (Ultravate® Cream Label) at Description.

ii. The '295 Patent Disclosed Topical Corticosteroid Compositions Comprising a Liquid Oil Component Comprising Diethyl Sebacate, Wherein at Least 50% of the Corticosteroid Is Solubilized in the Liquid Oil Component at Room Temperature (22°C) (Limitations 13.2, 13.4)

103. The '295 patent discloses various corticosteroid lotion formulations comprising both a liquid oil phase and an aqueous phase and discloses that the corticosteroid is entirely dissolved at room temperature (22°C) in the liquid oil phase. T. 326:13-327:10; *see also* DX-003 ('295 Patent) at 2:22-26, 3:68-4:10.

104. The '295 Patent teaches the use of sebacates, such as dialkyl sebacate, in topical corticosteroid formulations. T. 328:15-16; *see also* DX-003 ('295 Patent)

⁹ Citations to claim limitation numbers herein correspond to the listing of claim limitations in Appendix A to Padagis's Opening Post Trial Brief.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

at 1:40-44. The '295 Patent teaches that dialkyl sebacates, wherein the alkyl contains 1 to 10 carbons, are excellent vehicles for corticosteroids. T. 328:15-25, 599:6-600:1; DX-003 ('295 Patent) at 1:40-44. Diethyl sebacate is a dialkyl sebacate with two carbons. T. 328:20-329:2, 600:6-8.

105. Selection of diethyl sebacate from the group of dialkyl sebacates (wherein the alkyl contains 1 to 10 carbons) disclosed in the '295 patent would have been a matter of routine optimization for a person of ordinary skill in the art. T. 329:9-19. It would have been routine for a person of ordinary skill in the art to conduct solubility studies with the API and potential solvent as part of developing a topical formulation because it was known that with topical products, it is generally always beneficial to have the drug in solution, and solubility studies are required to assess the solubility of the drug in the potential solvents. T. 72:6-16, 371:24-372:10, 343:2-6, 612:10-25, 794:20-23.

iii. The '295 Patent and Blum Disclosed Topical Corticosteroid Compositions, Including Halobetasol, at Concentrations Within the Claimed Range of “0.025% or Less” (Limitation 13.3)

106. As discussed above, Blum discloses a topical composition comprising HP at a concentration of 0.02%. T. 163:10-20, 323:15-324:9; *see also* DX-002 (Blum) at 4.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

107. A person of ordinary skill in the art would have been motivated to use a concentration of HP in the range of 0.025% or less (or “0.04% or less”¹⁰ or “less than 0.05%”¹¹) to reduce risk of systemic side effects associated with 0.05% HP formulations and to allow for treatment for periods longer than two consecutive weeks. T. 162:15-163:9, 165:11-19, 212:4-24, 331:5-333:9. A skilled artisan prior to 2010 would have known that the risk of systemic side effects associated with topical corticosteroids is reduced when the concentration of the steroid is reduced. T. 123:7-14, 166:11-167:10, 673:13-674:6; 794:24-795:1.

108. Blum disclosed that HP at 0.02% produced clinical success in over 80% of patients treated after 3 weeks. T. 163:23-164:10, 324:14-325:15; *see also* DX-002 (Blum) at 5, Table 1.

109. Blum also disclosed that 0.02% HP was similarly as efficacious as the branded product Dermovate (81% “cured” or “significant improvement” vs. 86% “cured” or “significant improvement”), which was recognized as the most effective topical corticosteroid on the market at the time. T. 163:23-164:10, 324:14-325:15; *see also* DX-002 (Blum) at 5, Table 1.

110. Blum also disclosed that the 0.02% HP ointment provided only 9% less treatment success than the 0.05% HP ointment, and therefore a 60% reduction in HP

¹⁰ Limitations 16.1 and 20.1, '307 Patent.

¹¹ Limitation 16.1, '502 Patent.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

concentration resulted in only a 9% difference in efficacy. T. 163:23-164:10, 324:14-325:15; *see also* DX-002 (Blum) at 5, Table 1.

111. Blum performed a statistical analysis on the efficacy data and concluded that there were no statistically significant differences in the efficacy rates observed for the three treatment groups. T. 164:11-21, 325:20-326:9, 595:8-596:4, 675:14-16; *see also* DX-002 (Blum) at 6.

112. In view of the two-week restriction on the use of Ultravate® due to risk of HPA axis suppression, Blum's teaching of the efficacy of 0.02% HP ointment would have motivated a person of ordinary skill in the art to lower the concentration of HP to reduce the risk of HPA axis suppression without a significant reduction in efficacy. T. 212:4-21.

113. Blum does not teach away from the use of the 0.02% HP formulation or other formulations with a concentration of HP below 0.05%. Blum does not criticize or discredit the efficacy of the 0.02% HP ointment, and Blum does not suggest that the 0.02% HP ointment would be ineffective or inoperable in treating psoriasis. *See* DX-002 (Blum). A person of ordinary skill in the art would understand that the efficacy of the 0.02% HP ointment in Blum was statistically indistinguishable from the efficacy of the 0.05% HP and Dermovate treatments. T. 164:11-21; *see also* DX-002 (Blum) at 6.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

114. Blum teaches that “just like finding the dose for a systemic medication in order to develop a dermatological preparation it is most important to conduct double blind trials to find the right concentration in the treatment of patients with chronic plaque psoriasis.” DX-002 (Blum) at 6; *see also* T. 596:5-22.

115. In view of Blum’s teachings, a person of ordinary skill in the art would have reasonably expected that formulations with HP at 0.025% or less (“0.04% or less”¹² or “less than 0.05%”¹³) would be efficacious in treating skin disorders, including psoriasis. T. 164:22-10, 330:20-25.

116. The ’295 Patent teaches that its disclosures are applicable to any topically active anti-inflammatory steroid. T. 329:23-330:2; *see also* DX-003 (’295 Patent) at 2:6-10. HP is in the same class of steroids as those disclosed in the examples of the ’295 Patent. T. 330:5-8; *see also* DX-003 (’295 Patent) at 6:60-10:68. The ’295 Patent discloses a range of concentrations for the corticosteroids, preferably from about 0.025% to about 0.2% by weight. T. 327:16-328:5; *see also* DX-003 (’295 Patent) at 1:45-51. The ’295 Patent also discloses that for lotion formulations where the steroid is completely dissolved, the concentration of the steroid can range from 0.005% to about 0.6% by weight and are preferably between 0.02% and 0.05% by weight. T. 328:6-9; *see also* DX-003 (’295 Patent) at 2:61-3:2.

¹² Limitations 16.1 and 20.1, ’307 Patent.

¹³ Limitation 16.1, ’502 Patent.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

In view of these teachings, a skilled artisan would have been motivated to use a vehicle with a liquid oil component comprising a dicarboxylic acid ester, such as diethyl sebacate, for a lower concentration HP formulations because it would facilitate adequate delivery of the HP, improving the release and penetration of HP into the skin. T. 330:9-19.

iv. A Skilled Artisan Would Have Been Motivated to Modify and Combine the '295 Patent and Blum with a Reasonable Expectation of Success in Arriving at the Subject Matter of Claim 13 of the '307 Patent

117. A person of ordinary skill in the art would have been motivated to combine the teachings of the '295 Patent and Blum with a reasonable expectation of success. T. 329:21-331:3, 352:6-11.

118. Both the '295 Patent and Blum discuss the use of corticosteroids to treat skin disorders such as psoriasis. T. 331:1-3; DX-002 (Blum) at 4-6; DX-003 ('295 patent) at 1:10-16,

119. The '295 Patent teaches that its disclosures are applicable to any topically active anti-inflammatory steroid. T. 329:23-330:2; *see also* DX-003 ('295 Patent) at 2:6-10. HP is in the same class of steroids as those disclosed in the examples of the '295 Patent. T. 330:5-8; *see also* DX-003 ('295 Patent) at 6:60-10:68.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

120. A person of ordinary skill in the art formulating a concentration of HP at 0.025% or less would have been motivated to select a vehicle that would facilitate adequate drug delivery. T. 330:9-14. The '295 Patent teaches that dialkyl sebacates, wherein the alkyl contains 1 to 10 carbons, are excellent vehicles for corticosteroids. T. 328:15-25, 599:6-600:1; DX-003 ('295 Patent) at 1:40-44. Diethyl sebacate is a dialkyl sebacate with two carbons. T. 328:20-329:2, 600:6-8. A person of ordinary skill in the art would therefore have had a reasonable expectation that solubilizing halobetasol in a dialkyl sebacate, as taught by the '295 Patent, would have improved the release of halobetasol from the formulation and improved the penetration into the skin. T. 330:15-19.

121. Thus, claim 13 of the '307 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 patent and Blum. T. 343:16-345:17, 352:12-16.

b. Claim 13 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with the '566 Patent

i. Blum and the '566 Patent Disclosed Topical Compositions Comprising Halobetasol Propionate (Limitation 13.1)

122. As discussed above, Blum discloses topical compositions comprising HP at concentrations of 0.02% and 0.05%. T. 163:10-20, 323:15-325:15; *see also* DX-002 (Blum) at 4.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

123. Additionally, prior to 2010, HP was commercially available in topical ointment and cream formulations at a concentration of 0.05%. T. 43:18-44:1, 49:23-50:2, 482:21-483:5; *see also* DX-009 (Ultravate® Cream Label) at Description.

124. The '566 patent disclosed numerous examples of topical compositions comprising HP. T. 338:8-12; *see also* DX-004 ('566 Patent) at 8:19-14:58.

ii. The '295 Patent and the '566 Patent Disclosed Topical Corticosteroid Compositions Comprising a Liquid Oil Component Comprising Dicarboxylic Acid Esters (Including Diethyl Sebacate), Wherein At Least 50% of the Corticosteroid Is Solubilized in the Liquid Oil Component at Room Temperature (22°C) (Limitations 13.2, 13.4)

125. As discussed above, the '295 Patent discloses topical corticosteroid compositions containing a liquid oil component comprising diethyl sebacate wherein the corticosteroid is completely solubilized in the liquid oil component at room temperature (22°C). *See* Section II.B.3.a.ii *supra*.

126. The '566 Patent discloses topical corticosteroid compositions, including HP compositions, containing a liquid oil component comprising a dicarboxylic acid ester wherein the corticosteroid is completely solubilized in the liquid oil component at room temperature (22°C). T. 338:8-24; *see also* DX-004 ('566 Patent) at 4:56-5:6, 5:16-20, 5:26-38; 6:44-66, 8:19-14:58. The '566 Patent teaches that the use of dicarboxylic acid esters, such as dibutyl adipate (a dicarboxylic acid ester) or dibutyl adipate and isopropyl myristate (a

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

monocarboxylic acid ester), 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. T. 336:17-337:6, 338:15-24, 501:17-502:3; JTX-001 ('307 patent) at 5:56-58.; *see also* DX-004 ('566 Patent) at 3:20-25, 4:37-49.

iii. The '295 Patent and Blum Disclosed Topical Corticosteroid Compositions, Including Halobetasol, At Concentrations Within the Claimed Range of “0.025% or Less” (Limitation 13.3)

127. *See* Section II.B.3.a.iii *supra*.

iv. A Skilled Artisan Would Have Been Motivated to Modify and Combine the '295 Patent, Blum, and the '566 Patent With A Reasonable Expectation of Success In Arriving At the Subject Matter of Claim 13 of the '307 Patent.

128. As discussed in section II.B.3.a.iv *supra*, a skilled artisan prior to 2010 would have had a reasonable expectation of success in combining the teachings of the '295 Patent and Blum to prepare an effective topical formulation of HP at a concentration of “0.025% or less.” A person of ordinary skill in the art would have been further motivated to combine the teachings of the '295 Patent and Blum with the '566 Patent with a reasonable expectation of success. T. 342:15-17, 352:6-11.

129. The '295 and '566 Patents are both directed to improving the release and penetration of corticosteroids from topical formulations. T. 342:20-23; DX-003

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

(’295 Patent) at 1:6-44; DX-004 (’566 Patent) at 3:20-25, 4:37-49. Both the ’295 and ’566 Patents achieve the goal of improving release and penetration of corticosteroids by dissolving the steroid in a liquid oil phase containing a dicarboxylic acid ester. T. 342:24-343:1; DX-003 (’295 Patent) at 1:40-44; DX-004 (’566 Patent) at 3:20-25, 4:37-49. A person of ordinary skill in the art would have known that the steroid must be dissolved in the topical formulation in order to pass through a membrane, such as the skin. T. 343:2-4. Moreover, a skilled artisan would have understood the teachings of the ’566 Patent to be particularly applicable to a halobetasol formulation prepared according to the teachings of the ’295 Patent given that the examples in the ’566 Patent focus on halobetasol formulations. T. 343:7-10; *see also* DX-004 (’566 Patent) at 8:19-14:58.

130. Thus, the composition of claim 13 of the ’307 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the ’295 Patent, Blum, and the ’566 Patent. T. 343:16-345:17, 352:12-16.

c. Claim 13 of the ’307 Patent Would Have Been Obvious Over the ’295 Patent In View of Blum in Combination with JP ’228

i. Blum Disclosed Topical Compositions Comprising Halobetasol Propionate (Limitation 13.1)

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

131. As discussed above, Blum discloses topical compositions comprising HP at concentrations of 0.02% and 0.05%. T. 163:10-20, 323:15-325:15; *see also* DX-002 (Blum) at 4.

132. Additionally, prior to 2010, HP was commercially available in topical ointment and cream formulations at a concentration of 0.05%. T. 43:18-44:1, 49:23-50:2, 482:21-483:5; *see also* DX-009 (Ultravate® Cream Label) at Description.

ii. The '295 Patent and JP '228 Disclosed Topical Corticosteroid Compositions Comprising A Liquid Oil Component Comprising Diethyl Sebacate, Wherein At Least 50% of the Corticosteroid Is Solubilized in the Liquid Oil Component at Room Temperature (22°C) (Limitations 13.2, 13.4)

133. As discussed above, the '295 Patent discloses topical corticosteroid compositions containing a liquid oil component comprising diethyl sebacate wherein the corticosteroid is completely solubilized in the liquid oil component at room temperature (22°C). *See* Section II.B.3.a.ii *supra*.

134. JP '228 discloses topical oil-in-water cream emulsion corticosteroid formulations where the steroid is completely dissolved in an oil phase by one or more solvents, including the solvents diethyl sebacate, diisopropyl adipate, and triacetin. T. 339:23-340:12, 605:20-606:15; *see also* DX-005 (JP '228) at 10-11, Example 3.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

135. JP '228 discloses VCA testing of the formulations of the invention and teaches that the formulations of the invention exhibit “extremely good vasoconstriction action” and have “good drug release behavior and transdermal absorption, and hence has a significant pharmacological effect.” T. 340:18-341:7; DX-005 (JP '228) at 13-15. A person of ordinary skill in the art would understand that the term “transdermal absorption” as used in JP '228 refers to absorption of the corticosteroid into the dermal layer of the skin. T. 341:8-23, 617:25-618:1.

iii. The '295 patent, Blum, and JP '228 Disclosed Topical Corticosteroid Compositions, including Halobetasol, At Concentrations Within the Claimed Range of “0.025% or Less” (Limitation 13.3)

136. *See* Section II.B.3.a.iii *supra*.

137. Additionally, JP '228 teaches that the concentration of the corticosteroid in the topical formulations can range from 0.01% to 0.5% by weight. T. 605:1-15; *see also* DX-005 (JP '228) at 10.

iv. A Skilled Artisan Would Have Been Motivated to Modify and Combine the '295 Patent, Blum, and JP '228 With A Reasonable Expectation of Success In Arriving at the Subject Matter of Claim 13 of the '307 Patent

138. As discussed in Section II.B.3.a.iv above, a skilled artisan prior to 2010 would have had a reasonable expectation of success in combining the teachings of the '295 Patent and Blum to prepare an effective topical formulation of HP at a

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

concentration of “0.025% or less.” A person of ordinary skill in the art would have been further motivated to combine the teachings of the '295 Patent and Blum with JP '228 with a reasonable expectation of success. T. 342:17-19, 352:6-11.

139. The '295 Patent and JP '228 are both directed to improving the release and penetration of corticosteroids from topical formulations. T. 342:20-23; DX-003 ('295 Patent) at 1:6-44; DX-005 (JP '228) at 10-11, 13. Both the '295 Patent and JP '228 achieve the goal of improving release and penetration of corticosteroids by dissolving the steroid in a liquid oil phase containing a dicarboxylic acid ester. T. 342:24-343:1; DX-003 ('295 Patent) at 1:40-44; DX-005 (JP '228) at 10-11, 13. A person of ordinary skill in the art would have known that the steroid must be dissolved in the topical formulation in order to pass through a membrane such as the skin. T. 343:2-4.

140. Thus, claim 13 of the '307 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 Patent, Blum, and JP '228. T. 343:16-345:17, 352:12-16.

d. Claim 16 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum

141. As discussed above in connection with claim 13, Blum disclosed topical HP compositions; the '295 Patent disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate,

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

wherein at least 50% of the corticosteroid is dissolved in the liquid oil component at room temperature (22°C); the '295 Patent and Blum disclosed topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “0.04% or less”; and a skilled artisan would have been motivated to modify and combine the '295 Patent and Blum with a reasonable expectation of success. *See* Section II.B.3.a *supra*; *see also* T. 345:19-346:7, 352:6-11; (Limitations 16.1 & 16.2)

142. Claim 16 of the '307 patent further recites that the concentration of the liquid oil component is sufficient to dissolve the amount of HP in its entirety at 22°C. App'x A at I.A.2.3 (Limitation 16.3); T. 346:8-11. The '295 Patent discloses topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate, wherein the corticosteroid is completely solubilized in the liquid oil component at room temperature (22°C). T. 326:13-327:10, 346:12-18.

143. Claim 16 further recites a method for treating a disorder of the skin that is amenable to treatment with a topical corticosteroid by applying an amount of the composition that is effective in ameliorating the signs or symptoms of the disorder. App'x A at I.A.2.4 (Limitation 16.4); T. 346:19-24. Blum disclosed the use of HP at 0.02% to treat psoriasis, which produced clinical success in over 80% of patients after 3 weeks and was thus an amount effective in ameliorating the signs or symptoms of psoriasis. T. 163:14-164:10, 324:14-325:15, 346:25-347:3, 594:14-

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

18; *see also* DX-002 (Blum) at 4-6, Table 1. Psoriasis is a disorder of the skin amenable to treatment by a topical corticosteroid. D.I. 166 (Final Pretrial Order) at ¶34 (stipulated fact).

144. Claim 16 further recites topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “0.04% or less.” App’x A at I.A.2.1 (Limitation 16.1); T. 345:22-25. For the reasons discussed above, the ’295 Patent and Blum render obvious topical compositions comprising HP at a concentration less than 0.04%, and a skilled artisan would have been motivated with a reasonable expectation of success to prepare an effective topical HP composition at a concentration of “0.04% or less.” *See* Section II.B.3.a *supra*.

145. Thus, claim 16 of the ’307 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the ’295 Patent and Blum. T. 345:19-347:3, 352:12-16, 355:14-21.

e. Claim 16 of the ’307 Patent Would Have Been Obvious Over the ’295 Patent In View of Blum in Combination with the ’566 Patent

146. As discussed above in connection with claim 13, Blum and the ’566 Patent disclosed topical HP compositions; the ’295 Patent and the ’566 Patent disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate, wherein at least 50% of the corticosteroid is dissolved in the liquid oil component at room temperature (22°C); the ’295 Patent and Blum

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

disclosed topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “0.04% or less”; and a skilled artisan would have been motivated to modify and combine the '295 Patent, Blum, and the '566 Patent with a reasonable expectation of success. *See* Section II.B.3.b *supra*; *see also* T. 345:19-346:7, 352:6-11; (Limitations 16.1 & 16.2)

147. Claim 16 further recites that the concentration of the liquid oil component is sufficient to dissolve the amount of HP in its entirety at 22°C. App'x A at I.A.2.3 (Limitation 16.3); T. 346:8-11. The '295 Patent disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate, wherein the corticosteroid is completely solubilized in the liquid oil component at room temperature (22°C). T. 326:13-327:10, 346:12-18. The '566 Patent also teaches that the corticosteroids are dissolved in a liquid oil phase containing the dicarboxylic acid ester dibutyl adipate or dibutyl adipate and isopropyl myristate. T. 338:15-24.

148. Claim 16 further recites a method for treating a disorder of the skin that is amenable to treatment with a topical corticosteroid by applying an amount of the composition that is effective in ameliorating the signs or symptoms of the disorder. App'x A at I.A.2.4 (Limitation 16.4); T. 346:19-24. Blum disclosed the use of HP at 0.02% to treat psoriasis, which produced clinical success in over 80% of patients after 3 weeks and was thus an amount effective in ameliorating the signs or

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

symptoms of psoriasis. T. 163:14-164:10, 324:14-325:15, 346:25-347:3, 594:14-18; *see also* DX-002 (Blum) at 4-6, Table 1. Psoriasis is a disorder of the skin amenable to treatment by a topical corticosteroid. D.I. 166 (Final Pretrial Order) at ¶34 (stipulated fact).

149. Claim 16 further recites topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “0.04% or less.” App’x A at I.A.2.1 (Limitation 16.1); T. 345:22-25. For the reasons discussed above, the combination of the ’295 Patent, Blum, and the ’566 Patent render obvious topical compositions comprising HP at a concentration less than 0.04% and a skilled artisan would have been motivated with a reasonable expectation of success to prepare an effective topical HP composition at a concentration of “0.04% or less.” *See* Section II.B.3.b *supra*.

150. Thus, claim 16 of the ’307 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the ’295 Patent, Blum, and the ’566 Patent. T. 345:19-347:3, 352:12-16, 355:14-21.

f. Claim 16 of the ’307 Patent Would Have Been Obvious Over the ’295 Patent In View of Blum in Combination with JP ’228

151. As discussed above in connection with claim 13, Blum disclosed topical HP compositions; the ’295 Patent and JP ’228 disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

sebacate, wherein at least 50% of the corticosteroid is dissolved in the liquid oil component at room temperature (22°C); the '295 Patent, Blum, and JP '228 disclosed topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “0.04% or less”; and a skilled artisan would have been motivated to modify and combine the '295 Patent, Blum, and JP '228 with a reasonable expectation of success. *See* Section II.B.3.c *supra*; *see also* T. 345:19-346:7, 352:6-11; (Limitations 16.1 & 16.2).

152. Claim 16 further recites that the concentration of the liquid oil component is sufficient to dissolve the amount of HP in its entirety at 22°C. App'x A at I.A.2.3 (Limitation 16.3); T. 346:8-11. The '295 Patent disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate, wherein the corticosteroid is completely solubilized in the liquid oil component at room temperature (22°C). T. 326:13-327:10, 346:12-18. JP '228 discloses topical oil-in-water cream emulsion corticosteroid formulations where the steroid is completely dissolved in an oil phase by one or more solvents, including the solvents diethyl sebacate, diisopropyl adipate, and triacetin. T. 339:23-340:12, 605:20-606:15; *see also* DX-005 (JP '228) at 10-11, Example 3.

153. Claim 16 further recites a method for treating a disorder of the skin that is amenable to treatment with a topical corticosteroid by applying an amount of the composition that is effective in ameliorating the signs or symptoms of the disorder.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

App'x A at I.A.2.4 (Limitation 16.4); T. 346:19-24. Blum disclosed the use of HP at 0.02% to treat psoriasis, which produced clinical success in over 80% of patients after 3 weeks and was thus an amount effective in ameliorating the signs or symptoms of psoriasis. T. 163:14-164:10, 324:14-325:15, 346:25-347:3, 594:14-18; *see also* DX-002 (Blum) at 4-6, Table 1. Psoriasis is a disorder of the skin amenable to treatment by a topical corticosteroid. D.I. 166 (Final Pretrial Order) at ¶34 (stipulated fact).

154. Claim 16 further recites topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “0.04% or less.” App'x A at I.A.2.1 (Limitation 16.1); T. 345:22-25. For the reasons discussed above, the '295 Patent, Blum, and JP '228 render obvious topical compositions comprising HP at a concentration less than 0.04% and a skilled artisan would have been motivated with a reasonable expectation of success to prepare an effective topical HP composition at a concentration of “0.04% or less.” *See* Section II.B.3.c *supra*.

155. Thus, claim 16 of the '307 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 Patent, Blum, and JP '228. T. 345:19-347:3, 352:12-16, 355:14-21.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER**g. Claim 20 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum**

156. As discussed above in connection with claims 13 and 16, Blum disclosed topical HP compositions; the '295 Patent disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate, wherein the entirety of the corticosteroid (at least 25%) is dissolved in the liquid oil component at room temperature (22°C); the '295 Patent and Blum disclosed topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “0.04% or less”; and a skilled artisan would have been motivated to modify and combine the '295 Patent and Blum with a reasonable expectation of success. *See* Sections II.B.3.a and II.B.3.d *supra*; *see also* T. 347:5-21, 352:6-11; (Limitations 20.1, 20.2, 20.4).

157. Claim 20 further requires that the liquid oil component further comprises light mineral oil. App'x A at I.A.3.3-4 (Limitations 20.3 & 20.4); T. 347:22-23. The use of light mineral oil in topical pharmaceutical formulations was well-established prior to 2010. T. 347:24-25. The *Handbook of Pharmaceutical Excipients*, Sixth Edition (DX-201) teaches that light mineral oil is used primarily as an excipient in topical pharmaceutical formulations and is a well-known emollient. T. 348:23-349:22; *see also* DX-201 (Handbook) at 12. The *Handbook* also discloses recommended concentrations for light mineral oil in topical

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

emulsions, including topical lotions. T. 349:23-350:1; *see also* DX-201 (Handbook) at 12. A skilled artisan would have therefore been motivated to use light mineral oil in the formulation with a reasonable expectation of success to obtain these well-known benefits. T. 347:22-348:3; 348:12-350:1.

158. Thus, claim 20 of the '307 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 Patent and Blum. T. 347:5-350:1, 352:12-16.

h. Claim 20 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with the '566 Patent

159. As discussed above in connection with claim 13 and 16, Blum and the '566 Patent disclosed topical HP compositions; the '295 Patent and the '566 Patent disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate, wherein the entirety of the corticosteroid (at least 25%) is dissolved in the liquid oil component at room temperature (22°C); the '295 Patent and Blum disclosed topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “0.04% or less”; and a skilled artisan would have been motivated to modify and combine the '295 Patent, Blum, and the '566 Patent with a reasonable expectation of success. *See* Sections II.B.3.b and II.B.3.e *supra*; (Limitations 20.1, 20.2, 20.4).

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

160. Claim 20 further requires that the liquid oil component further comprises light mineral oil. App'x A at I.A.3.3-4 (Limitations 20.3 & 20.4); T. 347:22-23. The use of light mineral oil in topical pharmaceutical formulations was well-established prior to 2010. T. 347:24-25. The *Handbook of Pharmaceutical Excipients*, Sixth Edition (DX-201) teaches that light mineral oil is used primarily as an excipient in topical pharmaceutical formulations and is a well-known emollient. T. 348:23-349:22; *see also* DX-201 (Handbook) at 12. The *Handbook* also discloses recommended concentrations for light mineral oil in topical emulsions, including topical lotions. T. 349:23-350:1; *see also* DX-201 (Handbook) at 12. A skilled artisan would have therefore been motivated to use light mineral oil in the formulation with a reasonable expectation of success to obtain these well-known benefits. T. 347:22-348:3; 348:12-350:1.

161. Thus, claim 20 of the '307 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 Patent, Blum, and the '566 Patent. T. 347:5-350:1, 352:12-16.

i. Claim 20 of the '307 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with JP '228

162. As discussed above in connection with claim 13 and 16, Blum disclosed topical HP compositions; the '295 Patent and JP '228 disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate,

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

wherein the entirety of the corticosteroid (at least 25%) is dissolved in the liquid oil component at room temperature (22°C); the '295 Patent and Blum disclosed topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “0.04% or less”; and a skilled artisan would have been motivated to modify and combine the '295 Patent, Blum, and JP '228 with a reasonable expectation of success. *See* Sections II.B.3.c and II.B.3.f *supra*; (Limitations 20.1, 20.2, 20.4).

163. Claim 20 further requires that the liquid oil component further comprises light mineral oil. App'x A at I.A.3.3-4 (Limitations 20.3 & 20.4); T. 347:22-23. JP '228 discloses the use of a liquid oil component that includes both diethyl sebacate and light mineral oil to dissolve a corticosteroid. T. 340:4-8, 348:4-6; DX-005 (JP '228) at 10-12. Additionally, the use of light mineral oil in topical pharmaceutical formulations was well-established prior to 2010. T. 347:24-25. The *Handbook of Pharmaceutical Excipients*, Sixth Edition (DX-201) teaches that light mineral oil is used primarily as an excipient in topical pharmaceutical formulations and is a well-known emollient. T. 348:23-349:22; *see also* DX-201 (Handbook) at 12. The *Handbook* also discloses recommended concentrations for light mineral oil in topical emulsions, including topical lotions. T. 349:23-350:1; *see also* DX-201 (Handbook) at 12. A skilled artisan would have therefore been motivated to use

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

light mineral oil in the formulation with a reasonable expectation of success to obtain these well-known benefits. T. 347:22-348:3; 348:12-350:1.

164. Thus, claim 20 of the '307 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 Patent, Blum, and JP '228. T. 347:5-350:1, 352:12-16.

j. Claim 4 of the '502 Patent Would Have Been Obvious Over the '295 Patent In View of Blum

165. As discussed above in connection with claim 13 of the '307 patent, Blum disclosed topical HP compositions; the '295 Patent disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate and an aqueous component comprising water; the '295 Patent disclosed topical corticosteroid compositions at concentrations within the claimed range of “0.01% or less”; and a skilled artisan would have been motivated to modify and combine the '295 Patent and Blum with a reasonable expectation of success. *See* Section II.B.3.a *supra*; *see also* T. 350:2-351:5, 352:6-11; (Limitations 4.1 & 4.2).

166. Claim 4 of the '502 patent recites that the claimed composition is free of white petrolatum. App'x A at I.B.1.3 (Limitation 4.3); T. 351:6-7. A person of ordinary skill in the art would have been motivated to exclude white petrolatum from the formulation because white petrolatum (commonly known and used in the commercial the product Vaseline) is greasy and undesirable and is not liked by

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

patients. Tr. 339:3-4, 351:8-10. Additionally, the '295 Patent discloses examples that are free of white petrolatum, and claim 1 of the '295 Patent does not require white petrolatum, thus a skilled artisan would have had a reasonable expectation of success in excluding white petrolatum from the formulation. T. 351:11-12, 601:13-16.

167. Claim 4 further recites that the corticosteroid is halobetasol at a concentration of “0.01% or less.” App’x A at I.B.1.4 (Limitation 4.4); T. 351:17-19. A person of ordinary skill in the art would have been motivated to use a concentration of HP in the range of 0.01% or less to reduce risk of systemic side effects associated with 0.05% HP formulations and to allow for treatment for periods longer than two consecutive weeks. T. 162:15-163:9, 165:11-19, 212:4-21, 331:5-333:9. A skilled artisan prior to 2010 would have known that the risk of systemic side effects associated with topical corticosteroids is reduced when the concentration of the steroid is reduced. T. 123:7-14, 166:11-167:10, 673:13-674:6; 794:24-795:4.

168. Blum disclosed that HP at 0.02% produced clinical success in over 80% of patients treated after 3 weeks. T. 163:23-164:10, 324:14-325:15; *see also* DX-002 (Blum) at 5, Table 1.

169. Blum also disclosed that 0.02% HP was similarly as efficacious as the branded product Dermovate (81% “cured” or “significant improvement” vs. 86% “cured” or “significant improvement”), which was recognized as the most effective

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

topical corticosteroid on the market at the time. T. 163:23-164:10, 324:14-325:15; *see also* DX-002 (Blum) at 5, Table 1.

170. Blum also disclosed that the 0.02% HP ointment provided only 9% less treatment success than the 0.05% HP ointment, and therefore a 60% reduction in HP concentration resulted in only a 9% difference in efficacy. T. 163:23-164:10, 324:14-325:15; *see also* DX-002 (Blum) at 5, Table 1.

171. Blum performed a statistical analysis on the efficacy data and concluded that there were no statistically significant differences in the efficacy rates observed for the three treatment groups. T. 164:11-21, 325:20-326:9, 595:8-596:4, 675:14-16; *see also* DX-002 (Blum) at 6. Accordingly, Blum does not teach away from the use of the 0.02% HP formulation or other formulations with a concentration of HP below 0.05%.

172. In view of the two-week restriction on the use of Ultravate® due to risk of HPA axis suppression, Blum's teaching of the efficacy of 0.02% HP ointment would have motivated a person of ordinary skill in the art to further lower the concentration of HP to 0.01% further reduce the risk of HPA axis suppression without a significant reduction in efficacy. T. 212:4-21.

173. Blum does not teach away from the use of the 0.02% HP formulation or other formulations with a concentration of HP below 0.05%. Blum does not criticize or discredit the efficacy of the 0.02% HP ointment, and Blum does not

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

suggest that the 0.02% HP ointment would be ineffective or inoperable in treating psoriasis. *See* DX-002 (Blum). A person of ordinary skill in the art would understand that the efficacy of the 0.02% HP ointment in Blum was statistically indistinguishable from the efficacy of the 0.05% HP and Dermovate treatments. T. 164:11-21; *see also* DX-002 (Blum) at 6.

174. Blum teaches that “just like finding the dose for a systemic medication in order to develop a dermatological preparation it is most important to conduct double blind trials to find the right concentration in the treatment of patients with chronic plaque psoriasis.” DX-002 (Blum) at 6; *see also* T. 596:5-22.

175. In view of Blum’s teachings, a person of ordinary skill in the art would have reasonably expected that formulations with HP at 0.01% or less would be efficacious in treating skin disorders, including psoriasis. T. 164:22-10, 330:20-25.

176. The ’295 Patent teaches that its disclosures are applicable to any topically active anti-inflammatory steroid. T. 329:23-330:2; *see also* DX-003 (’295 Patent) at 2:6-10. HP is in the same class of steroids as those disclosed in the examples of the ’295 Patent. T. 330:5-8; *see also* DX-003 (’295 Patent) at 6:60-10:68. The ’295 Patent discloses a range of concentrations for the corticosteroids, preferably from about 0.025% to about 0.2% by weight. T. 327:12-328:5; *see also* DX-003 (’295 Patent) at 1:45-51. The ’295 Patent also discloses that for lotion formulations where the steroid is completely dissolved, the concentration of the

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

steroid can range from 0.005% to about 0.6% by weight and are preferably between 0.02% and 0.05% by weight. T. 328:6-9; *see also* DX-003 ('295 Patent) at 2:61-3:2. In view of these teachings, a skilled artisan would have been motivated to use a vehicle with a liquid oil component comprising a dicarboxylic acid ester, such as diethyl sebacate, for a lower concentration HP formulations because it would facilitate adequate delivery of the HP, improving the release and penetration of HP into the skin. T. 330:9-19.

177. Thus, claim 4 of the '502 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 Patent and Blum. T. 350:2-351:25, 352:12-16.

k. Claim 4 of the '502 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with the '566 Patent

178. As discussed above in connection with claim 13 of the '307 patent, Blum and the '566 Patent disclosed topical HP compositions; the '295 Patent and the '566 Patent disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate and an aqueous component comprising water; the '295 Patent disclosed topical corticosteroid compositions at concentrations within the claimed range of "0.01% or less"; and a skilled artisan would have been motivated to modify and combine the '295 Patent, Blum, and the

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

'566 Patent with a reasonable expectation of success. *See* Section II.B.3.b *supra*; *see also* T. 350:2-351:5, 352:6-11; (Limitations 4.1 & 4.2).

179. Claim 4 further recites that the claimed composition is free of white petrolatum. App'x A at I.B.1.3 (Limitation 4.3); T. 351:6-7. A person of ordinary skill in the art would have been motivated to exclude white petrolatum from the formulation because white petrolatum is greasy and undesirable and is not liked by patients. T. 351:8-10. Additionally, the '295 Patent discloses examples that are free of white petrolatum, and claim 1 of the '295 Patent does not require white petrolatum, thus a skilled artisan would have had a reasonable expectation of success in excluding white petrolatum from the formulation. T. 351:11-12, 601:13-16; DX-003 ('295 Patent) at 6:30-8:5, Examples 1-11, claim 1. The '566 Patent teaches the advantages of preparing formulations that exclude white petrolatum, explaining that petrolatum-based ointments are greasy, and it may be desirable to have cosmetically elegant (less greasy) topical products, such as creams, lotions, gels, and solutions. T. 338:25-339:8; *see also* DX-004 ('566 Patent) at 11:23-27.

180. Claim 4 further recites that the corticosteroid is halobetasol at a concentration of "0.01% or less." App'x A at I.B.1.4 (Limitation 4.4); T. 351:17-19. A skilled artisan would have been motivated to develop a formulation with a concentration of HP of 0.01% or less with a reasonable expectation of success for the reasons explained previously. *See* II.B.3.j *supra*.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

181. Thus, claim 4 of the '502 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 Patent, Blum, and the '566 Patent. T. 350:2-351:25, 352:12-16.

I. Claim 4 of the '502 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with JP '228

182. As discussed above in connection with claim 13 of the '307 patent, Blum disclosed topical HP compositions; the '295 Patent and JP '228 disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate and an aqueous component comprising water; the '295 Patent and JP '228 disclosed topical corticosteroid compositions at concentrations within the claimed range of "0.01% or less"; and a skilled artisan would have been motivated to modify and combine the '295 Patent, Blum, and JP '228 with a reasonable expectation of success. *See* Section II.B.3.c *supra*; *see also* T. 350:2-351:5, 352:6-11; (Limitations 4.1 & 4.2).

183. Claim 4 further recites that the claimed composition is free of white petrolatum. App'x A at I.B.1.3 (Limitation 4.3); T. 351:6-7. A person of ordinary skill in the art would have been motivated to exclude white petrolatum from the formulation because white petrolatum is greasy and undesirable and is not liked by patients. T. 351:8-10. Additionally, the '295 Patent discloses examples that are free of white petrolatum, and claim 1 of the '295 Patent does not require white

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

petrolatum, thus a skilled artisan would have had a reasonable expectation of success in excluding white petrolatum from the formulation. T. 351:11-12, 601:13-16; DX-003 ('295 Patent) at 6:30-8:5, Examples 1-11, claim 1. JP '228 does not teach the use of white petrolatum. T. 351:15-16.

184. Claim 4 further recites that the corticosteroid is halobetasol at a concentration of “0.01% or less.” App’x A at I.B.1.4 (Limitation 4.4); T. 351:17-19. A skilled artisan would have been motivated to develop a formulation with a concentration of HP of 0.01% or less with a reasonable expectation of success for the reasons explained previously. *See* II.B.3.j *supra*. Additionally, JP '228 teaches that the concentration of the corticosteroid in the topical formulations can range from 0.01% to 0.5% by weight. T. 605:1-15; *see also* DX-005 (JP '228) at 10.

185. Thus, claim 4 of the '502 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 Patent, Blum, and the JP '228. T. 350:2-351:25, 352:12-16.

**m. Claim 16 of the '502 Patent Would Have Been Obvious
Over the '295 Patent In View of Blum**

186. As discussed above in connection with claim 13 of the '307 patent and claim 4 of the '502 patent, Blum disclosed topical HP compositions; the '295 Patent disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate and an aqueous component comprising water; the '295

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

Patent and Blum disclosed topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “less than 0.05%”; a person of ordinary skill in the art would have been motivated to exclude white petrolatum from the formulation with a reasonable expectation of success; and a skilled artisan would have been motivated to modify and combine the '295 Patent and Blum with a reasonable expectation of success. *See* Sections II.B.3.a and II.B.3.j *supra*; (Limitations 16.1, 16.2, 16.3).

187. Claim 16 further recites the use of certain corticosteroids to treat skin disorders amenable to treatment with a topical corticosteroid over periods of treatment longer than two weeks by applying an amount that is effective in ameliorating the signs or symptoms of the disorder. App'x A at I.B.2.4-5 (Limitations 16.4 & 16.5); T. 353:13-16. Prior to 2010 a person of ordinary skill in the art would have had a reasonable expectation that a topical pharmaceutical composition with a concentration of HP below 0.05% could be safely used to treat psoriasis for a period longer than two consecutive weeks. T. 165:25-167:10. A skilled artisan prior to 2010 would have known that the risk of systemic side effects associated with topical corticosteroids is reduced when the concentration of the steroid is reduced. T. 123:7-14, 166:11-167:10, 673:13-674:6; 794:24-795:4. Additionally, Blum disclosed treatment of psoriasis with a topical composition comprising HP at a concentration of 0.02% for a period of 21 days, which produced

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

clinical success in over 80% of patients and was thus an amount effective in ameliorating the signs or symptoms of psoriasis. T. 163:14-164:10, 324:14-325:15, 346:25-347:3, 353:6-9, 594:14-18; *see also* DX-002 (Blum) at 4-6, Table 1. Psoriasis is a disorder of the skin amenable to treatment by a topical corticosteroid. D.I. 166 (Final Pretrial Order) at ¶34 (stipulated fact).

188. Thus, claim 16 of the '502 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 Patent and Blum. T. 352:18-353:17.

n. Claim 16 of the '502 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with the '566 Patent

189. As discussed above in connection with claim 13 of the '307 patent and claim 4 of the '502 patent, Blum and the '566 Patent disclosed topical HP compositions; the '295 Patent and the '566 Patent disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate and an aqueous component comprising water; the '295 Patent and Blum disclosed topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “less than 0.05%”; a person of ordinary skill in the art would have been motivated to exclude white petrolatum from the formulation with a reasonable expectation of success; and a skilled artisan would have been motivated to modify and combine the '295 Patent, Blum, and the '566 Patent with a reasonable

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

expectation of success. *See* Sections II.B.3.b and II.B.3.k *supra*; (Limitations 16.1, 16.2, 16.3).

190. Claim 16 further recites the use of certain corticosteroids to treat skin disorders amenable to treatment with a topical corticosteroid over periods of treatment longer than two weeks by applying an amount that is effective in ameliorating the signs or symptoms of the disorder. App'x A at I.B.2.4-5 (Limitations 16.4 & 16.5); T. 353:13-16. Prior to 2010 a person of ordinary skill in the art would have had a reasonable expectation that a topical pharmaceutical composition with a concentration of HP below 0.05% could be safely used to treat psoriasis for a period longer than two consecutive weeks. T. 165:25-167:10. A skilled artisan prior to 2010 would have known that the risk of systemic side effects associated with topical corticosteroids is reduced when the concentration of the steroid is reduced. T. 123:7-14, 166:11-167:10, 673:13-674:6; 794:24-795:4. Additionally, Blum disclosed treatment of psoriasis with a topical composition comprising HP at a concentration of 0.02% for a period of 21 days, which produced clinical success in over 80% of patients and was thus an amount effective in ameliorating the signs or symptoms of psoriasis. T. 163:14-164:10, 324:14-325:15, 346:25-347:3, 353:6-9, 594:14-18; *see also* DX-002 (Blum) at 4-6, Table 1. Psoriasis is a disorder of the skin amenable to treatment by a topical corticosteroid. D.I. 166 (Final Pretrial Order) at ¶34 (stipulated fact).

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

191. Thus, claim 16 of the '502 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 Patent, Blum, and the '566 Patent. T. 352:18-353:17.

o. Claim 16 of the '502 Patent Would Have Been Obvious Over the '295 Patent In View of Blum in Combination with the Temovate Label

192. As discussed above in connection with claim 13 of the '307 patent and claim 4 of the '502 patent, Blum disclosed topical HP compositions; the '295 Patent disclosed topical corticosteroid compositions comprising a liquid oil component comprising diethyl sebacate and an aqueous component comprising water; the '295 Patent and Blum disclosed topical corticosteroid compositions, including halobetasol, at concentrations within the claimed range of “less than 0.05%”; a person of ordinary skill in the art would have been motivated to exclude white petrolatum from the formulation with a reasonable expectation of success; and a skilled artisan would have been motivated to modify and combine the '295 Patent and Blum with a reasonable expectation of success. *See* Sections II.B.3.a and II.B.3.j *supra*; (Limitations 16.1, 16.2, 16.3).

193. Claim 16 further recites the use of certain corticosteroids, including clobetasol propionate, to treat skin disorders amenable to treatment with a topical corticosteroid over periods of treatment longer than two weeks by applying an amount that is effective in ameliorating the signs or symptoms of the disorder.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

App'x A at I.B.2.4-5 (Limitations 16.4 & 16.5); T. 353:13-16. Prior to 2010 a person of ordinary skill in the art would have had a reasonable expectation that a topical pharmaceutical composition with a concentration of HP below 0.05% could be safely used to treat psoriasis for a period longer than two consecutive weeks. T. 165:25-167:10. A skilled artisan prior to 2010 would have known that the risk of systemic side effects associated with topical corticosteroids is reduced when the concentration of the steroid is reduced. T. 123:7-14, 166:11-167:10, 673:13-674:6; 794:24-795:4. Additionally, Blum disclosed treatment of psoriasis with a topical composition comprising HP at a concentration of 0.02% for a period of 21 days, which produced clinical success in over 80% of patients and was thus an amount effective in ameliorating the signs or symptoms of psoriasis. T. 163:14-164:10, 324:14-325:15, 346:25-347:3, 353:6-9, 594:14-18; *see also* DX-002 (Blum) at 4-6, Table 1. Psoriasis is a disorder of the skin amenable to treatment by a topical corticosteroid. D.I. 166 (Final Pretrial Order) at ¶34 (stipulated fact).

194. Additionally, it was known prior to 2010 that the super-potent corticosteroid clobetasol propionate 0.05%, marketed as Temovate E®, could be safely applied for a period longer than two consecutive weeks when application of the composition was limited to less than 10% of the patient's total body surface area. T. 165:25-167:10, 354:3-24, 607:2-14; *see also* DX-006 (Temovate E® Label) at Dosage and Administration.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

195. The Temovate E® Label would have reinforced the expectation of a person of ordinary skill in the art that a topical composition comprising a corticosteroid, such as HP or clobetasol propionate, at less than 0.05% could be safely applied for periods longer than two consecutive weeks, especially when application is limited to 10% or less of the patient's total body surface area. T. 166:25-167:10.

196. Thus, claim 16 of the '502 patent would have been obvious to a skilled artisan prior to 2010 over the combination of the '295 Patent, Blum, and the Temovate E® Label. T. 352:18-354:24.

p. The Alleged Evidence Of Secondary Considerations Does Not Demonstrate Nonobviousness Of The '307 Or '502 Patents

i. No Unexpected Results

197. Plaintiffs have not demonstrated that the '307 and '502 patents are non-obvious due to unexpected results, specifically the result of maintaining similar efficacy and/or potency as Ultravate® (0.05% HP). T. 355:1-7.

198. None of the asserted claims of the '307 or '502 patents recite a lower limit for the concentration of HP, and the asserted claims therefore encompass embodiments that include concentrations below the 0.01% HP included in Bryhali® and Duobrii®. T. 671:3-10.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

199. To determine whether a composition of the type claimed in the '307 and '502 patents with a concentration of HP less than 0.01% would exhibit comparable efficacy to Ultravate®, a clinical test must be conducted with the composition. T. 671:20-25.

200. The '307 and '502 patents do not disclose any data or information regarding the efficacy or potency of any composition containing a concentration of HP less than 0.01%. T. 672:1-10.

201. Plaintiffs have not offered any evidence that a composition comprising HP at a concentration less than 0.01% falling within the claims of the '307 and '502 patents would exhibit similar potency and/or efficacy as Ultravate® (0.05% HP). *See* T. 54:1-12, 709:16-710:9.

202. Plaintiffs solely rely on Bryhali® and Duobrii® as evidence of compositions with a lower concentration of HP than Ultravate® but similar efficacy and potency. T. 54:1-12, 709:16-710:9. Bryhali® and Duobrii® both contain HP at 0.01%. T. 45:2-6, 46:8-12.

203. Plaintiffs' evidence of unexpected results is not commensurate in scope with the asserted claims of the '307 and '502 patents, which encompass concentrations of HP “of 0.04% *or less*” ('307 patent claims 16 & 20), “0.025% *or less*” ('307 patent claim 13), “0.01% (w/w) *or less*” ('502 patent claim 4), and “*less than* 0.05%” ('502 patent claim 16). App'x A at I.A-B; JTX-001 ('307 patent) at

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

claims 1, 13, 16, 20 (emphases added); JTX-004 ('502 patent) at claims 1, 4, 16 (emphases added).

204. Plaintiffs have not proven that the compositions of the asserted claims of the '307 and '502 patents unexpectedly provide preferential delivery of the corticosteroid into the skin rather than transdermal delivery through the through the skin and into the systemic circulation.

205. The '307 and '502 patents merely state that “[i]t is hypothesized that it is this solubilization within the formulation that, upon application of the formulation to the skin of a patient, provides delivery of the corticosteroid preferentially into the skin rather than providing transdermal delivery through the skin and into the systemic circulation. JTX-001 ('307 patent) at 4:40-45. There is not any data or other information provided in the '307 and '502 patents confirming the stated hypothesis that the claimed compositions provide preferential delivery of the corticosteroid into the skin rather than transdermal delivery through the through the skin and into the systemic circulation. T. 315:11-316:6.

206. The '307 and '502 patents do not disclose any data or testing on the systemic absorption of the corticosteroid for any of the disclosed formulations. T. 608:22-609:2, 618:2-6.

207. VCA testing does not measure the systemic absorption of a corticosteroid into the systemic circulation. T. 617:18-618:1.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

208. Plaintiffs have not offered any evidence or data that the compositions of the asserted claims of the '307 and '502 patents unexpectedly provide preferential delivery of the corticosteroid into the skin rather than transdermal delivery through the through the skin and into the systemic circulation. 608:5-10.

ii. No Reasonably Commensurate Long Felt Need

209. Plaintiffs have not demonstrated that the '307 and '502 patents are non-obvious because they solved a long-felt but unmet need for a super-potent corticosteroid that may be administered for a period of longer than two consecutive weeks. T. 355:1-7.

210. None of the asserted claims of the '307 or '502 patents recite a lower limit for the concentration of HP, and the asserted claims therefore encompass embodiments that include concentrations below the 0.01% HP included in Bryhali® and Duobrii®. App'x A at I.A-B; T. 671:3-10; JTX-001 ('307 patent) at claims 1, 13, 16, 20; JTX-004 ('502 patent) at claims 1, 4, 16.

211. The '307 and '502 patents do not disclose any data or information regarding the potency of any composition containing a concentration of HP less than 0.01%. T. 672:1-10.

212. The specification of the '307 and '502 patent encompasses steroid compositions with potencies below super-potent. 586:7-15.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

213. The asserted claims of the '307 and '502 patents do not recite or otherwise require that the claimed formulation is classified as a super-potent corticosteroid. App'x A at I.A-B; JTX-001 ('307 patent) at claims 1, 13, 16, 20; JTX-004 ('502 patent) at claims 1, 4, 16. The asserted claims of the '307 and '502 patents do not recite or otherwise require a commercial product. T. 583:22-584:3

214. Plaintiffs have not offered any evidence that a composition comprising HP at a concentration less than 0.01% falling within the claims of the Halobetasol Patents would exhibit similar potency as Ultravate® (0.05% HP). *See* T. 54:1-12, 709:16-710:9.

215. The claims of the '502 patent encompass compositions comprising any of five different corticosteroids, including the corticosteroid fluocinonide, at a concentration of less than 0.05%. App'x A at I.B; T. 586:17-20. Fluocinonide formulations were known prior to 2010 that were classified as potent and upper-mid potent. T. 587:1-4. The '502 patent does not disclose any data or testing demonstrating that a composition with fluocinonide at a concentration less than 0.05% falling within the scope of the claims of the '502 patent would be super-potent. T. 587:10-588:11. The '502 patent does not disclose any examples, data, or testing for any formulations comprising any corticosteroid other than HP. T. 587:5-588:16.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

216. Plaintiffs solely rely on Bryhali® and Duobrii® as evidence of compositions with a super-potent corticosteroid that may be administered for a period of longer than 2 weeks. T. 54:1-55:13, 709:16-710:9. Bryhali® and Duobrii® both contain HP at 0.01%. T. 45:2-6, 46:8-12.

217. Plaintiffs' evidence of long-felt but un-met need is not commensurate in scope with the asserted claims of the '307 and '502 patents, which encompass concentrations of HP "of 0.04% *or less*" ('307 patent claims 16 & 20), "0.025% *or less*" ('307 patent claim 13), "0.01% (w/w) *or less*" ('502 patent claim 4), and "*less than* 0.05%" ('502 patent claim 16). App'x A at I.A-B; JTX-001 ('307 patent) at claims 1, 13, 16, 20 (emphases added); JTX-004 ('502 patent) at claims 1, 4, 16 (emphases added).

218. [REDACTED]

219. [REDACTED]

220. Topical 0.05% halobetasol propionate products, including Ultravate and generic versions, remained on the market after the launch of Bryhali and Duobrii, [REDACTED]

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

██████ See PTX-143 (Psoriasis Market Data Tab: rows 863-912 (Bryhali), rows 2699-2746 (Duobrii), rows 3288-3433 (generic halobetasol propionate), rows 5567-5659 (Ultravate)).

iii. No Failure of Others

221. Plaintiffs have not demonstrated that the '307 and '502 patents are non-obvious due to failure of others. T. 355:1-7.

222. Plaintiffs have not offered any evidence that others tried and failed to develop the compositions of the '307 and '502 patents.

223. Padagis's Abbreviated New Drug Application to market a generic version of Ultravate® does not evidence failure of others to develop the compositions of the '307 and '502 patents because Padagis's generic product was required to use the same concentration and strength of HP as that included in Ultravate®. T. 710:12-711:13.

iv. No Commercial Success

224. Plaintiffs have not demonstrated that the '307 and '502 patents are non-obvious due to commercial success of Duobrii®. Plaintiffs have not asserted that the '307 and '502 patents are non-obvious due to commercial success of Bryhali®. *See* Section II.D., *infra*.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

4. The Asserted Claims of the '307 and '502 Patents are Indefinite

225. The asserted claims of the '307 and '502 patents are indefinite because a skilled artisan would not understand with reasonable certainty the scope of the “liquid oil component” recited in the asserted claims. T. 356:10-362:8.

226. The term “liquid oil component,” as recited in the asserted claims of the '307 and '502 patents, does not have a customary meaning in the field of pharmaceutical formulations. T. 579:23-580:1.

227. The Court has construed the term “liquid oil component” as follows: “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.” D.I. 83 at 23-24; T. 314:18-315:10, 356:14-22, 575:23-576:4. The language of this construction is drawn directly from column 4 of the specification of the '307 and '502 patents. T. 314:18-315:10, 356:14-22; *see also* JTX-001 ('307 patent) at 4:17-20.

228. The '307 and '502 patents disclose that the “liquid oil component” may contain additional components, such as hydrocarbons like mineral oil, light mineral oil, etc. T. 357:5-8; *see also* JTX-001 ('307 patent) at 4:18-34. Claim 19 of the '307 patent recites that the liquid oil component further comprises light mineral oil. T. 357:9-12; *see also* JTX-001 ('307 patent) at claim 19.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

229. Claim 8 of the '502 patent recites that the liquid oil component further comprises an emulsifying agent. T. 357:22-358:1; *see also* JTX-004 ('502 patent) at claim 8. Claim 8 further supports the understanding that the “liquid oil component” includes all ingredients that are liquid at room temperature of 22°C and practically insoluble or insoluble in water. *Id.* The '307 and '502 patents disclose that sorbitan monooleate is one of the emulsifying agents that may be included in the described formulations. T. 358:2-5; *see also* JTX-001 ('307 patent) at 6:40-51.

230. A person of ordinary skill in the art would have understood that sorbitan monooleate is liquid at room temperature (22°C) and is practically insoluble or insoluble in water. T. 358:6-359:15, 576:17-577:7. Sorbitan monooleate falls within the Court’s construction of the “liquid oil component.” T. 577:5-7.

231. Table 2 of the '307 and '502 patents presents the “concentration of liquid oil component” for Examples A-D of Table 1. T. 360:8-12, 583:1-6; JTX-001 ('307 patent) at Table 2. The recited values for the “concentration of liquid oil component” in Table 2 of the '307 and '502 patents exclude sorbitan monooleate from the calculation of the concentration of the liquid oil component. T. 361:10-22, 580:10-14; *see* JTX-001 ('307 patent) at Tables 1 & 2.

232. Table 2 is inconsistent with the Court’s construction of the “liquid oil component” and the description in the specification of the '307 and '502 patents that the liquid oil component “includes all ingredients of the formulation that are

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

practically insoluble or insoluble in water and which are liquid at room temperature of 22° C.” T. 360:25-361:22; *see also* JTX-001 (’307 patent) at 4:17-20. Table 2 is also inconsistent with the description of “liquid oil component” in other portions of the specification, and the HP patents provide no guidance on which meaning to apply when determining the components or concentration of the “liquid oil component.”

Id. A person of ordinary skill in the art would not be able to reconcile the inconsistent disclosures of the ’307 and ’502 patents with respect to the scope of the “liquid oil component.” T. 361:15-19, 580:22-581:23; *see also* DX-383 at ¶60.

233. Plaintiffs’ expert, Dr. Lane, previously declared under penalty of perjury in this case that a “POSA would not be able to reconcile Perrigo’s proposed construction of the term liquid oil component with the specification and claims of the [’307 and ’502 patents].” T. 361:15-19, 580:22-581:23; *see also* DX-383 at ¶60. The Court adopted Perrigo’s (now Padagis’s) proposed construction during claim construction, which is taken from the language in the specification. D.I. 83 at 23-24; T. 356:14-22; *see also* JTX-001 (’307 patent) at 4:17-20.

234. Dr. Lane’s proposed reading of the use of “liquid oil component” in Table 2 of the ’307 and ’502 patents as being limited solely to the solvents of the formulation is the same position offered by Plaintiffs and Dr. Lane during claim construction that this Court previously rejected. T. 578:14-579:8, 581:24-582:8; *see also* D.I. 83 at 23-24.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

235. A skilled artisan prior to 2010 would not have understood the scope of “liquid oil component” in the ’307 and ’502 patents with reasonable certainty. T. T. 356:10-362:8.

C. Findings of Fact Regarding the ’895 and ’787 Patents

236. The earliest priority date of the alleged invention of the claims of the ’895 and ’787 patents is June 18, 2015. T. 170:23-171:6, 365:5-10, 473:7-15, 567:14-17; JTX-002 (’895 patent) at 1; JTX-003 (’787 patent) at 1.

237. The ’895 and ’787 patents discuss topical pharmaceutical compositions comprising a combination of halobetasol propionate at 0.01% w/w and tazarotene at 0.045% w/w, and methods of treating psoriasis with such compositions. T. 172:1-7.

1. Person of Ordinary Skill in the Art

238. A person of ordinary skill in the art in June 2015 related to the ’895 and ’787 patents 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

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

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. T. 170:18-171:2, 365:5-10. A person of ordinary skill in the art should not be limited to a person who speaks English. T. 593:2-7.

239. Dr. Stern met the qualifications for a person of ordinary skill in the art as of June 2015. T. 171:3-6; DX-208 (Stern CV). Dr. Stern testified that his opinions would not change under Plaintiffs' definition of a person of ordinary skill in the art. T. 157:11-17.

240. Dr. Michniak-Kohn met the qualifications for a person of ordinary skill in the art as of June 2015. T. 314:7-9; DX-184 (Michniak-Kohn CV). Dr. Michniak-Kohn testified that her opinions would not change under Plaintiffs' definition of a person of ordinary skill in the art. T. 314:10-15.

2. Background and Prior Art

a. Tazarotene Was A Well-known Retinoid Approved For Treating Psoriasis Prior To June 2015

241. Topical retinoids are a topical treatment for psoriasis. T. 41:3-9, 44:6-20. Retinoids are a class of compounds derived from Vitamin A and, when used to treat psoriasis, they result in reduced hyperproliferation of skin cells. T. 41:3-9,

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

44:6-20. As of 2010, tazarotene was the only retinoid used for treating psoriasis.
623:21-624:3.

242. Tazarotene (“Taz”) is a retinoid that was commercially used to treat psoriasis prior to 2015 under the trade name Tazorac®. T. 44:18-23, 50:19-51:20, 169:3-10; *see also* DX-010 (Tazorac® Label) at 1. Tazorac® Cream was approved for treating psoriasis at Taz concentrations of 0.05% and 0.1%. T. 51:14-20, 108:25-109:19, 181:21-182:20; *see also* DX-010 (Tazorac® Label) at Indications and Usage. A person of ordinary skill in the art would have expected Taz at 0.05% to be effective in treating psoriasis prior to 2015. T. 51:18-20, 108:25-109:19.

243. Prior to 2015, topical Taz treatment was known to cause local skin irritation. T. 51:21-52:1, 109:20-110:2, 181:22-25; *see also* DX-010 (Tazorac® Label) at 5.2 Local Irritation.

244. Prior to 2015, treatment with 0.05% Taz was known to induce less irritation than treatment with 0.1% Taz. T. 182:1-5; *see also* DX-010 (Tazorac® Label) at 5.2 Local Irritation, 6.1 Clinical Trials Experience. The Tazorac® Label recommended that patients who experienced intolerable levels of irritation with 0.1% Taz be switched to the 0.05% Taz dose. T. 182:1-5; *see also* DX-010 (Tazorac® Label) at 5.2 Local Irritation.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

245. The Tazorac® Label teaches that there was little difference in the efficacy rates for treating psoriasis between the 0.05% Taz and 0.1% Taz formulations. T. 182:6-20; *see also* DX-010 (Tazorac® Label) at Clinical Studies.

b. Combining Taz With Topical Corticosteroids Was Recognized As A Desirable Combination Therapy For Psoriasis Prior To June 2015

246. Prior to 2015, combination topical therapy was the standard of care for treating psoriasis for most patients. T. 52:6-15, 624:8-10.

247. PTX-44 is a plaque psoriasis article authored by Plaintiffs' expert Dr. Linda Stein Gold and several Bausch employees. T. 684:5-25; *see also* PTX-44 at 1. PTX-44 teaches that fixed combinations are commonplace in dermatology, providing significant efficacy and tolerability benefits. T. 683:24-686:4; *see also* PTX-44 at Abstract. There is a long history of dermatologic products being combined successfully. T. 179:9-14.

248. It was known prior to 2015 that combining a topical corticosteroid and Taz would alleviate the irritation caused by topical Taz. T. 111:6-9. Prior to 2015, psoriasis therapies employing both Taz and a topical corticosteroid demonstrated improved efficacy over monotherapy with either treatment. T. 686:6-687:5; *see also* PTX-380 at 1162. Prior to 2015, combination therapy with Taz and a topical corticosteroid also yielded greater duration of posttreatment maintenance effects and decreased discontinuations due to posttreatment disease recurrence. T. 687:6-12;

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

see also PTX-380 at 1162. Prior to 2015, combination therapy with Taz and a topical corticosteroid was also known to mitigate the safety and tolerability concerns associated with use of either as monotherapy, evidenced by the low incidences of adverse events and steroid rebound in clinical trials. T. 687:13-21; *see also* PTX-380 at 1162.

i. Gollnick

249. Gollnick (DX-140), a medical journal article published in the British Journal of Dermatology in 1999, reports two clinical trials using the combination of Taz and various topical corticosteroids for the treatment of psoriasis. T. 168:17-169:2; *see also* DX-140 (Gollnick) at 1-3. In one study, the patients applied Taz and the corticosteroid or placebo on the same day at different times of the day for 12 weeks. T. 177:11-22; *see also* DX-140 (Gollnick) at 1-3. In the second study, the patients applied Taz and the corticosteroid or placebo on alternating days for 12 weeks. T. 178:1-9; *see also* DX-140 (Gollnick) at 1-3.

250. Both studies in Gollnick showed that combining Taz with a high potent topical corticosteroid significantly improved efficacy and reduced local skin effects compared to Taz plus placebo cream. T. 178:10-22; *see also* DX-140 (Gollnick) at 1, 5.

251. Gollnick states that “[c]ombination therapy with tazarotene and a topical corticosteroid appears logical because these agents have some different (as

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

well as some common) mechanisms of action and thus are likely to have additive or synergistic effects.” T. 178:15-17, 183:7-10, 185:3-8, 294:7-295:1, 695:25-696:5; DX-140 (Gollnick) at 2.

ii. Gandhi

252. Gandhi (DX-141), an Indian Patent Application published in 2012, disclosed topical formulations, including lotions, that include HP and Taz in a single formulation. T. 179:21-24; *see also* DX-141 (Gandhi) at 3-31. Gandhi disclosed Taz as part of the combination formulation at concentrations of 0.05% to 0.1%. T. 300:11-15; *see also* DX-141 (Gandhi) at 9.

253. Gandhi disclosed that HP and Taz “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.” T. 179:25-180:4, 185:9-12, 695:25-696:5; *see also* DX-141 (Gandhi) at 7.

iii. IDP-118 Study

254. As of January 24, 2014, the prior art disclosed a lotion used to treat psoriasis that contained 0.045% Taz and 0.01% HP in a single lotion. T. 666:16-667:14; *see also* DX-064 (IDP-118 Study) at 1-2.

255. The IDP-118 Study (DX-064) is a posting from ClinicalTrials.gov dated January 24, 2014 and described a Phase 2B study of IDP-118 Lotion compared

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

to monotherapy and vehicle lotions for treatment of psoriasis. T. 180:10-16; *see also* DX-064 (IDP-118 Study) at 1-2. The IDP-118 Study (DX-064) disclosed that IDP-118 Lotion included the combination of 0.01% HP and 0.045% Taz, which are identical to the concentrations of HP and Taz recited in the claims of the '895 and '787 patents. T. 134:22-135:3, 169:14-21, 180:10-22, 445:11-21, 449:21-25; *see also* DX-064 (IDP-118 Study) at 1-2.

c. The '824 Publication Disclosed Topical Corticosteroid Compositions, and Methods of Using those Compositions, Including Halobetasol Formulations Prior to June 2015

256. The '824 Publication (DX-142) shares the same specification as the '307 and '502 patents. T. 168:4-16, 669:24-670:1; *compare* DX-142 ('824 Publication) *with* JTX-001 ('307 patent) and JTX-004 ('502 patent); *see also* JTX-001 ('307 patent) at (65) Prior Publication Data. The '824 Publication discloses two formulations that fall within the scope of the claims of the '895 and '787 patents. T. 574:2-4.

257. The '824 Publication disclosed topical lotion formulations with a lower concentration of HP than Ultravate® (0.05% HP) but similar efficacy and potency as Ultravate® (0.05% HP). T. 181:4-14; *see also* DX-142 ('824 Publication) at [0035]. The '824 Publication disclosed that a topical lotion formulation with 0.01% HP exhibited a similar VCA score as Ultravate® (0.05% HP). T. 181:4-14, 367:19-368:17; *see also* DX-142 ('824 Publication) at Examples 1 and 3, Tables 1 and 3.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

The '824 Publication also disclosed that the topical lotion formulations with a lower concentration of HP than Ultravate® could be safely administered for periods longer than two consecutive weeks. T. 181:4-14; *see also* DX-142 ('824 Publication) at [0035]. The '824 Publication would have been interesting to a person of skill in the art because of these teachings. T. 219:15-20.

258. The '824 Publication discloses a total of 7 example formulations that include a concentration of HP less than 0.05%. DX-142 ('824 Publication) at Tables 1, 4, and 5. Formulation C in Table 1 and Formulation 4A in Table 4 include a concentration of 0.01% HP. DX-142 ('824 Publication) at Tables 1 and 4. Formulation B in Table 1, Formulation 4B in Table 4, and the formulation in Table 5 each include a concentration of 0.025% HP. DX-142 ('824 Publication) at Tables 1, 4, and 5. Formulations A and D in Table 1 include a concentration of 0.035% HP. DX-142 ('824 Publication) at Table 1. The '824 Publication discloses that each of Formulations A-D from Table 1 exhibited VCA scores similar to Ultravate®. DX-142 ('824 Publication) at [0040], Table 3.

259. The '824 Publication discloses only two lotion formulations that contain 0.01% HP: (1) formulation C in Table 1 and (2) Formulation 4A in Table 4. T. 367:19-369:5, 670:9-20; *see also* DX-142 ('824 Publication) at Tables 1 & 4. Formulation 4A in Table 4 of the '824 Publication is identical to the vehicle of IDP-118 Lotion disclosed in the '895 and '787 patents. T. 139:3-12, 610:25-611:17; *see*

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

also DX-142 ('824 Publication) at Table 4; JTX-002 ('895 Patent) at Table 4; JTX-003 ('787 patent) at Table 4. Example 4 of the '824 publication describes a method for making Formulation 4A. T. 368:21-370:24; *see also* DX-142 ('824 Publication) at Example 4.

260. The '824 Publication teaches topical lotions comprising HP dissolved in a liquid oil component that consists of diethyl sebacate and light mineral oil. T. 366:4-367:15; *see also* DX-142 ('824 Publication) at [0012], [0014], [0022], [0026]. The '824 Publication disclosed a method for manufacturing a lotion formulation comprising 0.01% HP, an aqueous phase comprising carbomer copolymer type B and carbomer homopolymer type A, and a liquid oil phase consisting of diethyl sebacate and light mineral oil that dissolved the HP. T. 368:21-370:24; *see also* DX-142 ('824 Publication) at Example 4.

d. Bausch's Representations to the FDA

261. Bausch believed its representations to the FDA during the approval process for Duobrii® and Bryhali® were true and accurate when they were made. T. 106:10-17, 458:20-459:2.

262. Bausch submitted its Investigational New Drug Application ("IND") for Duobrii® in October 2011. T. 455:25-456:7. In a submission to the FDA in 2011 as part of the IND for Duobrii®, Bausch represented to the FDA that applying a topical corticosteroid in conjunction with tazarotene alleviates the irritation and

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

also treats the psoriasis, citing to an article published in 1998 for support. T. 110:3-8; *see also* JTX-009-3 at BAU00002788, 2814-2815.

263. In that same 2011 submission, Bausch represented to FDA that HP and Taz were appropriate to be combined because they have different mechanisms of action. T. 111:10-17; *see also* JTX-009-3 at BAU00002788. HP and Taz were known to have different mechanisms of action prior to 2011. T. 111:15-19.

264. In that same 2011 submission, Bausch represented to FDA that Taz “in combination with a corticosteroid, the irritation is reduced and a synergistic effect allows for longer duration of treatment and remission,” citing to a 2011 article for support. T. 111:20-112:1; *see also* JTX-009-3 at BAU00002788.

265. In that same 2011 submission, Bausch represented to FDA that “[c]linical studies (see Section 2.5.4.1) have demonstrated that the combined clinical use of tazarotene with a topical corticosteroid results in greater and more rapid improvement than with corticosteroid or tazarotene alone.” T. 114:22-115:2; *see also* JTX-009-3 at BAU00002789.

266. In that same 2011 submission, Bausch represented to FDA that the concept of combining Taz, with a high potency corticosteroid, HP, for the treatment of plaque psoriasis is based on the known efficacies and safety of each of these active components as exemplified by the approved listed drugs, tazarotene cream 0.05 percent and 0.01 percent tazarotene and Ultravate® Cream, 0.05 percent halobetasol

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

propionate. T. 115:14-116:2; *see also* JTX-009-3 at BAU00002789. Bausch's Vice President of R&D stated that "tazarotene was an automatic choice because that was the only retinoid approved at that point." T. 69:1-2.

267. In that same 2011 submission, Bausch represented to FDA that "IDP-118 lotion will contain a lower concentration of halobetasol propionate, i.e., 0.01 percent or 0.025 percent, than the listed drug, Ultravate® Cream 0.05 percent, to potentially support longer treatment duration than the recommended two-week duration for Ultravate®." T. 119:8-15; *see also* JTX-009-3 at BAU00002791.

268. In that same 2011 submission, Bausch represented to FDA that IDP-118 will contain tazarotene "at a concentration of 0.045 percent comparable to the listed drug Tazorac® Cream 0.05 percent." T. 120:8-14; *see also* JTX-009-3 at BAU00002791. Bausch did not optimize the concentration of Taz in Duobrii®. T. 87:11-20. Bausch's rationale for selecting a Taz concentration of 0.045% was that it was comparable to the marketed percentage of 0.05% in Tazorac. T. 121:20-122:5.

269. In that same 2011 submission, Bausch represented to FDA that "[l]iterature based on the daily combined use of tazarotene and a mid-potent or potent corticosteroid for plaque psoriasis for 12 weeks demonstrated enhanced efficacy of the combination treatment over that of the monotherapies with no significant safety issues." T. 122:6-16; *see also* JTX-009-3 at BAU00002811.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

270. In an additional submission to FDA in 2011 as part of the Investigational New Drug Application (“IND”) for Duobrii®, Bausch represented to FDA that “[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.” T. 125:2-8; JTX-011-3 at BAU00054957.

271. In an additional submission to FDA in 2011 as part of the Investigational New Drug Application (“IND”) for Duobrii®, Bausch represented to FDA that the concept for combining tazarotene with halobetasol propionate is based on, “the potential for additive or synergistic effects due to different mechanisms of action.” T. 693:17-24, 694:17-22; *see also* JTX-009-2 at BAU00002589.

272. In an additional submission to FDA as part of the IND for Duobrii®, Bausch represented to FDA that 0.045% Taz was expected to provide the potential for efficacy in the treatment of psoriasis similar to that of Tazorac® Cream 0.05 percent. T. 700:7-21; *see also* JTX-009-5 at BAU00013662.

273. In that same submission, Bausch represented to FDA based on references published in 1998 and 1999, that adjunctive use of tazarotene with topical mid- to high-potency corticosteroids had been shown to provide a synergistic effect

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

allowing for longer durations of treatment and remission.” T. 701:13-22, 702:16-703:14; *see also* JTX-009-5 at BAU00013661.

274. In that same submission, Bausch represented to FDA that based on a reference from 2000, “application of a mid- or high-potency topical corticosteroid in conjunction with tazarotene has been shown to markedly reduce the incidence of adverse reactions and improve tolerability in the early weeks of treatment when adverse reactions associated with tazarotene are most likely.” T. 703:16-704:11; *see also* JTX-009-5 at BAU00013661.

3. The asserted claims of the '895 and '787 patents are invalid as obvious

a. Claim 3 Of The '895 Patent Would Have Been Obvious Over The '824 Publication In Combination With Gollnick And The IDP-118 Study

275. Claim 3 of the '895 patent depends from Claim 2 which depends from Claim 1. T. 172:13-23. Claim 3 of the '895 patent is directed to a topical pharmaceutical composition for treating psoriasis comprising an oil-in-water emulsion that includes 0.01% w/w HP and 0.045% w/w Taz, a dermatologically acceptable carrier, an oil phase in the oil-in-water emulsion that comprises a liquid oil component that is liquid at 22° C and consists of diethyl sebacate and light mineral oil. T. 172:13-23; *see also* JTX-002 ('895 patent) at Claim 3. Claim 3 also recites that the composition is capable of providing synergistic efficacy and

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

synergistic reduction of at least an adverse event selected from the group consisting of itching, burning, and stinging (the “Synergy Limitations”). T. 172:13-23; *see also* JTX-002 (’895 patent) at Claim 3. Claim 3 also requires that the emulsion is a lotion and that the HP and Taz are dissolved in the liquid oil component. T. 172:13-23; *see also* JTX-002 (’895 patent) at Claim 3.

i. **A POSA Would Have Been Motivated To Combine HP And Taz In A Single Formulation To Treat Psoriasis (Limitations 3.1, 3.2)**

276. Gollnick (DX-140), a medical journal article published in the British Journal of Dermatology in 1999, reports two clinical trials using the combination of Taz and various topical corticosteroids for the treatment of psoriasis. T. 168:17-169:2; *see also* DX-140 (Gollnick) at 1-3. In one study, the patients applied Taz and the corticosteroid or placebo on the same day at different times of the day for 12 weeks. T. 177:11-25; *see also* DX-140 (Gollnick) at 1-3. In the second study, the patients applied Taz and the corticosteroid or placebo on alternating days for 12 weeks. T. 178:1-9; *see also* DX-140 (Gollnick) at 1-3.

277. Both studies in Gollnick showed that combining Taz with a highly potent topical corticosteroid significantly improved efficacy and reduced local skin effects compared to Taz plus placebo cream. T. 178:10-22; *see also* DX-140 (Gollnick) at 1, 5.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

278. A person of ordinary skill in the art would have been motivated by Gollnick with a reasonable expectation of success to combine Taz and HP, a more potent corticosteroid than those studied in Gollnick, to improve the efficacy of treatment and reduce local skin irritation. T. 178:24-179:2.

279. A person of ordinary skill in the art would have been motivated to combine Taz and HP in a single formulation to improve the convenience of the treatment and improve patient adherence. T. 179:3-14, 681:15-18. Combining HP and Taz in a single formulation would also avoid issues relating to layering the two products in two separate vehicles. T. 681:19-23. A person of ordinary skill in the art would have known that fixed combination therapies are commonplace in dermatology and that there was a long history of dermatologic products being combined successfully, which would further support the skilled artisan's motivation to combine the two actives in a single vehicle. T. 179:9-14, 683:24-686:4; *see also* PTX-44 at Abstract.

280. A person of ordinary skill in the art would have been further motivated to combine HP and Taz in a single formulation to treat psoriasis with a reasonable expectation of success by the IDP-118 Study. T. 180:5-22. The IDP-118 Study (DX-064) is a posting from ClinicalTrials.gov dated January 24, 2014 and described a Phase 2B study of IDP-118 Lotion compared to monotherapy and vehicle lotions. T. 180:10-16; *see also* DX-064 (IDP-118 Study) at 1-2. The IDP-118 Study (DX-

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

064) disclosed that IDP-118 Lotion included the combination of 0.01% HP and 0.045% Taz, which are identical to the concentrations of HP and Taz recited in the claims of the '895 and '787 patents. T. 180:10-22; *see also* DX-064 (IDP-118 Study) at 1-2.

ii. A POSA Would Have Been Motivated To Use 0.01% HP In The Combination Product (Limitation 3.1)

281. The '824 Publication disclosed topical lotion formulations with a lower concentration of HP than Ultravate® (0.05% HP) but similar efficacy and potency as Ultravate® (0.05% HP). T. 181:4-14; *see also* DX-142 ('824 Publication) at [0035]. The '824 Publication disclosed that a topical lotion formulation with 0.01% HP exhibited a similar VCA score as Ultravate® (0.05% HP). T. 181:4-14, 367:19-368:17; *see also* DX-142 ('824 Publication) at Examples 1 and 3. The '824 Publication also disclosed that the topical lotion formulations with a lower concentration of HP than Ultravate® could be safely administered for periods longer than two consecutive weeks. T. 181:4-14; *see also* DX-142 ('824 Publication) at [0035].

282. A person of ordinary skill in the art would have been motivated to use 0.01% HP in combination with Taz with a reasonable expectation of success in view of the '824 Publication's disclosure that 0.01% was nearly as potent and efficacious

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

as 0.05% HP but provided greater safety and allowed for a longer duration of treatment. T. 180:23-181:14.

283. A person of ordinary skill in the art would have been further motivated to select a concentration of 0.01% HP for the combination based on the IDP-118 Study, which disclosed that IDP-118 Lotion included the combination of 0.01% HP and 0.045% Taz, which are identical to the concentrations of HP and Taz recited in the claims of the '895 and '787 patents. T. 180:10-22, 666:24-667:14; *see also* DX-064 (IDP-118 Study) at 1-2.

284. A person of ordinary skill in the art who was aware of the disclosure of a lotion with 0.01% HP and 0.045% Taz in the IDP-118 Study would have been motivated to look to the '824 Publication for information on a vehicle for a composition with 0.01% HP because it is the only prior art reference that a POSA would have known to explicitly disclose 0.01% HP formulations. T. 298:4-25, 667:15-668:13, 669:24-670:1. The '824 Publication provides two vehicle choices for a lotion containing 0.01% HP – formulation C in Table 1 and Formulation 4A in Table 4. T. 670:12-20; *see also* DX-142 ('824 Publication) at Tables 1, 4. The '824 Publication was the only prior art reference that explicitly disclosed a vehicle for a composition containing 0.01% HP. T. 299:1-6, 667:15-668:13, 669:24-670:1.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

285. The IDP-118 Study would have motivated the person of ordinary skill in the art to select the concentration of 0.01% HP from among the various HP concentrations disclosed in the '824 Publication. T. 298:20-25.

286. The '824 Publication discloses that formulations with HP at 0.035%, 0.025%, and 0.01% each provided similar VCA scores as Ultravate®. DX-142 ('824 Publication) at [0040], Tables 1, 3. A person of ordinary skill in the art would have known that a lower concentration of HP would provide a lower risk of systemic adverse events. T. 123:7-14, 166:11-167:10, 673:13-674:6; 794:24-795:4. A person of ordinary skill in the art would have therefore been motivated to select the 0.01% concentration of HP from the formulations that provide similar VCA scores as Ultravate® in order to minimize the risks of systemic adverse events. T. 123:7-14, 166:11-167:10, 219:15-20, 673:13-674:6; 794:24-795:4; *see also* DX-142 ('824 Publication) at [0040], Tables 1, 3.

iii. A POSA Would Have Been Motivated To Use 0.045% Taz In The Combination Product (Limitation 3.2)

287. A person of ordinary skill in the art would have been motivated to select a concentration of 0.045% Taz for the combination based on the IDP-118 Study, which disclosed that IDP-118 Lotion included the combination of 0.01% HP and 0.045% Taz, which are identical to the concentrations of HP and Taz recited in the

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

claims of the '895 and '787 patents. T. 180:10-22, 666:24-667:14; *see also* DX-064 (IDP-118 Study) at 1-2.

288. A person of ordinary skill in the art would have also been motivated to reduce the concentration of Taz from 0.05% to 0.045% with a reasonable expectation of success because they would understand that 0.045% is comparable to 0.05% and would offer the potential for similar efficacy as 0.05% Taz with lower potential for irritation. T. 87:13-17, 120:8-14, 373:23-374:15, 435:10-17, 700:7-21; *see also* JTX-009-3 at BAU00002791; JTX-009-5 at BAU00013662.

289. A person of ordinary skill in the art would have also arrived at a concentration of 0.045% Taz through routine optimization of the concentration because 0.045% is comparable to the concentration of 0.05% in the commercialized Tazorac® product. T. 377:1-9.

iv. The '824 Publication Disclosed The Claimed Dermatologically Acceptable Carrier (Limitation 3.3)

290. The '824 Publication (DX-142) shares the same specification as the '307 and '502 patents. T. 168:4-16, 669:24-670:1; *compare* DX-142 ('824 Publication) *with* JTX-001 ('307 patent) and JTX-004 ('502 patent). The '824 Publication discloses two formulations that fall within the scope of the claims of the '895 and '787 patents. T. 574:2-4. Formulation 4A in Table 4 of the '824 Publication is identical to the vehicle of IDP-118 Lotion disclosed in the '895 and

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

'787 patents. T. 139:3-12, 610:25-611:17; *see also* DX-142 ('824 Publication) at Table 4; JTX-002 ('895 Patent) at Table 4; JTX-003 ('787 patent) at Table 4.

291. The '824 Publication teaches topical lotions comprising HP dissolved in a liquid oil component that is liquid at room temperature (22°C) and consists of diethyl sebacate and light mineral oil. T. 366:4-367:15; *see also* DX-142 ('824 Publication) at [0012], [0014], [0022], [0026].

292. The '824 Publication discloses a total of only 7 example formulations that include a concentration of HP less than 0.05%. DX-142 ('824 Publication) at Tables 1, 4, and 5. Given this limited universe of possibilities, a person of ordinary skill in the art would have considered and found it obvious to try each of the 7 formulations. T. 431:21-432:1.

293. A person of ordinary skill in the art would have been motivated to use Formulation 4A from the '824 Publication as a vehicle for the 0.01% HP and 0.045% Taz combination because it is one of only two formulations disclosed in the '824 Publication that includes 0.01% HP, the same concentration of HP disclosed by the IDP-118 Study, and because the '824 Publication discloses a method of making Formulation 4A. T. 298:11-299:6, 367:19-369:5, 670:9-20; *see also* DX-142 ('824 Publication) at Tables 1 & 4. Additionally, Formulation 4A does not contain propylene glycol as an ingredient, and a skilled artisan would have known that propylene glycol was known to be an irritating compound and would have been

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

motivated to select a formulation that did not include propylene glycol. DX-142 DX-142 ('824 Publication) at Table 4; T. 86:17-87:9, 128:10-23, 137:11-19; JTX-011-3 at BAU00054964.

294. A person of ordinary skill in the art would have also been motivated to select a formulation with 0.01% HP, such as Formulation 4A, given the knowledge that a lower concentration of HP will present a lower risk of systemic side effects and the '824 Publication's teaching that 0.01% could provide a similar VCA score as Ultravate®, 0.025% HP, and 0.035% HP. T. 123:7-14, 166:11-167:10, 219:15-20, 673:13-674:6; 794:24-795:4; *see also* DX-142 ('824 Publication) at [0040], Tables 1, 3.

v. **Synergy Is An Inherent Property Of IDP-118 And Would Have Been Reasonably Expected (Limitation 3.4)**

295. Applying the IDP-118 formulation to patients suffering from psoriasis naturally and inherently results in any synergistic efficacy and any synergistic reduction in adverse events that are observed. T. 185:17-186:2. If synergies are provided by IDP-118, they are an inherent property of the IDP-118 formulation. T. 185:17-186:2.

296. Moreover, 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

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

to have additive or synergistic effects.” T. 178:15-17, 183:7-10, 185:3-8, 294:7-295:1, 695:25-696:5; *see also* DX-140 (Gollnick) at 2. Given Gollnick’s statement and the knowledge of a person of ordinary skill in the art regarding the mechanisms of action of HP and Taz, a person of ordinary skill in the art would have reasonably expected that the combination of 0.01% HP and 0.045% Taz would be capable of providing the claimed synergistic efficacy and a synergistic reduction of an adverse event. T. 184:20-185:16, 294:15-295:1.

297. A person of ordinary skill in the art would understand that the word “synergy” as used in Gollnick and Bausch’s FDA submissions to have a specific definition that is consistent with the Court’s construction of “synergistic efficacy” and a “synergistic reduction in an adverse event.” T. 293:1-7.

298. DX-127 (Kircik 2011) teaches that the term “synergy” has an established definition in “pharmaceutical discussions” and “pharmaceutical discourse,” which means “the sum of the two agents’ combined action is greater than the sum of the efficacy of the constituent parts.” T. 697:8-698:2, 702:8-11; *see also* DX-127 (Kircik 2011) at 1. DX-127 also teaches that “[w]ithin pharmacological discourse synergy indicates not only that agents are compatible but that the product of their combined action is greater than the sum of the efficacy of the constituent parts.” T. 697:8-698:2, 702:8-11; *see also* DX-127 (Kircik 2011) at 1.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

299. Gollnick's discussion of combination therapies with Taz and corticosteroids is within pharmacological discourse.

300. Bausch's submissions to the FDA during the approval process for Duobrii® are within pharmacological discourse.

301. Synergy under this Court's construction is not rare in the context of fixed-dose combinations for psoriasis. There are three FDA approved fixed-dose combinations for psoriasis – Duobrii®, Taclonex®, and Enstilar®. T. 692:18-22. Duobrii® and Taclonex® both demonstrate synergy under this Court's construction, and there has not been a clinical trial performed with Enstilar® that would enable a determination of whether Enstilar® also demonstrates synergy. T. 692:18-22.

vi. The '824 Publication Disclosed Lotion Emulsions (Limitation 3.6)

302. The '824 Publication disclosed a method for manufacturing emulsion formulations that are lotions comprising 0.01% HP, an aqueous phase comprising carbomer copolymer type B and carbomer homopolymer type A, and a liquid oil phase consisting of diethyl sebacate and light mineral oil that dissolved the HP. T. 368:21-370:24; *see also* DX-142 ('824 Publication) at Example 4.

303. A person of ordinary skill in the art would have been motivated to use Formulation 4A from the '824 Publication as a vehicle for the 0.01% HP and 0.045% Taz combination because it is one of only two formulations disclosed in the '824

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

Publication that includes 0.01% HP, the same concentration of HP disclosed by the IDP-118 Study and because the '824 Publication discloses a method of making Formulation 4A. T. 298:11-299:6, 367:19-369:5, 670:9-20; *see also* DX-142 ('824 Publication) at Tables 1 & 4.

304. The IDP-118 Study also disclosed the combination of 0.01% HP and 0.045% Taz in a lotion. T. 180:10-22, 666:16-667:14; *see also* DX-064 (IDP-118 Study) at 1-2.

vii. A POSA Would Have Expected HP And Taz Would Be Dissolved In The Liquid Oil Component Of The '824 Publication (Limitation 3.5)

305. The '824 Publication disclosed that HP was completely dissolved in the liquid oil component of the formulation at room temperature (22°C). T. 366:4-367:3, 370:3-24; *see also* DX-142 ('824 Publication) at [0016], Example 4.

306. The '824 Publication discloses a total of only 7 example formulations that include a concentration of HP less than 0.05%. DX-142 ('824 Publication) at Tables 1, 4, and 5. Given this limited universe of possibilities, a person of ordinary skill in the art would have considered and found it obvious to try each of the 7 formulations. T. 431:21-432:1.

307. A person of ordinary skill in the art would have been motivated to use Formulation 4A from the '824 Publication as a vehicle for the 0.01% HP and 0.045% Taz combination because it is one of only two formulations disclosed in the '824

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

Publication that includes 0.01% HP, the same concentration of HP disclosed by the IDP-118 Study and because the '824 Publication discloses a method of making Formulation 4A. T. 298:11-299:6, 367:19-369:5, 670:9-20; *see also* DX-142 ('824 Publication) at Tables 1 & 4.

308. Adding 0.045% Taz to the 0.01% HP lotion formulation disclosed in the '824 Publication would have been a matter of routine optimization, and a person of ordinary skill in the art would have reasonably expected 0.045% Taz would be dissolved by the liquid oil component of the lotion formulation disclosed in the '824 Publication given Taz's known chemical properties and its known solubility in lipophilic vehicles. T. 370:25-373:1. Additionally, prior to 2015, Taz was known to dissolve in diisopropyl adipate, which is similar to the diethyl sebacate solvent disclosed in the '824 Publication and claimed in the '895 and '787 patents. T. 373:2-21; *see also* DX-203 ('716 Patent) at Example 1.

309. Determining the solubility of Taz in the liquid oil component disclosed in the '824 Publication would have been a matter of routine solubility studies. T. 370:25-373:1, 612:10-25, 794:20-23. A person of ordinary skill in the art would have known that it was routine to assess the solubility of the active ingredients of a drug formulation in the vehicles. T. 370:25-371:19. A person of ordinary skill in the art would have also known that it was routine to test for interactions between

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

active ingredients when formulating a combination product with more than one active ingredient. T. 372:14-22.

viii. A POSA Would Have Been Motivated To Combine The '824 Publication, Gollnick, And The IDP-118 Study With A Reasonable Expectation Of Success

310. A person of ordinary skill in the art would have been motivated to combine the '824 Publication, Gollnick, and the IDP-118 Study with a reasonable expectation of success. T. 182:21-183:2.

311. The '824 publication and Gollnick, and the IDP-118 Study all deal with treating psoriasis with topical corticosteroids, and Gollnick and the IDP-118 Study both deal with treating psoriasis with topical Taz. T. 184:6-13. The '824 Publication discloses 0.01% HP in a lotion with similar efficacy to 0.05% HP that can be safely administered for longer than two consecutive weeks. T. 183:4-6, 184:6-8, 184:14-19. Gollnick teaches that combining Taz and a topical corticosteroid enhances the efficacy of treatment and will likely provide synergistic effects. T. 183:7-10. The IDP-118 Study teaches the combination of HP and Taz in a single lotion vehicle for treating psoriasis at the exact concentrations claimed in claim 3 of the '895 patent. T. 183:14-18.

312. Thus, claim 3 of the '895 patent would have been obvious to a person of ordinary skill in the art over the combination of the '824 Publication. Gollnick,

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

and the IDP-118 Study. T. 167:13-168:3, 170:4-17, 186:7-187:17, 194:14-16, 374:17-375:22, 379:8-19.

b. Claim 3 Of The '895 Patent Would Have Been Obvious Over The '824 Publication In Combination With Gollnick And The Tazorac® Label

i. A POSA Would Have Been Motivated To Combine HP And Taz In A Single Formulation To Treat Psoriasis (Limitations 3.1, 3.2)

313. A person of ordinary skill in the art would have been motivated to combine HP and Taz in a single formulation to treat psoriasis with a reasonable expectation of success in view of Gollnick for the reasons discussed above. *Supra* Section II.C.3.a.i.

ii. A POSA Would Have Been Motivated To Use 0.01% HP In The Combination Product (Limitation 3.1)

314. A person of ordinary skill in the art would have been motivated to use 0.01% HP in a combination with Taz with a reasonable expectation of success in view of the '824 Publication as discussed above. *Supra* Section II.C.3.a.ii.

iii. A POSA Would Have Been Motivated To Use 0.045% Taz In The Combination Product (Limitation 3.2)

315. Tazorac® Cream was approved for treating psoriasis at Taz concentrations of 0.05% and 0.1%. T. 51:14-20, 108:25-109:19, 181:21-182:20; *see also* DX-010 (Tazorac® Label) at Indications and Usage. A person of ordinary skill

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

in the art would have expected Taz at 0.05% to be effective in treating psoriasis prior to 2015. T. 51:18-20, 108:25-109:19.

316. Prior to 2015, topical Taz treatment was known to cause local skin irritation. T. 51:21-52:1, 109:20-110:2, 181:22-25; *see also* DX-010 (Tazorac® Label) at 5.2 Local Irritation.

317. Prior to 2015, treatment with 0.05% Taz was known to induce less irritation than treatment with 0.1% Taz. T. 182:1-5; *see also* DX-010 (Tazorac® Label) at 5.2 Local Irritation, 6.1 Clinical Trials Experience. The Tazorac® Label recommended that patients who experienced intolerable levels of irritation with 0.1% Taz be switched to the 0.05% Taz dose. T. 182:1-5; *see also* DX-010 (Tazorac® Label) at 5.2 Local Irritation.

318. A person of ordinary skill in the art would have been motivated to reduce the concentration of Taz from 0.05% to 0.045% with a reasonable expectation of success to further reduce the irritation potential of the treatment. T. 181:15-182:5.

319. A person of ordinary skill in the art would have reasonably expected that 0.045% Taz would be efficacious for psoriasis. T. 182:6-20. The Tazorac® Label teaches that there was little difference in the efficacy rates for treating psoriasis between the 0.05% Taz and 0.1% Taz formulations. T. 182:6-20; *see also* DX-010 (Tazorac® Label) at Clinical Studies. Therefore, a person of ordinary skill in the art would have reasonably expected that a further lowering of the Taz concentration by

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

only 10% would lower irritation and not substantially impact efficacy and thereby improve the product. T. 182:17-20.

320. A person of ordinary skill in the art would have also been motivated to reduce the concentration of Taz from 0.05% to 0.045% with a reasonable expectation of success because they would understand that 0.045% is comparable to 0.05% and would offer the potential for similar efficacy as 0.05% Taz. T. 120:8-14, 373:23-374:15, 435:10-17, 700:7-21; *see also* JTX-009-3 at BAU00002791; JTX-009-5 at BAU00013662.

321. A person of ordinary skill in the art would have also arrived at a concentration of 0.045% Taz through routine optimization of the concentration because 0.045% is comparable to the concentration of 0.05% in the commercialized Tazorac® product. T. 377:1-9.

iv. The '824 Publication Disclosed The Claimed Dermatologically Acceptable Carrier (Limitation 3.3)

322. The '824 Publication disclosed the dermatologically acceptable carrier claimed in claim 3 of the '895 patent for the reasons explained above. *Supra* Section II.C.3.a.iv.

v. Synergy Is An Inherent Property Of IDP-118 And Would Have Been Reasonably Expected (Limitation 3.4)

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

323. The capability of providing synergistic efficacy and a synergistic reduction in an adverse event recited in claim 3 of the '895 patent are inherent properties of IDP-118 and would have reasonably been expected from the combination of 0.01% HP and 0.045% Taz for the reasons explained above. *Supra* Section II.C.3.a.v.

vi. The '824 Publication Disclosed Lotion Emulsions (Limitation 3.6)

324. The '824 Publication disclosed emulsion formulations that are lotions as explained above. *Supra* Section II.C.3.a.vi.

vii. A POSA Would Have Expected HP And Taz Would Be Dissolved In The Liquid Oil Component Of The '824 Publication (Limitation 3.5)

325. A person of ordinary skill in the art would have reasonably expected that HP and Taz would be dissolved in the liquid oil component of the '824 Publication for the reasons explained above. *Supra* Section II.C.3.a.vii.

viii. A POSA Would Have Been Motivated To Combine The '824 Publication, Gollnick, And The Tazorac® Label With A Reasonable Expectation Of Success

326. A person of ordinary skill in the art would have been motivated to combine the '824 Publication, Gollnick, and the Tazorac® Label with a reasonable expectation of success. T. 182:21-183:2.

327. The '824 publication and Gollnick both deal with treating psoriasis with topical corticosteroids, and Gollnick and the Tazorac® Label both deal with treating

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

psoriasis with topical Taz. T. 184:6-13. The '824 Publication discloses 0.01% HP in a lotion with similar efficacy to 0.05% HP that can be safely administered for longer than two consecutive weeks. T. 183:4-6, 184:6-8, 184:14-19. Gollnick teaches that combining Taz and a topical corticosteroid enhances the efficacy of treatment and will likely provide synergistic effects. T. 183:7-10. The Tazorac® Label teaches that using a concentration of 0.045% Taz is reasonably likely to reduce irritation and maintain efficacy. T. 183:11-13.

328. Thus, claim 3 of the '895 patent would have been obvious to a person of ordinary skill in the art over the combination of the '824 Publication, Gollnick, and the Tazorac® Label. T. 167:13-168:3, 170:4-17, 186:7-187:17, 194:14-16, 374:17-375:22, 379:8-19.

c. Claim 3 Of The '895 Patent Would Have Been Obvious Over The '824 Publication In Combination With Gollnick And Gandhi

i. A POSA Would Have Been Motivated To Combine HP And Taz In A Single Formulation To Treat Psoriasis (Limitations 3.1, 3.2)

329. A person of ordinary skill in the art would have been motivated to combine HP and Taz in a single formulation to treat psoriasis with a reasonable expectation of success for the reasons discussed above. *Supra* Section II.C.3.a.i.

330. A person of ordinary skill in the art would have been further motivated to combine HP and Taz in a single formulation to treat psoriasis with a reasonable

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

expectation of success by Gandhi. T. 179:15-180:4. Gandhi (DX-141), an Indian Patent Application published in 2012 disclosed topical formulations, including lotions, that include HP and Taz in a single formulation. T. 179:21-24; *see also* DX-141 (Gandhi) at 3-31.

ii. A POSA Would Have Been Motivated To Use 0.01% HP In The Combination Product (Limitation 3.1)

331. A person of ordinary skill in the art would have been motivated to use 0.01% HP in a combination with Taz with a reasonable expectation of success in view of the '824 Publication as discussed above. *Supra* Section II.C.3.a.ii.

iii. A POSA Would Have Been Motivated To Use 0.045% Taz In The Combination Product (Limitation 3.2)

332. A person of ordinary skill in the art would have been motivated to use 0.045% Taz in combination with 0.01% HP with a reasonable expectation of success for the reasons explained above. *Supra* Section II.C.3.a.iii.

333. A person of ordinary skill in the art would have been further motivated to select a concentration of 0.045% Taz for the combination, and would have had a reasonable expectation of success in doing so, based on Gandhi, which disclosed Taz as part of the combination at a concentration of 0.05%, which is comparable to the 0.045% concentration claimed in claim 3 of the '895 patent. T. 120:8-14, 121:20-122:5, 300:11-15, 377:1-9, 671:20-25; *see also* DX-141 (Gandhi) at 9.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

iv. **The '824 Publication Disclosed The Claimed Dermatologically Acceptable Carrier (Limitation 3.3)**

334. The '824 Publication disclosed the dermatologically acceptable carrier claimed in claim 3 of the '895 patent for the reasons explained above. *Supra* Section II.C.3.a.iv.

v. **Synergy Is An Inherent Property Of IDP-118 And Would Have Been Reasonably Expected (Limitation 3.4)**

335. The capability of providing synergistic efficacy and a synergistic reduction in an adverse event recited in claim 3 of the '895 patent are inherent properties of IDP-118 and would have reasonably been expected from the combination of 0.01% HP and 0.045% Taz for the reasons explained above. *Supra* Section II.C.3.a.v.

336. Moreover, Gandhi disclosed HP and Taz “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.” T. 179:25-180:4, 185:9-12, 695:25-696:5; *see also* DX-141 (Gandhi) at 7.

337. A person of ordinary skill in the art would understand that the word “synergy” as used in Gollnick, Gandhi, and Bausch’s FDA submissions to have a

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

specific definition that is consistent with the Court's construction of "synergistic efficacy" and a "synergistic reduction in an adverse event." T. 293:1-7.

338. Gandhi's discussion of synergy resulting from the combination of HP and Taz in a single formulation is within pharmacological discourse.

vi. The '824 Publication Disclosed Lotion Emulsions (Limitation 3.6)

339. The '824 Publication disclosed emulsion formulations that are lotions as explained above. *Supra* Section II.C.3.a.vi.

340. Gandhi also disclosed the combination of HP and Taz in a lotion. T. 179:21-24; *see also* DX-141 (Gandhi) at 3-31.

vii. A POSA Would Have Expected HP And Taz Would Be Dissolved In The Liquid Oil Component Of The '824 Publication (Limitation 3.5)

341. A person of ordinary skill in the art would have reasonably expected that the HP and Taz would be dissolved in the liquid oil component of the '824 Publication for the reasons explained above. *Supra* Section II.C.3.a.vii.

viii. A POSA Would Have Been Motivated To Combine The '824 Publication, Gollnick, And Gandhi With A Reasonable Expectation Of Success

342. A person of ordinary skill in the art would have been motivated to combine the '824 Publication, Gollnick, and Gandhi with a reasonable expectation of success. T. 182:21-183:2.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

343. The '824 publication and Gollnick, and Gandhi all deal with treating psoriasis with topical corticosteroids, and Gollnick and Gandhi both deal with treating psoriasis with topical Taz. T. 184:6-13. The '824 Publication discloses 0.01% HP in a lotion with similar efficacy to 0.05% HP that can be safely administered for longer than two consecutive weeks. T. 183:4-6, 184:6-8, 184:14-19. Gollnick teaches that combining Taz and a topical corticosteroid enhances the efficacy of treatment and will likely provide synergistic effects. T. 183:9-12. Gandhi teaches the combination of HP and Taz in a single lotion that provides synergistic effects for treating psoriasis. T. 183:19-25.

344. Thus, claim 3 of the '895 patent would have been obvious to a person of ordinary skill in the art over the combination of the '824 Publication, Gollnick, and Gandhi. T. 167:13-168:3, 170:4-17, 186:7-187:17, 194:14-16, 374:17-375:22, 379:8-19.

d. Claim 6 Of The '895 Patent Would Have Been Obvious

345. Claim 6 of the '895 patent incorporates the limitations of claim 1 and additionally requires that an aqueous phase of the emulsion comprises a carbomer copolymer type B and a carbomer homopolymer type A, and that the diethyl sebacate is present at a concentration of 2.5-3.5 percent by weight of the composition, the light mineral oil is present at a concentration of 7.5-8.5 percent by weight of the composition, the carbomer copolymer type B is present at a concentration of 0.3-0.5

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

percent by weight of the composition, and the carbomer homopolymer type A is present at a concentration of 0.5-0.7 percent by weight of the composition. App'x A at II.A.2.6 (Limitations 6.5, 6.6); T. 172:13-25, 375:23-376:14.

346. The limitations of Claim 1 (Limitations 6.1-6.4) have been addressed above with respect to claim 3 of the '895 Patent. *See* Section II.C.3.a-c *supra*. The '824 Publication discloses the additional dependent limitations of claim 6 of the '895 patent (Limitations 6.5 & 6.6). T. 375:23-377:22.

347. Formula 4A of the '824 Publication discloses a pharmaceutical composition for treating psoriasis comprising 0.01% HP, diethyl sebacate at 2.97%, light mineral oil from 8.03%, and an aqueous phase that includes Pemulen TR-1 (carbomer copolymer type B) at 0.4% and Carbomer 981 (carbomer homopolymer type A) at 0.6%. T. 375:23-377:22; *see also* DX-142 ('824 publication) at Table 4; (Limitations 6.5 & 6.6).

348. The '824 Publication discloses a total of only 7 example formulations that include a concentration of HP less than 0.05%. DX-142 ('824 Publication) at Tables 1, 4, and 5. Given this limited universe of possibilities, a person of ordinary skill in the art would have considered and found it obvious to try each of the 7 formulations. T. 431:21-432:1.

349. A person of ordinary skill in the art would have been motivated to use Formulation 4A from the '824 Publication as a vehicle for the 0.01% HP and 0.045%

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

Taz combination because it is one of only two formulations disclosed in the '824 Publication that includes 0.01% HP, the same concentration of HP disclosed by the IDP-118 Study and because the '824 Publication discloses a method of making Formulation 4A. T. 298:11-299:6, 367:19-369:5, 670:9-20; *see also* DX-142 ('824 Publication) at Tables 1 & 4. Additionally, Formulation 4A does not contain propylene glycol as an ingredient, and a skilled artisan would have known that propylene glycol was known to be an irritating compound and would have been motivated to select a formulation that did not include propylene glycol. DX-142 DX-142 ('824 Publication) at Table 4; T. 86:17-87:9, 128:10-23, 137:11-19; JTX-011-3 at BAU00054964.

350. A person of ordinary skill in the art would have also been motivated to select a formulation with 0.01% HP, such as Formulation 4A, given the knowledge that a lower concentration of HP will present a lower risk of systemic side effects and the '824 Publication's teaching that 0.01% HP could provide a similar VCA score as Ultravate®, 0.025% HP, and 0.035% HP. T. 123:7-14, 166:11-167:10, 219:15-20, 673:13-674:6; 794:24-795:4; *see also* DX-142 ('824 Publication) at [0040], Tables 1, 3.

351. Given the teachings of the '824 Publication, and the reasons described in Section II.C.3.a-c above for claim 3 of the '895 patent, a skilled artisan would have found claim 6 of the '895 patent obvious in view of:

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

- The '824 Publication in combination with Gollnick and the Tazorac® Label;
- The '824 Publication in combination with Gollnick and the IDP-118 Study; and
- The '824 Publication in combination with Gollnick and Gandhi.

T. 167:13-168:3, 170:4-17, 187:18-188:7, 194:14-16, 375:23-377:22, 379:8-19.

e. Claim 4 Of The '787 Patent Would Have Been Obvious

352. Claim 4 of the '787 patent depends from claim 3 which depends from claim 1. App'x A at II.B. T. 173:4-15. Claim 4 of the '787 patent is directed to:

- 1) a method of treating psoriasis by topically applying a topical pharmaceutical composition to an affected area of a body of a subject suffering from psoriasis; wherein the composition comprises an oil-in-water emulsion that includes 0.01% w/w HP;
- 2) 0.045% w/w Taz;
- 3) an aqueous dermatologically acceptable carrier comprising carbomer copolymer type B, carbomer homopolymer type A, and a liquid oil comprising diethyl sebacate and light mineral oil
- 4) the composition is capable of providing synergistic efficacy and synergistic reduction of at least an adverse event selected from the group consisting of itching, burning, and stinging;

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

- 5) the method is carried out one or more times per day for a period of time sufficient to treat such psoriasis;
- 6) the composition is an oil-in-water emulsion; and
- 7) the HP and Taz are dissolved in a component of said liquid oil of the oil-in-water emulsion.

App'x A at II.B.1; T. 173:4-15; *see also* JTX-003 ('787 patent) at claim 4.

353. The method of treating and Limitations 4.1, 4.2, 4.4, and 4.7 have been addressed above with respect to claim 3 of the '895 patent. *Supra* Section II.C.3.a-c. Limitation 4.6 is disclosed by the '824 Publication. T. 369:6-370:24; *see also* DX-142 ('824 Publication) at Example 4. Limitation 4.5 is disclosed by Gollnick and would have been obvious in view of common practice of treatments with topical corticosteroids. T. 188:22-189:4; *see also* DX-140 (Gollnick) at 2-3.

354. Limitation 4.3 is disclosed by the '824 publication. T. 369:6-370:24; *see also* DX-142 ('824 Publication) at Example 4. Formulation 4A of the '824 Publication discloses a lotion formulation with an aqueous dermatologically acceptable carrier comprising carbomer copolymer type B, carbomer homopolymer type A, and a liquid oil comprising diethyl sebacate and light mineral oil. T. 369:6-370:24; *see also* DX-142 ('824 Publication) at Example 4.

355. The '824 Publication discloses a total of only 7 example formulations that include a concentration of HP less than 0.05%. DX-142 ('824 Publication) at

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

Tables 1, 4, and 5. Given this limited universe of possibilities, a person of ordinary skill in the art would have considered and found it obvious to try each of the 7 formulations. T. 431:21-432:1.

356. A person of ordinary skill in the art would have been motivated to use Formulation 4A from the '824 Publication as a vehicle for the 0.01% HP and 0.045% Taz combination because it is one of only two formulations disclosed in the '824 Publication that includes 0.01% HP, the same concentration of HP disclosed by the IDP-118 Study and because the '824 Publication discloses a method of making Formulation 4A. T. 298:11-299:6, 367:19-369:5, 670:9-20; *see also* DX-142 ('824 Publication) at Tables 1 & 4. Additionally, Formulation 4A does not contain propylene glycol as an ingredient, and a skilled artisan would have known that propylene glycol was known to be an irritating compound and would have been motivated to select a formulation that did not include propylene glycol. DX-142 DX-142 ('824 Publication) at Table 4; T. 86:17-87:9, 128:10-23, 137:11-19; JTX-011-3 at BAU00054964.

357. A person of ordinary skill in the art would have also been motivated to select a formulation with 0.01% HP, such as Formulation 4A, given the knowledge that a lower concentration of HP will present a lower risk of systemic side effects and the '824 Publication's teaching that 0.01% HP could provide a similar VCA score as Ultravate®, 0.025% HP, and 0.035% HP. T. 123:7-14, 166:11-167:10,

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

219:15-20, 673:13-674:6; 794:24-795:4; *see also* DX-142 ('824 Publication) at [0040], Tables 1, 3.

358. A person of ordinary skill in the art would have found it obvious to apply the composition recited in claim 4 of the '787 patent to an affected area of a body of a subject suffering from psoriasis once or more times per day for a period of time sufficient to treat the patient's psoriasis (Limitations 4.1 & 4.5) because such an application would be standard in the application of topical psoriasis products and within the common knowledge in the field of dermatology. T. 188:22-25. Additionally, Gollnick teaches that applying a combination of Taz and a corticosteroid once per day was effective at both 8 and 12 weeks for treating psoriasis. T. 189:1-4; *see also* DX-140 (Gollnick) at 2-3.

359. Given the teachings of the '824 Publication and Gollnick, and the reasons described in Section II.C.3.a-c above for claim 3 of the '895 patent, a skilled artisan would have found claim 4 of the '787 patent obvious in view of:

- The '824 Publication in combination with Gollnick and the Tazorac® Label;
- The '824 Publication in combination with Gollnick and the IDP-118 Study; and
- The '824 Publication in combination with Gollnick and Gandhi.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

T. 167:13-168:3, 170:4-17, 188:8-189:9, 194:14-16, 370:25-373:1, 377:23-378:23, 379:8-19.

f. Claim 5 of the '787 patent

360. Claim 5 of the '787 patent is a method of treating claim that depends from claim 3 and additionally recites that the oil-in-water emulsion is a lotion. App'x A at II.B.2; T. 173:1-174:4.

361. The method of treating and the limitations from claim 3 (Limitations 5.1-5.6) have been addressed above with respect to claim 4 of the '787 patent. *Supra* Section II.C.e. The limitation requiring that the oil-in-water emulsion is a lotion (Limitation 5.7) has been addressed above with respect to claim 3 of the '895 patent. *Supra* Section II.C.3.a-c. Therefore, a skilled artisan would have found claim 5 of the '787 patent obvious in view of:

- The '824 Publication in combination with Gollnick and the Tazorac® Label;
- The '824 Publication in combination with Gollnick and the IDP-118 Study; and
- The '824 Publication in combination with Gollnick and Gandhi.

T. 167:13-168:3, 170:4-17, 189:10-190:7, 194:14-16, 377:23-378:23, 379:8-19.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

g. Claim 7 of the '787 patent

362. Claim 7 of the '787 patent incorporates the method of claim 1 and additionally requires: (1) applying the composition once per day for eight weeks; and (2) the method continues to provide relief to psoriasis for a period of four weeks after the eight weeks of application. App'x A at II.B.3.6-7 (Limitations 7.6 & 7.7); T. 173:1-21.

363. The method of treating and the limitations of claim 1 (Limitations 7.1-7.5) have been addressed above in the discussion of claim 4 of the '787 patent. *See* Section II.C.3.e *supra*.

i. It Would Have Been Obvious To Apply The Combination Of 0.01% HP And 0.045% Taz For A Period Of Eight Weeks (Limitation 7.6)

364. A person of ordinary skill in the art would have reasonably expected that an eight-week treatment period would be sufficient to effectively treat psoriasis with a combination of HP and Taz. T. 190:8-21. Gollnick's Figure 1 disclosed that treatment success achieved with the Taz plus high potency corticosteroid was roughly the same at weeks 8 and 12. T. 190:16-19; *see also* DX-140 (Gollnick) at Fig. 1. Given this teaching, a person of ordinary skill in the art would have reasonably expected that an eight-week treatment period is adequate to effectively treat psoriasis with the combination of HP and Taz and would have been motivated to administer the treatment for this period of time. T. 190:16-21.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

365. A person of ordinary skill in the art would have reasonably expected that a combination product with 0.01% HP could be safely administered for an extended period of time in view of the teachings of the '824 Publication, which teaches that the concentration of 0.01% HP, which is one-eighth the concentration of HP in Ultravate® (0.05% HP), allows for greater safety and longer treatment periods. T. 190:22-191:8. A person of ordinary skill in the art would therefore have reasonably expected that a combination product with 0.01% HP could be safely administered for up to 8 consecutive weeks.

ii. **The Continued Relief To Psoriasis Provided By The Claimed Method Is An Inherent Property Of IDP-118 And Would Have Been Expected (Limitation 7.7)**

366. The length of relief of psoriasis symptoms provided by IDP-118 is simply the result of the natural reactions of the patient's disease to the IDP-118 formulation. T. 192:10-18. The extended relief of psoriasis is therefore an inherent property of the IDP-118 formulation applied to the skin of psoriasis patients. T. 192:3-7.

367. Additionally, a person of ordinary skill in the art would have reasonably expected the combination of 0.01% HP and 0.045% Taz to continue to provide relief to a patient's psoriasis for up to four weeks after an eight-week treatment periods. T. 191:9-14. Prior to 2015, Taz was known to provide a maintenance effect after cessation of therapy that could last up to four weeks after therapy was stopped. T.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

704:12-705:9; *see also* DX-151 at 293. Gollnick's Figure 1 disclosed that there was little loss in efficacy rates between the cessation of therapy and the 4-week follow up visit at week 16 for the combination of Taz and a high-potent corticosteroid. T. 191:15-192:2; *see also* DX-140 (Gollnick) at Fig. 1. The Tazorac Label® also teaches that Taz provided sustained relief to psoriasis after cessation of therapy. T. 192:10-21; *see also* DX-010 (Tazorac Label®) at Clinical Studies.

368. Therefore, a skilled artisan would have found claim 7 of the '787 patent obvious in view of:

- The '824 Publication in combination with Gollnick and the Tazorac® Label;
- The '824 Publication in combination with Gollnick and the IDP-118 Study; and
- The '824 Publication in combination with Gollnick and Gandhi.

T. 167:13-168:3, 170:4-17, 192:22-20, 193:21-194:16, 377:23-378:23, 379:8-19.

4. The Alleged Evidence Of Secondary Considerations Does Not Demonstrate Nonobviousness Of The '895 Or '787 Patents

369. There is no evidence of secondary considerations, including unexpected results, industry praise, skepticism, or long-felt but unmet need, that demonstrates that the '895 or '787 patents would not have been obvious to a skilled artisan prior to June 2015. T. 194:17-21, 378:24-379:7.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

a. No unexpected results

370. Plaintiffs have not shown that the claims of the '895 and '787 patents reflect any unexpected results that are suggestive of nonobviousness.

371. The capability of providing synergistic efficacy and a synergistic reduction in an adverse event claimed in the '895 and '787 patents is not an unexpected result. A person of ordinary skill in the art would have reasonably expected the combination of 0.01% HP and 0.045% Taz to be capable of providing the claimed synergies. *Supra* Section II.C.3.a-c.

372. Synergy under this Court's construction is not rare in the context of fixed-dose combinations for psoriasis. There are three FDA approved fixed-dose combinations for psoriasis – Duobrii®, Taclonex®, and Enstilar®. T. 692:18-22. Duobrii® and Taclonex® both demonstrate synergy under this Court's construction, and there has not been a clinical trial performed with Enstilar® that would enable a determination of whether Enstilar® also demonstrates synergy. T. 692:18-22.

b. No industry praise

373. Plaintiffs have not shown that Duobrii® has received any industry praise that is suggestive of nonobviousness for the '895 and '787 patents.

c. No skepticism

374. Plaintiffs have not shown that there was skepticism of those in the field indicative of nonobviousness of the '895 and '787 patents.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

375. Plaintiffs' only evidence of skepticism consists of self-serving testimony that is unsupported by any objective evidence. Plaintiffs' evidence therefore fails to prove that those in the field of dermatology were skeptical regarding the compositions and methods covered by the claims of the '895 and '787 patents.

d. No Long-Felt But Unmet Need

376. Plaintiffs have not demonstrated that the '895 and '787 patents are non-obvious because they solved the long-felt but unmet need for a super-potent corticosteroid that may be administered for a period of longer than two consecutive weeks.

377. Prior to the '895 and '787 Patents, the '824 Publication disclosed a super-potent 0.01% HP formulation that could be administered for a period of longer than two consecutive weeks. T. 181:4-14; *see also* DX-142 ('824 Publication) at [0035].

378. [REDACTED]

379. [REDACTED]

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

380. Topical 0.05% halobetasol propionate products, including Ultravate and generic versions, remained on the market after the launch of Duobrii, [REDACTED]
[REDACTED] See PTX-143 (Psoriasis Market Data Tab: rows 2699-2746 (Duobrii), rows 3288-3433 (generic halobetasol propionate), rows 5567-5659 (Ultravate)).

e. No Failure Of Others

381. Plaintiffs have not demonstrated that the '895 and '787 patents are non-obvious due to failure of others.

382. Plaintiffs have not offered any evidence that others tried and failed to develop the compositions and methods of the '895 and '787 patents.

383. Padagis's Abbreviated New Drug Application to market a generic version of Ultravate® does not evidence failure of others to develop the compositions of the '895 and '787 patents because Padagis's generic product was required to use the same concentration and strength of HP as that included in Ultravate®. T. 710:12-711:13.

D. Duobrii is not a commercial success that demonstrates non-obviousness

384. Plaintiffs have not proven that Duobrii® has achieved commercial success that is indicative of nonobviousness of the asserted patents.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

385. Plaintiffs have not asserted that Bryhali® is a commercially successful product. T. 743:19-22.

386. Plaintiffs have not proven that Duobrii® is coextensive with the asserted claims of the '307, '502, '895, and/or '787 patents. T. 744:5-9 (Dr. Sean Sheridan testifying that he was not offering any opinion that any product was coextensive with any patents).

387. Duobrii® is not coextensive with the asserted claims of the '307 and '502 patents at least because Duobrii® contains tazarotene as an active ingredient. T. 46:8-12. None of the asserted claims of the '307 and '502 patents recite tazarotene as an active ingredient. JTX-001 (*see* claims 1, 4, 13, 16, 19, 20); JTX-004 (*see* claims 1, 4, 13, 16).

388. Duobrii is not coextensive with the asserted claims of the '307 and '502, patents at least because the asserted claims cover concentrations of HP other than 0.01% HP, including concentrations of HP “of 0.04% or less” ('307 patent claims 16 & 20), “0.025% or less” ('307 patent claim 13), “0.01% (w/w) *or less*” ('502 patent claim 4), and “less than 0.05%” ('502 patent claim 16). App'x A at I.A-B; JTX-001 ('307 patent) at claims 1, 13, 16, 20; JTX-004 ('502 patent) at claims 1, 4, 16 (emphasis added).

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

389. Plaintiffs have failed to prove that there is a sufficient nexus between Duobrii® commercial performance and the asserted claims of the '307, '502, '895, and/or '787 patents.

390. There is insufficient nexus between Duobrii®'s commercial performance and the asserted claims of the '307 and '502 patents at least because a benefit of Duobrii® is that it's a fixed combination and patients gets the benefit of both active ingredients (HP and tazarotene) every time they apply Duobrii®, and the asserted claims of the '307 and '502 patents do not recite tazarotene as an active ingredient. T. 46:8-16; JTX-001 (*see* claims 1, 4, 13, 16, 19, 20); JTX-004 (*see* claims 1, 4, 13, 16).

391. There is insufficient nexus between Duobrii®'s commercial performance and the asserted claims of the '307, '502, '895, and '787 patents at least because a benefit of Duobrii® results from the lack of propylene glycol in formulation, which was removed during development of Duobrii® and replaced with sorbitol because propylene glycol was known to be an irritating compound. T. 128:10-23 (Dr. Radhakrishnan Pillai testifying that IDP-118 formulation was altered to remove propylene glycol and replaced with sorbitol because sorbitol was not known to be irritating). The asserted claims of the '307, '502, '895, and '787 patents cover compositions that include propylene glycol as an ingredient. *See* App'x A.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

The asserted claims of the '307, '502, '895, and '787 patents cover compositions that do not include sorbitol as an ingredient. *See* App'x A.

392.

[REDACTED]

393.

[REDACTED]

394.

[REDACTED]

14

[REDACTED]

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

[REDACTED]

[REDACTED]

395.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

396.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

397.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

398. The overall psoriasis market is relevant for evaluating the market share of Duobrii®, including Class 1 topicals, Class 2 topicals, Class 3 topicals, branded combos, vitamin D, and systemic oral drugs. T. 768:4-21; DX-504 (Bryhali Market Summary TRx Tab). Competitors to Duobrii® in the psoriasis market also include injectable products, including Cosentyx®, Taltz®, Skyrizi®, Tremfya®, and Ilumya®. T. 768:24-769:25; DX-288 at BAU00530302; DX-303 at BAU00535692.

[REDACTED] T. 772:7-20; DX-304 (Psoriasis Market Data Tab and Siliq Market Data Tab).

[REDACTED]

[REDACTED] T. 772:7-20; DX-304 (Psoriasis Market Data Tab).

399. [REDACTED]

[REDACTED]

[REDACTED]

400. [REDACTED]

[REDACTED]

[REDACTED]

401. [REDACTED]

[REDACTED]

[REDACTED]

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

402. [REDACTED]

403. [REDACTED]

404. [REDACTED]

405. The overall impact that the COVID-19 pandemic had on Duobrii's® commercial performance is speculative and has not been quantified. T. 764:2-12; 773:10-775:3; 775:19-22; *see also* 759:10-14.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

406. Plaintiffs have not presented any evidence that the COVID-19 pandemic negatively impacted Duobrii's® sales to a greater extent in 2021 than it did in 2020. T. 758:16-19.

407. The global market for psoriasis treatment exhibited a higher growth of 11.1% in 2020 as compared to 2019, and psoriasis treatment experienced higher-than-anticipated demand across all regions compared to pre-pandemic levels. DX-135 at p. 1 of 8; T. 773:17-774:11.

408. During the COVID-19 pandemic, telemedicine services played a major part in the psoriasis market growth. DX-135; T. With telemedicine services, the psoriasis management market showed higher success rates than normal care. DX-135 at p. 1 of 8; T. 774:13-18.

409. [REDACTED]

[REDACTED]

[REDACTED]

410. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

CONCLUSIONS OF LAW

Padagis proposes that this Court reach the following Conclusions of Law based on the evidence presented at trial:¹⁵

I. DEFENDANTS HAVE SHOWN ALL ASSERTED CLAIMS ARE INVALID BY CLEAR AND CONVINCING EVIDENCE

1. The party asserting patent invalidity bears the burden of proving invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 97-98 (2011). Included in this standard is the burden to prove, by clear and convincing evidence, that an invalidating reference is prior art. *See Plexxikon Inc. v. Novartis Pharm. Corp.*, 525 F. Supp. 3d 1104, 1112 (N.D. Cal. Mar. 15, 2021). However, once a party makes a *prima facie* case of invalidity, the burden of persuasion to show by clear and convincing evidence that the contrary is true shifts to the patentee. *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1328-29 (Fed. Cir. 2008).

¹⁵ To the extent that any of the identified Proposed Conclusions of Law are determined to constitute an issue of fact, Padagis hereby incorporates such issues into Padagis's Proposed Findings of Fact. To the extent that any issue identified in Padagis's Proposed Findings of Fact is determined to constitute an issue of law, Padagis hereby incorporates such issues into Padagis's Proposed Conclusions of Law.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER**A. The Claim Term “Liquid Oil Component” Renders All Asserted Claims of the ’307 and ’502 Patents Indefinite**

2. A patent must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112 ¶ 2 (pre-AIA) (stating a patent must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”). “[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).

3. “It cannot be sufficient that a court can ascribe *some* meaning to a patent’s claims[.]” *Id.* at 2130 (emphasis in original). “The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) *cert. denied*, 136 S. Ct. 59 (2015). “[A] claim is 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. v. Biosig Instr., Inc.*, 134 S.Ct. 2120, 2130 n.8). Where a claim term is used in one part of a

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

patent “in a manner that is inconsistent with the use of that same term” in another part of the patent, courts have held the affected claims invalid for indefiniteness. *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). For example, in construing the term “overlay activation signal,” the district court in *TVnGO* emphasized that a skilled artisan reviewing the patents “cannot know what happens upon receipt of an overlay activation signal because the patents teach two different results.” *Id.*

4. All Asserted Claims of the '307 and '502 patents are invalid as indefinite under 35 U.S.C. § 112 ¶ 2 (pre-AIA) because a person of ordinary skill in the art would not understand the scope of the claimed “liquid oil component” with reasonable certainty. F. 225-235.¹⁶

B. The Asserted Claims Are Obvious Over the Prior Art

5. “A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a) (pre-AIA); *see* 35 U.S.C. § 103(a) (AIA) (“A patent for a claimed invention

¹⁶ Citations to Padagis’s Proposed Findings of Fact, *supra*, are referred to herein as “F. [paragraph #].”

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious.”); *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

6. The date of invention is “presumed to be the filing date of the parent application.” *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000). The burden of establishing an earlier priority date to avoid asserted prior art rests with the patent owner, not the defendant. *Tech. Licensing Corp.*, 545 F.3d at 1328-29; *see also Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1379-80 (Fed. Cir. 2015).

7. “Obviousness under 35 U.S.C. § 103(a) is ultimately a legal question, based on underlying factual determinations.” *Eisai Co. Ltd. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1356 (Fed. Cir. 2008). “The factual determinations underpinning the legal conclusion of obviousness include 1) the scope and content of the prior art, 2) the level of ordinary skill in the art, 3) the differences between the claimed invention and the prior art, and 4) evidence of secondary factors, also known as objective indicia of non-obviousness.” *Id.* (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)); *see also Prometheus Labs., Inc. v. Roxane Labs., Inc.*, 805 F.3d 1092, 1097-98 (Fed. Cir. 2015) (citing *KSR*, 550 U.S. at 406; *Graham*, 383 U.S. at 17-18)).

8. Although the clear and convincing standard may be met more easily when the cited prior art was not previously considered by the examiner, the burden of proof

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

remains the same irrespective of whether the examiner had previously considered the reference. *See Solder Removal Co. v. U.S. Int'l Trade Comm'n*, 582 F.2d 628, 632 (C.C.P.A. 1978). Only when “no prior art other than that which was considered by the [examiner] is relied on by the attacker” does the burden include showing that the PTO was wrong its decision to grant the patent. *Power Oasis, Inv. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305 (Fed. Cir. 2008) (quoting *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1359 (Fed. Cir. 1984).

1. Level of Ordinary Skill In The Art

9. The person of ordinary skill in the art is a hypothetical person presumed to know all of the teachings of the prior art references at the time the invention was made. *See Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1576 (Fed. Cir. 1984) (describing the person of ordinary skill in the art as “the inventor working in his shop with the prior art references—which he is presumed to know—hanging on the walls around him”). The person of ordinary skill in the art is attributed with knowledge of all prior art references. *In re Sernaker*, 702 F.2d 989, 994 (Fed. Cir. 1983).

10. A person of ordinary skill in the art may be an individual who is part of a team of individuals. *See Pernix Ireland Pain DAC v. Alvogen Malta Operations Ltd.*, 323 F. Supp. 3d 566, 597 (D. Del. 2018) (finding that “a person of ordinary skill in the art would be a person or *team of persons*”) (emphasis added);

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

GlaxoSmithKline, LLC, v. Banner Pharmacaps, Inc., C.A. 11–046–RGA, 2013 WL 4082232, at *2, *9 (D. Del. Aug. 9, 2013) (finding that the “level of skill in the art is high, and would allow for a team of drug development scientists”); *see also Endo Pharm. Sols. Inc. v. Custopharm, Inc.*, 234 F.Supp.3d 587, 598 (D. Del. 2017); *Warner Chilcott Co., LLC v. Lupin Ltd.*, Civil Action Nos. 11–5048 (JAP), 12–2928(JAP), 2014 WL 202659, at *10 (D.N.J. Jan. 17, 2014) (stating that “[t]he POSA may be a composite of different types of individuals.”) (citations omitted).

11. In determining the level of ordinary skill in the art, a court should consider the following factors: (1) the types of problems encountered in the art; (2) prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology involved; and (5) the educational level of active workers in the field. *Daiichi Sankyo Co., Ltd. v. Apotex Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007); *see also U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1564 (Fed. Cir. 1997). “Not all such factors may be present in every case, and one or more . . . may predominate in a particular case.” *Envtl. Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 696-97 (Fed. Cir. 1983).

12. “While it may be easier to prove obviousness if each limitation of the claimed invention is found in the prior art, the level of skill of one of ordinary skill in the art can, at times, fill in the gap when limitations of the claimed invention are

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

not specifically found in the prior art.” *Belden Techs., Inc. v. Superior Essex Commc’ns LP*, 802 F. Supp. 2d 555, 563 (D. Del. 2011).

2. Scope and Content of the Prior Art

13. Pursuant to 35 U.S.C. 102 (Pre-AIA), a person is not entitled to a patent if: “(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or . . . (e) the invention was described in – (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language”

14. Pursuant to 35 U.S.C. 102 (AIA), a person is not entitled to a patent if: “(1) the claimed invention as patented, described in a printed publication, or in

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.”

15. Unlike § 102(b), in order to qualify as prior art under § 102(a), a reference must be “by others.” However, if the disclosure occurred more than one year prior to the earliest priority date of the challenged patent, a reference, even a reference that is the inventors’ own work, qualifies as prior art under § 102(b). *In re Katz*, 687 F.2d 450, 454 (C.C.P.A. 1982). The term “others” in § 102(a) refers to “any entity which is different from the inventive entity. The entity need only differ by one person to be ‘by others.’” MPEP § 2132 (III). Because disclosure of one’s own work less than a year before the priority date does not constitute a bar, in some instances the court must look beyond the listed authors and inventors and consider whether “the portions of the reference relied on as prior art, and the subject matter of the claims in question, represent the work of a common inventive entity.” *Riverwood Intern. Corp. v. R.A. Jones & Co., Inc.*, 324 F.3d 1346, 1356 (Fed. Cir. 2003); *In re Katz*, 687 F.2d at 454-55.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

16. “The scope of the prior art includes all analogous art.” *Donner Tech., LLC v. Pro Stage Gear, LLC*, 979 F.3d 1353, 1359 (Fed. Cir. 2020). Whether prior art is analogous is determined by two separate tests: “(1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *Id.* (quoting *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004)). “A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” *In re Klein*, 647 F.3d 1343, 1348 (quotation omitted). If a reference’s disclosure relates to the same problem as that addressed by the claimed invention, “that fact supports use of that reference in an obviousness [finding].” *Id.* (quotation omitted). The field of endeavor is determined “by reference to explanations of the invention’s subject matter in the patent application, including the embodiments, function, and structure of the claimed invention.” *In re Bigio*, 381 F.3d at 1325.

17. A prior art reference that is “not published in peer-reviewed journals or authored by one skilled in the art” nevertheless may “support the conclusion that [the] claims . . . are invalid as obvious.” *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1374-75 (Fed. Cir. 2005). Thus, merely criticizing “the

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

credentials of [a prior art] author[] . . . is not enough to avoid invalidating the claims” in view of the reference. *Id.*

18. “Under § 103, . . . a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein.” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003); *accord Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991). Under Section 103, with respect to “a prior art patent,” “a presumption arises that both the claimed and unclaimed disclosures . . . are enabled.” *Amgen*, 314 F.3d at 1355.

19. Apart from prior art references, “[a]dmissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness.” *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007) (citing *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988) (“A statement in a patent that something is in the prior art is binding on the applicant and patentee for determinations of anticipation and obviousness.”)); *Sjolund v. Musland*, 847 F.2d 1573, 1577-79 (Fed. Cir. 1988) (admission in the patent specification “must [be] accepted . . . as prior art, as a matter of law”); *In re Fout*, 675 F.2d 297, 300-01 (C.C.P.A. 1982) (“We hold that appellants’ admission that they had actual knowledge of the prior . . . invention described in the preamble constitutes an admission that it is prior art to them.”); *In re Nomiya*, 509 F.2d 566, 570-71 (C.C.P.A. 1975) (representations in the

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

specification are “accepted at face value as admissions” of what is “considered ‘prior art’ for any purpose, including use as evidence of obviousness under § 103”).

20. The fact that a reference was previously considered by the PTO merely goes to the weight of that reference’s evidence and does not increase the burden of proof or preclude a finding of invalidity. *See Sciele Pharma, Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259-1260 (Fed. Cir. 2012); *see also Surface Tech., Inc. v. U.S. Int’l Trade Comm’n*, 801 F.2d 1336, 1340-41 (Fed. Cir. 1986). A finding of invalidity may be appropriate where the reference was considered by the PTO, but the Examiner failed to give proper consideration to the teachings of that reference. *See PharmaStem*, 491 F.3d at 1366.

21. In fact, “[w]hether a reference was previously considered by the PTO, the burden of proof is the same: clear and convincing evidence.” *Sciele Pharma*, 684 F.3d at 1260 (citing *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238, 2250 (2011)). “The burden does not suddenly change to something higher— ‘extremely clear and convincing evidence’ or ‘crystal clear and convincing evidence’—simply because the prior art references were considered by the PTO.” *Id.* “In short, there is no heightened or added burden that applies to invalidity defenses that are based upon references that were before the Patent Office.” *Id.*

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

a. The IDP 118 Study is a Prior Art Printed Publication and Does not Qualify for the Experimental Use Exception

i. The IDP 118 Study Qualifies as a Printed Publication

22. A reference is proven to be a “printed publication” upon a showing that such document “has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.” *In re Wyer*, 655 F.2d 221, (CCPA 1981); *Voter Verified, Inc. v. Premiere Election Solutions*, 698 F.3d 1374, 1380 (Fed. Cir. 2012).

23. In order for a reference to be a printed publication, if the reference was sufficiently disseminated at the time of its publication, it need not be easily searchable nor indexed. *Jazz Pharm., Inc. v. Amneal Pharm., LLC*, 895 F.3d 1347, 1359 (Fed. Cir. 2018) (“We have consistently held that indexing or searchability is unnecessary for a reference to be a printed publication under § 102(b)”).

24. Electronic publications, including online data bases and internet publications, are “printed publications” provided the publications were accessible to persons concerned with the art to which the document relates. *See id.* at 227; MPEP § 2128 (II)(A). Prior art disclosures on the internet are considered to be publicly available as of the date the item was publicly posted. MPEP § 2128 (II)(A).

25. Evidence showing routine business practices can be used to establish the date on which a publication became accessible to the public. Specific evidence

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

showing when the document actually became available is not always necessary. *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988), (holding that evidence submitted by Intel regarding undated specification sheets showing how the company usually treated such specification sheets was enough to show that the sheets were accessible by the public before the critical date.)

26. Deposition testimony under Fed. R. Civ. P. 30(b)(6) is binding on the entity designating the witness. *See, e.g., Sanofi-Aventis v. Sandoz, Inc.*, 272 F.R.D. 391, 393 (D.N.J. 2011).

27. The IDP 118 Study (DX-064) qualifies as a prior art printed publication under AIA 35 U.S.C. § 102(a). F. 31-38.

ii. The IDP 118 Study Does Not Qualify for the Experimental Use Exception

28. The experimental use exception is a judge-made doctrine that may negate the “public use” or “on sale” statutory bars to patentability under pre-AIA 35 U.S.C. § 102(b) and AIA 35 U.S.C. §102(a)(1) for inventions that were in “public use” or “on sale” prior to the relevant priority date, if the public use or sale was undertaken primarily for purposes of experimentation to reduce the patent to practice. *See, e.g., Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1328 (Fed. Cir. 2019).

29. The experimental use exception does not apply to printed publications; it is an exception to negate prior art public uses or on sale bar activities. *See id.*

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

Bausch has provided no case law in which the experimental use exception was applied to negate the prior art status of a printed publication. *Sanofi v. Glenmark Pharm. Inc.*, 204 F. Supp. 3d 665 (D. Del. 2016), is instructive on this point. In *Sanofi*, the District of New Jersey noted that clinical trial protocol published on ClinicalTrials.gov disclosed “all but two elements of the asserted independent claims,” and the court assessed whether the remaining limitations would have been obvious over the ClinicalTrials.gov record and an additional prior art reference. See *id.* at 687-96. The court did not apply the experimental use exception in this analysis, nor did the court find that the protocol published on ClinicalTrials.gov was not prior art because it fell within the experimental use exception. *Id.* Instead, the court applied the experimental use exception to the defendant’s argument that the asserted patent was invalid because it was “in public use” during clinical trials prior to the relevant priority date. See *id.* at 696-99.

30. A use may be experimental only if it is designed to test claimed features of the invention or to determine whether an invention will work for its intended purpose. *Gilead Sciences, Inc. v. Sigmapharm Labs., LLC*, Civil Action No. 10–4931 (SDW)(MCA), 2014 WL 1293309, at *6 (D. N.J. Mar. 31, 2015). To determine whether the experimental use doctrine applies, courts must consider whether the activities in question “were experiments as opposed to an attempt to profit from the invention, that is, whether the primary purpose of the [activities] was

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

to conduct experimentation.” *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1365 (Fed. Cir. 2008) (citation omitted). “Neither profit, revenue, nor even an actual sale is required for the use to be a commercial offer under section 102(b)” *Id.* In deciding whether a use qualifies as an experimental use, court consider factors, such as: “(1) the length of the test period, (2) any confidentiality agreement, (3) any records of testing, (4) any monitoring and control of the test results, (5) the number of tests, and (6) the length of the test period in relation to tests of similar inventions.” *Eli Lilly and Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1381 (Fed. Cir. 2006).

31. The Federal Circuit has observed that its “cases distinguish between the standard required to show that a particular invention would work for its intended purpose and the standard that governs FDA approval of new drugs, including the various stages of clinical trials.” *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1372 (Fed. Cir. 2017). Once an invention is reduced to practice, further testing will not qualify as experimental use for purposes of the experimental use negation under § 102(b). *EZ Dock v. Schafer Sys., Inc.*, 276 F.3d 1347, 1352 (Fed. Cir. 2002); *see also Bayer Schering Pharma AG v. Barr Labs., Inc.*, Civil Action No. 05–cv–2308 (PGS), 2008 WL 628592, at *42 (D. N.J. Mar. 3, 2008) (“A use may not be experimental if the invention at issue was reduced to practice.”); *Small v. Nobel Biocare USA, LLC*, Nos. 05 Civ. 3225(NRB), 06 Civ. 683(NRB),

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

2013 WL 3972459, at *12 (“It is well established that experimental use concludes upon an invention's reduction to practice.”).

32. “Th[e] experimental-use doctrine draws a “distinction between inventions put to experimental use and products sold commercially,” in the interest of protecting both “the public’s right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention.” *See Sunoco Partners Marketing & Terminals L.P. v. U.S. Venture, Inc.*, 32 4th. 1161 (Fed. Cir. 2022) (reversing the district court’s determination that the on-sale bar defense was negated by the experimental use doctrine). But any attempt to use the invention for a profit and not by way of experiment before the critical date will deprive the inventor of his right to a patent. *Id.* at 1168 (citation and internal quotation marks omitted). In determining whether testing constitutes an experiment within the meaning of the experimental use doctrine, the testimony of the inventors that their subjective intent was experimental is “of minimal importance” and courts instead focus on the objective evidence. *Id.* at 1174.

33. “In accordance with the goals underlying the experimental use doctrine and the strong public interest in gaining rapid access to useful inventions, courts have limited the types of experimentation that trigger application of the exception.” *SmithKline Beecham Corp. v. Apotex Corp.*, 286 F. Supp. 2d 925, 933 (N.D. Ill. 2001). The experimentation cannot be for the purpose of market testing, commercial

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

profit, or testing for suitability for a customer's unclaimed needs. *Id.* “Nor can it aim to satisfy regulatory testing requirements unrelated to the claimed features of the patented invention.” *Id.* (citing *Pennwalt Corp. v. Akzona, Inc.*, 740 F.2d 1573, 1580 (Fed.Cir.1984)). The mere fact that a sale or use occurs as part of a regulatory testing procedure “*does not make such uses or sales per se experimental* for purposes of 35 U.S.C. § 102(b).” *Pennwalt Corp.*, 740 F.2d at 1580 (emphasis added).

34. As noted above, one of the factors courts consider when determining whether a use is experimental is whether the inventor maintained confidentiality during the alleged experiment. *See, e.g., Eli Lilly and Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1381 (Fed. Cir. 2006) (emphasizing that drug manufacturer “maintained confidentiality throughout the duration of the [clinical] study” when applying experimental use exception to the public use statutory bar). An inventor’s failure to monitor the use of his invention, and his “failure to impose confidentiality agreements on those” exposed to his invention is “enough to place the claimed features of the patents in the public’s possession.” *Netscape Commcn’s Corp. v. Konrad*, 295 F.3d 1315, 1323 (Fed. Cir. 2002). The fact that an entity that is funding the experimentation and owns the invention has its own confidentiality safeguards in place does not excuse the inventor from “his failure to protect the confidentiality of his invention.” *Id.* at 1322. “[T]he limitation, restriction, or

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

obligation of secrecy of others using the invention is owed to [the inventor], not the persons or entities providing the funding. The *onus is on . . . the inventor . . .* to protect the confidentiality of his invention and its use by others before the critical date.” *Id.* (citation omitted) (emphasis added). Bausch expected that the information it submitted to ClinicalTrials.gov regarding Study No. NCT02045277 would be published on the ClinicalTrials.gov website and did not have any expectation of confidentiality with respect to the information it submitted to the ClinicalTrials.gov regarding Study No. NCT02045277. F. ¶36. Bausch was not required to submit the concentrations of the active ingredients in IDP-118 to ClinicalTrials.gov. F. ¶34.

35. The Federal Circuit has noted that medical procedures at a doctor’s office or at a hospital are to some degree inherently non-public. *TP Labs., Inc. v. Prof’l Positioners, Inc.*, 724 F.2d 972 (Fed. Cir. 1984). But the fact that purportedly experimental use occurs in such “an inherently non-public environment does not by itself render the use non-public under § 102(b).” *Arrow Int’l., Inc. v. Spire Biomedical, Inc.*, 635 F. Supp. 2d 46, 76 (D. Mass. 2009). Indicia that confidentiality has not been maintained in such a setting, and, thus, that the use is not experimental, includes the fact that the procedures “were conducted no differently than any other hospital procedure[,]” the absence of evidence showing that medical personnel involved with the procedure were informed that the use was experimental and not publicly available, and the failure to have patients sign consent forms or otherwise

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

advise them that they were participating in an experimental use of a medical product.
Id.

36. Courts also consider the degree of control exercised by the inventor over the experimentation. *In re Hamilton*, 882 F.2d 1576, 1581 (Fed. Cir. 1989). “The experimental use doctrine operates in the inventor's favor to allow *the inventor* to refine his invention or to assess its value relative to the time and expense of prosecuting a patent application. If it is not the inventor or someone under his control or “surveillance” who does these things, there appears to [be] no reason why he should be entitled to rely upon them to avoid the statute.” *Id.* at 1581.

37. The IDP 118 Study (DX-064) does not qualify for the experimental use exception. F. 31-38.

3. Differences Between the Claimed Invention and the Prior Art

38. Obviousness is judged under “an expansive and flexible approach” driven by common sense. *KSR*, 550 U.S. at 415. The Court’s obviousness “analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 416. Similarly, “if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *Id.* at 417.

39. Where a claim “simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at 417 (quotation omitted). In general, a claim is invalid for obviousness if “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention,” and “would have had a reasonable expectation of success in doing so.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007).

40. A patent claim may be found obvious when there is a teaching, suggestion or motivation within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, select particular elements from those information sources, and combine them in the way they were combined by the inventor. *See KSR*, 550 U.S. at 418-20. When there is pressure to solve a problem and “there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.” *KSR*, 550 U.S. at 421. “If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” *Id.* In such instances, “the fact that a combination was obvious to try might show that it was obvious under § 103.” *Id.*

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

“On the issue of obviousness, the combined teachings of the prior art as a whole must be considered.” *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985).

41. Routine experimentation on the part of an artisan does not support non-obviousness. *See Pfizer*, 480 F.3d at 1368 (“The experimentation needed, then, to arrive at the subject matter claimed in the ’303 patent was ‘nothing more than routine’ application of a well-known problem-solving strategy”) (citing *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 809 (Fed. Cir. 1989)). “Among the inventions that the law deems obvious are those modest, routine, everyday, incremental improvements of an existing product or process that confer commercial value (otherwise they would not be undertaken) but do not involve sufficient inventiveness to merit patent protection.” *Ritchie v. Vast Resources, Inc.*, 563 F.3d 1334, 1337 (Fed. Cir. 2009). For example, “routine experimentation with different standard grades of a material used in a product—standard in the sense that their properties, composition, and method of creation are well known, mak[e] successful results of the experimentation predictable.” *Id.* Likewise, in *Ecolab*, the plaintiff-appellant argued that the jury could have reasonably concluded that the prior art did not disclose the “achieving at least a one log₁₀ reduction in the microbial population” limitation recited in some of the claims. *See Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1349 n. 2 (Fed. Cir. 2009). The Federal Circuit noted that “evidence

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

established that one skilled in the art would have known how to vary the PAA concentration or other parameters in order to achieve the disclosed one log₁₀ reduction” and concluded that “[s]uch experimentation is routine and cannot render an otherwise obvious claim valid.” *Id.* (citation omitted).

42. Although it “can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements,” a court “need not seek out precise teachings directed to the specific subject matter of the challenged claim.” *KSR*, 550 U.S. at 418. Nor can a court allow its “analysis” to “be confined by” an “overemphasis on the . . . explicit content” of prior art references. *Id.* at 419. Rather, a court must “take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418.

43. Finding a motivation to combine prior art references is not a rigid endeavor. “Far from requiring evidence of an explicit motivation to combine,” the Federal Circuit has likewise made clear that “an implicit motivation” is enough. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1366 (Fed. Cir. 2006) (emphasis removed). The Federal Circuit has “repeatedly held” that a combination may be obvious “even absent any hint of suggestion in the [prior art] references themselves.” *Id.* at 1368. A court that requires the prior art “clearly and unequivocally [to] disclose” a “motivation to combine” therefore “err[s] by taking an overly cramped view of what the prior art teaches.”

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

Allergan, Inc. v. Apotex Inc., 754 F.3d 952, 963-64 (Fed. Cir. 2014). “[T]here is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention.” *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997).

44. The Supreme Court has established that the subject matter of a patent claim can be proven obvious if there existed at the time of the alleged invention “a known problem for which there was an obvious solution encompassed by the patent’s claims.” *KSR*, 550 U.S. at 420. If “a person of ordinary skill can implement a predictable variation” or if “a technique has been used to improve one device[] and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way,” § 103 bars patentability. *Id.* at 417. “[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420. A person of skill in the art’s motivation to optimize a piece of prior art or to combine pieces of prior art need not result from an explicit teaching within the art but, instead, can result from “[t]he normal desire of scientists or artisans to improve upon what is already generally known” to satisfy the obviousness inquiry. *See In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003).

45. A person of ordinary skill in the art’s motivation to combine pieces of prior art is not limited to only the best or preferred combinations of art. The Federal

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

Circuit’s “case law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention.” *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (emphasis omitted). Obviousness does not require proof that something is “the best option, only that it be a suitable option from which the prior art did not teach away.” *Par Pharm. Inc. v. TWi Pharm., Inc.*, 773 F.3d 1186, 1198 (Fed. Cir. 2014). “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. 2015) (internal quotations omitted) (citing *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012); *see also In re Mouttet*, 686 F.3d at 1344 (“a known system such as an arithmetic/logic unit does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” (internal quotations omitted))); *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (“The prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed in the ’198 application.”); *see also Merck*, 874 F.2d at 807 (providing that the fact “[t]hat the [prior art] discloses a multitude” of other “combinations does not render [a] particular formulation less obvious”); *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (“A known or obvious composition does

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

not become patentable simply because it has been described as somewhat inferior to some other product for the same use.”).

46. “[T]he expectation of success need only be reasonable, not absolute.” *Pfizer*, 480 F.3d at 1364; *see also Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). Obviousness does not require an absolute predictability of success, but rather only “a reasonable expectation of success” in making the invention. *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1291 (Fed. Cir. 2013); *see also In re Merck*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (“Obviousness does not require absolute predictability. Only a reasonable expectation that the beneficial result will be achieved is necessary to show obviousness.”) (citations omitted). Thus, “obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.” *Pfizer*, 480 F.3d at 1364. Courts have found that a person of ordinary skill is particularly likely to have a reasonable expectation of success when optimizing methods that are already practiced in the prior art. *See, e.g., id.* at 1371-72.

47. A person of ordinary skill in the art is expected to apply the knowledge and known routine testing and experimental methods in the appropriate field of endeavor. Where the “prior art . . . predicted [that] the results” of routine testing and experimental methods in the field of endeavor would be favorable, the fact that a

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

skilled artisan would have “had to verify through routine testing” a claimed drug’s “expected traits” “does not compel a conclusion of non-obviousness.” *Id.* at 1367.

48. Moreover, the presence of multiple options does not amount to teaching away from a particular option, even when one of the options may have been preferred. *Bayer Pharma AG v. Watson Labs., Inc.*, 874 F.3d 1316, 1327 (Fed. Cir. 2017) (“In assessing whether prior art teaches away, that better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes”) (internal quotations omitted); *see also In re Mouttet*, 686 F.3d at 1334.

49. A *prima facie* case of obviousness exists where a claimed range or value overlaps with a range disclosed in the prior art. *In re Peterson*, 315 F.3d 1325, 1329-1330 (Fed. Cir. 2003); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed.Cir.2006) (“Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness.”). There are several ways a patentee may rebut that presumption. *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018). First, a modification of a process parameter may be patentable if it produces a new and unexpected result, which is different in kind and not merely in degree from the results of the prior art. *Id.* (internal quotation marks omitted) (citation omitted). A claimed range that demonstrates such unexpected results is referred to as a “critical” range, and the patentee has the burden of proving criticality. *Id.* (citation omitted). Second, a patentee may rebut the presumption of

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

obviousness by showing that the prior art taught away from the claimed range. *Id.* (citation omitted). Third, a change to a parameter may be patentable if the parameter was not recognized as “result-effective.” *Id.* (citing *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (citing *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977))). Fourth, disclosure of very broad ranges may not invite routine optimization. *Id.* (citations omitted).

50. With respect to a result effective variable, “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955); *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977). “While the absence of any disclosure regarding the relationship between the variable and the affected property may preclude a finding that the variable is result-effective, the prior art need not provide the exact method of optimization for the variable to be result-effective. A recognition in the prior art that a property is affected by the variable is sufficient to find the variable result-effective.” *In re Applied Materials, Inc.*, 692 F.3d 1289, 1297 (Fed. Cir. 2012).

51. A reference includes an inherent characteristic if that characteristic is the “natural result” flowing from the reference’s explicitly recited teachings. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001); *see also Par Pharm., Inc. v. TWi Pharm., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) (explaining

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

that 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.”). For example, a compound (and, therefore, its inherent physical properties) may be deemed to have been inherently disclosed by a reference that teaches the manner by which that compound would have been made. *See Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). Newly discovered results of known processes are inherent and unpatentable. *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). Similarly, 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) (“[The prior art’s] express teachings render the claimed . . . formulation obvious, and the claimed [blood concentration] adds nothing of patentable consequence. . . . To hold otherwise would allow any formulation—no matter how obvious—to become patentable merely by testing and claiming an inherent property”); *see also AstraZeneca LP v. Breath Ltd.*, 542 F. App’x 971, 979-80 (Fed. Cir. 2013) (affirming the district court’s obviousness finding of a method of treatment claim where, *inter alia*, the district court had found that a POSA “would have expected budesonide to exhibit the depot effect, which is an inherent property of the drug regardless of how it is delivered to the lung.”);

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

Purdue Pharm. Products L.P. v. Actavis Elizabeth LLC, Civil Action No. 12–5311 (JLL)(JAD), 2015 WL 5032650, at *46 (D. N.J. Aug. 25, 2015) (“[H]ere, the Court finds that in light of the dosages delineated in the ’809 patent and *Patat*, the concentrations in the ’809 patent are disclosed, if not inherent, and therefore obvious.”); *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, Civil Action No. 14–882–LPS, 2017 WL 1199767, at *35 (finding that defendants established that “the pharmacokinetic responses that are incorporated as limitations into certain asserted claims of the Acorda Patents are ‘inherent in the claimed dosing and [are] taken directly from the prior art.’”) (citations omitted).

52. In the context of genus claims, evidence that a single embodiment falling within the scope of the genus would have been obvious in view of the prior art is sufficient to render the genus claim obvious. *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1281 (Fed. Cir. 2015) (“It is a long-established rule that claims which are broad enough to read on obvious subject matter are un-patentable even though they also read on nonobvious subject matter.”); *see also Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001) (“Our case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim.”). That remains true when an element of a genus claim is satisfied through an inherency theory. *See, e.g., Par Pharm., Inc. v. TWi Pharm., Inc.*, 120 F. Supp. 3d 468, 475 (D. Md. July 28, 2015), *aff’d*, 624 Fed. Appx. 756

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

(Fed. Cir. 2015) (“Par has not pointed to any authority requiring TWi to show that the claimed food effect limitations are inherent in *every* formulation claimed by the ’576 patent. In the obviousness context, examples are enough.”).

53. Expert opinions that are unsupported or inconsistent with the record should be disregarded. *See, e.g., Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372, 1378–79 (Fed. Cir. 2017) (“[W]e must disregard the testimony of an expert that is plainly inconsistent with the record.”); *see also Ericsson Inc. v. Intellectual Ventures I LLC*, 890 F.3d 1336, 1346 (Fed. Cir. 2018) (“To contradict a reference, an unsupported opinion is not substantial evidence.”).

54. The Court must treat oral testimony of an inventor “with skepticism due to the possibility of an inventor’s self-interest in obtaining or maintaining an existing patent.” *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 968 (Fed. Cir. 2014).

4. Any Purported Secondary Considerations of Nonobviousness Do Not Outweigh the *Prima Facie* Case of Obviousness for All Asserted Claims

55. A patentee may attempt to rebut the obviousness of a claimed invention by presenting secondary considerations of nonobviousness. *WMS Gaming Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999).

56. The patentee bears the burden of producing evidence to establish the existence of secondary considerations supporting non-obviousness. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1353 (Fed. Cir. 2013)

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

(“[T]he presumption of validity does not relieve the patentee of any responsibility to set forth evidence in opposition to a challenger's *prima facie* case which, if left un rebutted, would be sufficient to establish obviousness”). In this regard, “argument and conjecture are insufficient.” *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1393 (Fed. Cir. 1988) (quotations and citation omitted). “These legal inferences or subtests . . . focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible of judicial treatment than are the highly technical facts often present in patent litigation.” *Graham*, 383 U.S. at 35-56.

57. While evidence of these factors must be considered, such 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) (“[O]bjective evidence of nonobviousness simply cannot overcome . . . a strong *prima facie* case of obviousness.”).

i. **Bausch Has Not Demonstrated Nexus to the Asserted Claims**

58. Evidence concerning secondary considerations may or may not be relevant to a determination of non-obviousness in a particular case. *Graham*, 383 U.S. at 18 (“As indicia of obviousness or nonobviousness, these inquiries may have relevancy.”).

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

59. A “nexus between the merits of the claimed invention and evidence of secondary considerations is required in order for the evidence to be given substantial weight in an obviousness decision. Put another way, commercial success or other secondary 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. Thomson Corp.*, 532 F.3d 1318, 1327-28 (Fed. Cir. 2008) (citations omitted). “Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (emphasis omitted); *see also In re GPAC*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) (“For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.”). Even “impressive” evidence of secondary considerations is not “entitled to weight” unless “it is relevant to the claims at issue.” *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

60. To weigh against a finding of obviousness, “objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support.” *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008) (quoting *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983)); *see also In re Dill*, 604 F.2d 1356, 1361 (C.C.P.A. 1979) (“The evidence presented to rebut a

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

prima facie case of obviousness must be commensurate in scope with the claims to which it pertains.”). Thus, if evidence of secondary considerations relates to a narrow aspect of a much broader claim, such evidence is not commensurate with the scope of the claims and fails to establish the non-obviousness of the asserted claims. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1336 (Fed. Cir. 2010) (“Because the claims are broad enough to cover devices that either do or do not solve the ‘short fill’ problem, Abbott’s objective evidence of non-obviousness fails because it is not ‘commensurate in scope with the claims which the evidence is offered to support.’”) (quoting *In re Grasselli*, 713 F.2d at 743); *MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc.*, 731 F.3d 1258, 1264-65 (Fed. Cir. 2013) (holding that district court erred where its “analysis of the secondary considerations of nonobviousness involved only fragrance-specific uses, but the [asserted claims] are not fragrance-specific”); *In re Greenfield*, 571 F.2d 1185, 1189 (C.C.P.A. 1978) (finding evidence of secondary considerations was not commensurate with the scope of the claims where evidence related to only one compound and there was not adequate basis to conclude that other compounds included within the scope of the claims would behave in the same manner.).

ii. **Bausch Has Not Shown that Bryhali or Duobrii Satisfied a Long-Felt, Unmet Need**

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

61. Evidence that an invention “satisfied a long-felt and unmet need that existed on the patent’s filing date is a secondary consideration of nonobviousness.” *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009); *see also KSR*, 550 U.S. at 406 (termed “long felt but unsolved needs”). Establishing long-felt need requires two steps; first, it is necessary to establish that an art-recognized problem existed for a long period of time without a solution. *In re Gershon*, 372 F.2d 535, 538 (C.C.P.A. 1967); *see also In re Sebela Patent Lit.*, Civil Action No.: 14-6414 (CCC) (MF), 2017 WL 3449054, at *24 (D. N.J. Aug. 11, 2017) (finding that a need that pre-dated the claimed priority date by “only around four years . . . was not **long-felt**.”) (citation omitted) (emphasis added). Second, “once a long-felt need is established, evidence must show that the claimed invention satisfied that need.” *In re Gardner*, No. 2011-1310, 2011 WL 5516077, at *4 (Fed. Cir. Nov. 14, 2011) (citing *In re Cavanagh*, 436 F.2d 491, 496 (C.C.P.A. 1971)); *Medtronic Inc. v. Intermedics, Inc.*, 799 F.2d 734, 740 (Fed. Cir. 1986) (finding the jury’s finding of the absence of the satisfaction of a long-felt need to be supported by substantial evidence); *E.I. DuPont De Nemours and Co. v. Monsanto Co.*, 903 F. Supp. 680 (D. Del. 1995) (finding that “DuPont has not established that its LUMENA fibers *satisfied* a long-felt need.”) (emphasis added). “[E]vidence of long-felt need can cut two ways: On the one hand, long-felt need might be considered evidence of non-obviousness, but on the other hand, to the extent that other factors

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

support obviousness, the existence of ‘market pressure to solve a problem’ can support a finding of obviousness” *Shuffle Master, Inc. v. MP Games LLC*, 553 F. Supp. 2d 1202, 1225 (D. Nev. 2008) (citing *KSR*, 550 U.S. at 420-421).

62. Federal Circuit precedent “requires that the applicant submit actual evidence of long-felt need, as opposed to argument.” *In re Kahn*, 441 F.3d 977, 990-91 (Fed. Cir. 2006). “[A]bsent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness.” *Id.* (citing *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004)). Accordingly, an assertion of long-felt need must be rejected when the patentee “provide[s] no evidence to explain how long [any relevant] need was felt, . . . when the problem first arose,” or how the “need [was] alleviated by the patent.” *Perfect Web Techs.*, 587 F.3d at 1332.

63. Even if there is evidence that the “claimed [invention] may have been beneficial,” that evidence is not probative if “others had previously solved the long-felt need.” *In re PepperBall Techs., Inc.*, 469 F. App’x 878, 882-83 (Fed. Cir. 2012); *see also Newell Co. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988) (“[O]nce another supplied the key element, there was no long-felt need”).

64. “[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem.” *Perfect Web Techs.*, 587 F.3d at 1332-33 (“Evidence that an invention satisfied a long-felt and unmet need

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

that existed on the patent's filing date is a secondary consideration of nonobviousness."); *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n.*, 988 F.2d 1165, 1178 (Fed. Cir. 1993).

65. In order to establish that a long-felt but unmet need existed, a patentee must provide evidence that there was a long-felt but unmet need for the claimed *invention*. See *In re Gardner*, 2011 WL 5516077, at *4 ("the Board determined that the argument was unsupported by any evidence, and failed to establish that a long-felt need existed for the claimed invention as opposed to extended range vehicles of unspecified configuration and operation."); see also, e.g., *B. Braun Melsungen AG v. Terumo Med. Corp.*, 778 F. Supp. 2d 506, 516 (D. Del. 2011) (emphasizing "long-felt need for the invention"). "Where the differences between the prior art and the claimed invention are [] minimal . . . it cannot be said that any long-felt need was unsolved." *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1304 (Fed. Cir. 2010). This is because even if a patented product improves "some aspects" of the available market, this is not evidence of an actual long-felt need existing. *May v. Carriage, Inc.*, 688 F. Supp. 408, 420 (N.D. Ind. 1988) ("Although the Stewart patent may have improved on some aspects of the slide-out room for travel trailers, there is no evidence of 'long-felt need' or failure of others in attempts to develop needed improvements."). The claimed invention cannot satisfy a long-felt need if that need was already met by the prior art. *Geo. M. Martin*, 618 F.3d at

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

1305 (rejecting long felt need argument where the prior art had already met the alleged “need”).

66. Evidence of long-felt, unmet need may not be reasonably commensurate with the scope of the claims if it goes only to a single embodiment of the claims. *See AstraZeneca LP v. Breath Ltd.*, 88 F. Supp. 2d 326, 389 (D.N.J. 2015). Similarly, evidence of long-felt, unmet need is insufficient if the claims are broad enough to cover embodiments that do and do not solve the long-felt need. *See Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1325, 1336 (Fed. Cir. 2010) (“Because the claims are broad enough to cover devices that either do or do not solve the ‘short fill’ problem, Abbott’s objective evidence of non-obviousness fails because it is not ‘commensurate in scope with the claims which the evidence is offered to support.’” (citing *in re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983))); *see also Medtronic Inc. v. Edwards Lifesciences Corp.*, Case No. SACV 12-00327-JVS (MLGx), 2013 WL 12113417 (C.D. Cal. Sept. 17, 2013) (“Nonetheless, regardless of the dispute over a ‘long-felt need,’ Medtronic’s reliance on that secondary consideration is unavailing because the claimed invention is much broader than rapid pacing for THV implantation.”). Additionally, a long-felt need may not be satisfied if the purportedly inadequate prior art products remain in use. *See Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp. 2d 305, 344 (D. Del. 2010).

iii. Bausch Has Not Shown Failure of Others

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

67. When asserted as a secondary consideration of nonobviousness, “[t]he purpose of evidence of failure of others is to show indirectly the presence of a significant defect in the prior art, while serving as a simulated laboratory test of the obviousness of the solution to a skilled artisan.” *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1082 (Fed. Cir. 2012) (citation and quotations omitted).

68. Evidence that others in the art tried and failed to develop inventions similar to the patentee’s can be a relevant secondary consideration. However, “an unsolved problem is not evidence of non-obviousness unless skilled workers in the art have tried and failed to solve the problem.” *Ecolchem*, 227 F.3d at 1378. Actual evidence of failure of others must be shown, as “the mere passage of time without the claimed invention is not evidence of nonobviousness.” *Iron Grip*, 392 F.3d at 1325. Even if a plaintiff can meet its burden of proving that others have tried to solve the same problem but failed, the failure of others is probative only where the evidence shows that the prior failure occurred because “the devices lacked the claimed features.” *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1313 (Fed. Cir. 2006). Thus, in conducting a failure of others analysis, the relevant problem is solely that which the patent-in-suit purports to solve. *Cubist Pharm., Inc. v. Hospira, Inc.*, 805 F.3d 1112, 1126 (Fed. Cir. 2015); *see also, DyStar*, 464 F.3d at 1371-72 (holding that

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

failed attempt was not evidence of secondary consideration of obviousness when failure was due to cost and not technical difficulty).

69. Alleged failures of others that pre-date the publication of asserted invalidating prior art generally has little relevance and should not be considered. *See Graham*, 383 U.S. at 36 (“[U]nsuccessful attempts to reach a solution . . . made before [the publication of the prior art] became wholly irrelevant.”).

iv. Bausch Has Not Demonstrated Any Unexpected Results

70. “One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of ‘unexpected results,’ *i.e.*, to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.” *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). *see also In re DeBlauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984) (“It is well settled that unexpected results must be established by factual evidence.”). “To be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention.” *Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014) (citations omitted). Where the unexpected results “actually results from something other than what is

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *Warner Chilcott Co., LLC v. Teva Pharm. USA, Inc.*, 89 F. Supp. 3d 641, 669 (D. N.J. 2015) (citation and internal quotation marks omitted) (finding that “unrelated factors could equally be the reason for the observed result” and, thus, “there [was] an absence of sufficient evidence of nexus . . .”).

71. The relevant time period for the “unexpected results” inquiry is whether the results would have been unexpected by one of ordinary skill in the art at the time of the patentee’s application and based on knowledge available at that time. *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997).

72. “[I]n order to properly evaluate whether a superior property was unexpected, the court should . . . consider[] what properties were expected.” *Pfizer Inc. v. Apotex, Inc.*, 480 F.3d at 1371. Unexpected results cannot be established if there is no evidence of what a POSA would have expected at the time of invention. *Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp. 2d 305, 348 (D. Del. 2010) (“[T]he patent owner must first show what properties were expected.”) (citation omitted).

73. Evidence of unexpected results must make a comparison of the results achieved by the claimed invention with the results from the closest prior art. *See, e.g., Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1363 (Fed. Cir. 2012) (“Wrigley needed to demonstrate that the results were unexpected to a

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

significant degree beyond what was already known about the effect of combining” the prior art.); *Novartis Pharm. Corp. v. West-Ward Pharm. Int’l, Ltd.*, 287 F. Supp. 3d 505, 552 (D. Del. 2017) (“Since Plaintiffs have failed to identify the closest prior art, let alone compare the RADIANT-3 study to any piece of prior art, they have failed to carry their burden to establish unexpected results by a preponderance of the evidence.”). “Given the enormous variety of technologies and claimed subject matter, no all-encompassing principle or test can be delineated for determining the closest prior art. However, an almost self-evident guideline would appear effective in most cases. A comparison of the *claimed* invention with the disclosure of each cited reference to determine the number of claim limitations in common with each reference, bearing in mind the relative importance of particular limitations, will usually yield the closest single prior art reference.” *In re Merchant*, 575 F.2d 865, 868 (C.C.P.A. 1978). The closest prior art need not be commercially available. *See Trs. of Columbia Univ. v. Illumina, Inc.*, No. 2014-1547, 2015 WL 4385761, at *14 (Fed. Cir. July 17, 2015) (“there is no requirement that the closest prior art be commercialized.”) (citing *In re Merchant*, 575 F.2d at 869); *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1369-70 (Fed. Cir. 2003) (finding no error in the district court’s obviousness finding which was based on prior art “even if they had not been commercialized[.]”). To be probative in the validity inquiry, the supposedly unexpectedly superior result must be “different in kind and not merely in degree

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

from the results of the prior art.” *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir. 2013) (internal quotation marks and citation omitted); *Bristol-Myers, Inc.*, 752 F.3d at 977 (“Unexpected properties, however, do not necessarily guarantee that a new compound is nonobvious. While a ‘marked superiority’ in an expected property may be enough in some circumstances to render a compound patentable, a ‘mere difference in degree; is insufficient.”)

74. “A showing that a drug was slightly more or less effective than the prior art would suggest does not constitute an ‘unexpected result’ for purposes of assessing obviousness.” *Acorda*, 2017 WL 1199767, at *36 (citing *Galderma Labs*, 737 F.3d at 739 and *In re Merck*, 800 F.2d at 1098-99).

75. To show unexpected results over a claimed range, the patentee should compare a sufficient number of tests inside and outside the claimed range to show the criticality of the range at which the alleged unobvious results were obtained. *Application of Hill*, 284 F.2d 955, 959 (C.C.P.A. 1960).

76. An alleged unexpected result does not support non-obviousness if it “is not unexpected or surprising, but is a product of routine optimization that would have been obvious to one of skill in the art.” *Senju Pharm. Co. v. Lupin Ltd.*, 780 F.3d 1337, 1353 (Fed. Cir. 2015).

v. **Bausch Has Not Shown Industry Praise for Bryhali or Duobrii**

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

77. Evidence of industry praise for a claimed invention or a product that embodies the patent claims may support a finding of nonobviousness because “[a]ppreciation by contemporaries skilled in the field of the invention is a useful indicator of whether the invention would have been obvious to such persons at the time it was made.” *Vulcan Eng'g Co. v. Fata Aluminium, Inc.*, 278 F.3d 1366, 1373 (Fed. Cir. 2002).

78. As with other secondary considerations, a plaintiff relying on evidence of industry praise must demonstrate a nexus between the praise and the claimed invention. *See, e.g., PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1365 (Fed. Cir. 2007) (“The problem with [Plaintiffs’ evidence of praise] is that there was no indication that the praise for the inventors’ work was based on any inventive contribution they made, as opposed to their proof, through laboratory work, that fetal blood contains large numbers of stem cells. As noted, the former is a basis for patentability; the latter is not.”); *see also Geo. M. Martin Co. v. All. Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1305 (Fed. Cir. 2010).

79. For evidence of industry praise to weigh in favor of nonobviousness, such evidence must be commensurate in scope with the scope of the claims. *See, e.g., Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328 (Fed. Cir. 2008).

vi. Duobrii is Not a Commercial Success and Bausch Did Not Assert Commercial Success for Bryhali

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

80. Commercial success is a legal construct that is premised on the idea that if a product is economically successful due to the novel and claimed features of the patented invention, it may provide objective evidence of nonobviousness of those claims. *Merck & Co. Inc. v. Teva Pharm., USA, Inc.*, 395 F.3d 1364, 1376-77 (Fed. Cir. 2005). But, “commercial success without invention will not make patentability.” *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 153 (1950). Commercial success as a secondary consideration “exists largely to provide a means for patentees to show in close cases that subject matter that appears obvious is in law unobvious because a high degree of commercial success permits the inference that others have tried and failed to reach a solution.” *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1383 (Fed. Cir. 2005) (citing *Merck & Co.*, 395 F.3d at 1376).

81. To be relevant to the obviousness inquiry, the commercial success of a product must be attributable to the allegedly novel features of the claimed invention. *Merck & Co.*, 395 F.3d at 1376-77. In other words, there must be a causal relationship, or “nexus,” between the unique merit of the claimed invention and the marketplace success of the product. *Id.* at 1376; *Galderma Labs.*, 737 F.3d at 740 (“Evidence of commercial success . . . is only significant if there is a nexus between the claimed invention and the commercial success.”) (quotation and citation omitted)).

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

82. A patentee's assertion of commercial success is therefore "undermined as a matter of law by [the] failure to introduce evidence related to the nexus between [the claimed invention] and the commercial success of products embodying the invention." *ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1361 (Fed. Cir. 2015). This is because the "commercial success of a product can have many causes unrelated to patentable inventiveness" *Ritchie v. Vast Res., Inc.*, 563 F.3d 1334, 1336 (Fed. Cir. 2009). Consequently, "[c]ommercial success is relevant only if it flows from the merits of the claimed invention." *Sjolund*, 847 F.2d at 1582. If the commercial success is due to "a feature not claimed," then such success is irrelevant because there is no nexus between the commercial success and the claimed invention. *Id.*; *see also Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1370 (Fed. Cir. 2011) (finding no nexus between commercial success and patented feature where marketing and sales data did not refer to purportedly distinguishing feature of patented product). Where a nexus has not been "shown between the claimed invention and the evidence of commercial success," and other "factors [are] identified as contributing to" commercial success, "including marketing efforts," "the fact that [a commercial embodiment of the claimed invention is] successful does not alter the obviousness analysis." *Wm. Wrigley*, 683 F.3d at 1363.

83. Also, if the purported commercial success is due to an element in the prior art, no nexus exists. *Galderma Labs.*, 737 F.3d at 740 ("[I]f the feature that

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

creates the commercial success was known in the prior art, the success is not pertinent.” (quotation and citations omitted)); *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1369-70 (Fed. Cir. 2011); *see Campbell Soup Co. v. Gamon Plus, Inc.*, 10 F.4th 1268, 1278 (Fed. Cir. 2021) (explaining that “merely t[ying] commercial success and praise to aspects of the label area that were already present in the prior art” was insufficient to establish nexus). “[T]he asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art.” *J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997) (citation omitted).

84. Whether a commercial product meets internal sales projections is relevant to the commercial success analysis. *See Santarus, Inc. v. Par Pharm, Inc.*, 694 F.3d 1344, 1357 (Fed. Cir. 2012) (upholding finding of no commercial success where sales “fell far short of Santarus’ own expectations.”); *see also Santarus, Inc. v. Par Pharm., Inc.*, 720 F. Supp. 2d 427, 453-54 (D. Del. 2010), *aff’d in part, rev’d in part*, 694 F.3d 1344 (Fed. Cir. 2012) (reversing in part on other grounds) (finding a lack of commercial success and noting that “Zegerid’s sales fell far short of Santarus’ own expectations. Santarus had at one time projected sales of \$2 billion by 2008, approximately twenty times actual Zegerid sales for that year.” (internal citations omitted)).

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

85. Evidence that a commercial product's sales are not growing supports a finding of no commercial success. *See, e.g., Santarus, Inc. v. Par Pharm., Inc.*, 720 F. Supp. 2d 427, 455 (D. Del. 2010), *aff'd in part, rev'd in part*, 694 F.3d 1344 (Fed. Cir. 2012) (reversing in part on other grounds) (“Zegerid’s share of the PPI prescription market was no longer growing as of the most recent sales reporting period. . . . For these reasons, the court finds that Zegerid has not achieved commercial success.”).

86. “The mere fact that generic pharmaceutical companies seek approval to market a generic version of a drug, without more, is not evidence of commercial success that speaks to the non-obviousness of patent claims.” *Galderma Labs*, 737 F.3d at 740. A generic pharmaceutical company’s belief that it can make a profit selling a generic version of a product “tells us very little about the level of commercial success of the patented invention relative to the prior art or the extent to which commercial success of the branded drug is due to the merits of the claimed invention beyond what is readily available in the prior art” and does not support a finding of obviousness. *Id.* (internal quotation marks omitted); *see also Mitsubishi Chem. Corp. v. Barr Labs., Inc.*, 718 F. Supp. 2d 382, 443-44 (“The burdensome NDA procedures provides generic drug manufacturers with an incentive to copy an already approved drug so that they can avail themselves of the less burdensome ANDA procedure of the Hatch-Waxman Act.”).

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER**vii. Bausch Has Not Demonstrated Industry Skepticism**

87. Evidence of skepticism within the relevant industry may support the nonobviousness of an invention. *See, e.g., WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1335 (Fed. Cir. 2016); *see also Transocean Offshore Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1304-05 (Fed. Cir. 2010). “Doubt or disbelief by skilled artisans regarding the likely success of a combination or solution weighs against the notion that one would combine elements in references to achieve the claimed invention.” *WBIP, LLC*, 829 F.3d at 1335. However, “evidence of skepticism must be specific to the invention, not generic to the field.” *Auris Health, Inc. v. Intuitive Surgical Operations, Inc.*, 32 F.4th 1154, 1159 (Fed. Cir. 2022). “Skepticism expressed in a private communication is likely less considered and less self-scrutinized than statements of skepticism intended to be published to the scientific community.” *ViiV Healthcare UK Ltd. v. Lupin Ltd.*, 6 F. Supp. 3d 461, 497 (D. Del. 2013).

viii. Copying Is Not Probative of Nonobviousness in the Context of Generic Drugs

88. Because copying “is required for FDA approval” of generic drugs, “evidence of copying in the ANDA context is not probative of nonobviousness.” *Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013); *Galderma Labs.*, 737 F.3d at 740 (“The mere fact that generic

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

pharmaceutical companies seek approval to market a generic version of a drug . . . does not support a finding of non-obviousness.”); *Allergan, Inc. v. Watson Labs., Inc.-Fla.*, 869 F. Supp. 2d 456, 485 (D. Del. 2012) (“[A]s several courts have recognized, demonstration that a defendant has copied a patented invention is not compelling evidence of non-obviousness in the Hatch-Waxman context due to the unique nature of the ANDA process.”); *Immunex Corp. v. Sandoz Inc.*, 395 F. Supp. 3d 366, 406 (D.N.J. 2019) (“In the pharmaceutical realm, however, copying is generally not considered evidence of nonobviousness for matters in the ANDA context.”).

89. “Evidence of copying of a feature in a patent owner’s commercial product is ‘not sufficient to demonstrate nonobviousness of the claimed invention’ where, as here, there is a ‘substantial question of validity raised by the prior art references’ cited by the accused infringer.” *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 816 F.3d 788, 805-06 (Fed. Cir. 2016 (en banc), *vacated in part on other grounds on reh’g en banc*, 839 F.3d 1034 (Fed. Cir. 2016)).

5. Obviousness Conclusions

90. The Asserted Claims of the ’307 and ’502 patents are invalid as obvious under 35 U.S.C. § 103. F. Section II.A, B.1-3, and D.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

91. Any purported secondary considerations do not overcome the strong *prima facie* case of obviousness of the Asserted Claims of the '307 and '502 patents.

F. Section II.B.3.p and II.D.

92. The Asserted Claims of the '307 and '502 patents are invalid as obvious under 35 U.S.C. § 103 in view of the '295 patent and Blum. F. Section II.B.3.a, d, g, j, m.

93. The Asserted Claims of the '307 and '502 patents are invalid as obvious under 35 U.S.C. § 103 in view of the '295 patent, Blum, and the '566 Patent. F. Section II.B.3.b, e, h, k, n.

94. The Asserted Claims of the '307 and '502 patents are invalid as obvious under 35 U.S.C. § 103 in view of the '295 patent, Blum, and JP '228. F. Section II.B.3.c, f, i, l.

95. Claim 16 of the '502 patent is invalid as obvious under 35 U.S.C. § 103 in view of the '295 patent, Blum, and the Temovate E Label. F. Section II.B.3.o.

96. The Asserted Claims of the '787 and '895 patents are invalid as obvious under 35 U.S.C. § 103. F. Section II.A, C, and D.-4

97. Any purported secondary considerations do not overcome the strong *prima facie* case of obviousness of the Asserted Claims of the '787 and '895 patents. F. Section II.C.4 and II.D.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

98. The Asserted Claims of the '787 and '895 patents are invalid as obvious under 35 U.S.C. § 103 in view of Gollnick, the '824 Publication, and the Tazorac Label. F. Section II.C.3.b, d-g.

99. The Asserted Claims of the '787 and '895 patents are invalid as obvious under 35 U.S.C. § 103 in view of Gollnick, the '824 Publication, and the IDP-118 Study. F. Section II.C.3.a, d-g.

100. The Asserted Claims of the '787 and '895 patents are invalid as obvious under 35 U.S.C. § 103 in view of Gollnick, the '824 Publication, and Gandhi. F. Section II.C.3.c-g.

II. REMEDY

A. Bausch is Not Entitled to Any Relief

101. It is axiomatic that an invalid patent cannot be infringed. 35 U.S.C. § 282; *see IPXL Holdings, LLC v. Amazon.com, Inc.*, 430 F.3d 1377, 1380 (Fed. Cir. 2005) (“Because the claims in suit are invalid, we need not visit the question of whether the district court erred in determining that the claims were not infringed.”).

102. A patent owner is only entitled to a remedy under 35 U.S.C. § 271(e)(4) if a valid patent claim is infringed. Here, Padagis has shown by clear and convincing evidence that all asserted claims are invalid, and Bausch is therefore not entitled to any remedies.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

103. “[A]n exceptional case is simply one that stands out from others with respect to the substantive strength of a party’s litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated. District courts may determine whether a case is ‘exceptional’ in the case-by-case exercise of their discretion, considering the totality of the circumstances.” Tightly contested litigation is “quite ordinary,” not exceptional. *See Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, No. 07-1000 (MLC), 2015 WL 5921035, at *3 (D.N.J. Oct. 9, 2015) (citing *NXP B.V. v. Blackberry, Ltd.*, 58 F. Supp. 3d 1313, 1319 (M.D. Fla. 2014)). Shifting arguments after discovery “does not render a case exceptional; rather, it illustrates that the [party] properly used discovery throughout the course of litigation as a means to refine or change their arguments.” *Id.* at *7. “A fee award with a deterrent impact on generic pharmaceuticals and a compensatory effect on branded pharmaceuticals, particularly in a typical patent case, would run afoul of the policies underlying the Hatch-Waxman Act.” *Id.* at *8.

104. Bausch is not entitled to a judgment that Padagis’s HP ANDA Product infringes any valid Asserted Claim of the ’307 patent or the ’502 patent. F. 1.

105. Bausch is not entitled to a judgment that Padagis’s Combination ANDA Product infringes any valid Asserted Claim of any of the ’307, ’502, ’787, or ’895 patent. F. 2.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

106. Bausch is not entitled to an order under 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval for Padagis to commercially make, use, or sell the drug product that is the subject of Padagis's HP ANDA be not earlier than the latest of the expiration dates of the '307 and '502 patents. F. 3.

107. Bausch is not entitled to an order under 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval for Padagis to commercially make, use, or sell the drug product that is the subject of Padagis's Combination ANDA be not earlier than the latest of the expiration dates of the '307, '502, '787, and '895 patents. F. 4.

108. Bausch is not entitled to an injunction under 35 U.S.C. § 271(a) enjoining Padagis from making, using, offering to sell, selling, or importing the drug product that is the subject of Padagis's HP ANDA during the term of the '307 and '502 patents. F. 5.

109. Bausch is not entitled to an injunction under 35 U.S.C. § 271(a) enjoining Padagis from making, using, offering to sell, selling, or importing the drug product that is the subject of Padagis's Combination ANDA during the term of the '307, '502, '787, and '895 patents. F. 6.

110. Bausch is not entitled to an injunction under 35 U.S.C. § 271(b) enjoining Padagis from making, using, offering to sell, selling, or importing the drug

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

product that is the subject of Padagis's HP ANDA during the term of the '307 and '502 patents. F. 7.

111. Bausch is not entitled to an injunction under 35 U.S.C. § 271(b) enjoining Padagis from making, using, offering to sell, selling, or importing the drug product that is the subject of Padagis's Combination ANDA during the term of the '307, '502, '787, and '895 patents. F. 8.

112. Bausch is not entitled to an injunction under 35 U.S.C. § 271(c) enjoining Padagis from making, using, offering to sell, selling, or importing the drug product that is the subject of Padagis's HP ANDA during the term of the '307 and '502 patents. F. 9.

113. Bausch is not entitled to an injunction under 35 U.S.C. § 271(c) enjoining Padagis from making, using, offering to sell, selling, or importing the drug product that is the subject of Padagis's Combination ANDA during the term of the '307, '502, '787, and '895 patents. F. 10.

114. Bausch is not entitled to judgment that the Asserted Claims of the '307, '502, '787, and '895 patents are not invalid.

115. If Bausch proves infringement of any valid asserted claim, Bausch is not entitled to costs under Fed. R. Civ. P. 54(d)(1). F. 11.

116. Bausch has not established that this case is an exceptional case meriting the award of attorney's fees to the prevailing party under 35 U.S.C. § 285. F. 12.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

117. Bausch is not entitled to any relief that it seeks in this case.

B. Padagis is Entitled to a Judgment of Invalidity

118. Padagis is entitled to a judgment that the Asserted Claims of the '307 patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 103 and/or 112. F. 13.

119. Padagis is entitled to a judgment that the Asserted Claims of the '502 patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 103 and/or 112. F. 14.

120. Padagis is entitled to a judgment that the Asserted Claims of the '787 patent are invalid for failure to satisfy the requirements of 35 U.S.C. § 103. F. 15.

121. Padagis is entitled to a judgment that the Asserted Claims of the '895 patent are invalid for failure to satisfy the requirements of 35 U.S.C. § 103. F. 16.

122. Padagis is entitled to a judgment ordering that Bausch's Complaints be dismissed with prejudice and judgment be entered in favor of Padagis. F. 17.

123. Padagis is entitled to a judgment declaring this case exceptional and awarding Padagis its reasonable attorneys' fees and costs under 35 U.S.C. § 285. F. 18.

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

Respectfully submitted,
FOX & ROTHSCHILD, LLP

Dated: November 15, 2022

/s/ Karen A. Confoy

Karen A. Confoy
Cali R. Spota
Princeton Pike Corporate Center
997 Lenox Drive
Lawrenceville, NJ 08648
Tel: (609) 896-3600
Fax: (609) 896-1469
kconfoy@foxrothschild.com
cspota@foxrothschild.com

*Attorneys for Padagis Israel
Pharmaceuticals Ltd and Padagis US LLC*

Of Counsel:

Joseph M. Reisman (*admitted Pro Hac Vice*)
KNOBBE, MARTENS, OLSON & BEAR, LLP
12790 El Camino Real
San Diego, CA 92130
(858) 707-4000 Telephone
(858) 707-4001 Facsimile
joseph.reisman@knobbe.com
Bill Zimmerman (*admitted Pro Hac Vice*)
Andrea L. Cheek (*admitted Pro Hac Vice*)
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Ave. N.W. Ste. 900
Washington D.C. 20006
(202) 640-6400 Telephone
(202) 640-6401 Facsimile
bill.zimmerman@knobbe.com
andrea.cheek@knobbe.com

Carol Pitzel Cruz (*admitted Pro Hac Vice*)
KNOBBE, MARTENS, OLSON & BEAR, LLP
925 Fourth Avenue, Suite 2500
Seattle, WA 98104

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

(206) 405-2000 Telephone
(206) 405-2001 Facsimile
carol.pitzel.cruz@knobbe.com

Brian C. Barnes (Admitted *Pro Hac Vice*)
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main St., 14th Floor
Irvine, CA 92614
(949) 760-0404 Telephone
(949) 760-9502 Facsimile
brian.barnes@knobbe.com

ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

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:

William P. Deni, Jr. Charles H. Chevalier J. Brugh Lower GIBBONS P.C. One Gateway Center Newark, New Jersey 07102 wdeni@gibbonslaw.com cchevalier@gibbonslaw.com jlower@gibbonslaw.com	Thomas P. Steindler April E. Weisbruch David Mlaver MCDERMOTT WILL & EMERY LLP 500 North Capitol Street N.W. Washington, D.C. 20001 tsteindler@mwe.com aweisbruch@mwe.com dmlaver@mwe.com
--	--

November 15, 2022

/s/ Karen A. Confoy
Karen A. Confoy