2021-1969

United States Court of Appeals for the Federal Circuit

UNIVERSITY OF MASSACHUSETTS, CARMEL LABORATORIES, LLC,

Plaintiffs-Appellants,

– v. –

L'OREAL S.A., L'OREAL USA, INC.,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Delaware, Case No. 1:17-cv-00868-CFC-SRF, Honorable Colm F. Connolly, U.S. District Judge

BRIEF FOR DEFENDANTS-APPELLEES L'ORÉAL S.A. AND L'ORÉAL USA, INC.

NAVEEN MODI
STEPHEN B. KINNAIRD
PAUL HASTINGS LLP
2050 M Street, NW
Washington, DC 20036
(202) 551-1700
naveenmodi@paulhastings.com
stephenkinnaird@paulhastings.com

KATHERINE F. MURRAY
BROWNE GEORGE ROSS O'BRIEN ANNAGUEY & ELLIS LLP
2121 Avenue of the Stars, Suite 2800
Los Angeles, California 90067
(310) 274-7100
kmurray@bgrfirm.com

ERIC W. DITTMANN
ISAAC S. ASHKENAZI
BRUCE M. WEXLER
NICHOLAS A. TYMOCZKO
KARTHIK R. KASARANENI
PAUL HASTINGS LLP
200 Park Avenue
New York, New York 10166
(212) 318-6000
ericdittmann@paulhastings.com
isaacashkenazi@paulhastings.com
brucewexler@paulhastings.com
nicholastymoczko@paulhastings.com
karthikkasaraneni@paulhastings.com

Attorneys for Defendants-Appellees L'Oréal S.A. and L'Oréal USA, Inc.

OCTOBER 14, 2021

EXEMPLARY CLAIMS

U.S. Patent No. 6,423,327

1. A method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin, without increasing dermal cell proliferation, the method comprising topically applying to the skin a composition comprising a concentration of adenosine in an amount effective to enhance the condition of the skin without increasing dermal cell proliferation, wherein the adenosine concentration applied to the dermal cells is 10^{-4} M to 10^{-7} M.

U.S. Patent No. 6,645,513

1. A method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin, without increasing dermal cell proliferation, the method comprising topically applying to the skin a composition comprising a concentration of adenosine in an amount effective to enhance the condition of the skin without increasing dermal cell proliferation, wherein the adenosine concentration applied to the dermal cells is 10^{-3} M to 10^{-7} M.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2021-1969

Short Case Caption University of Massachusetts v. L'Oreal S.A.

Filing Party/Entity Appellees L'Oréal S.A. and L'Oréal USA, Inc.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 10/14/2021

Signature: /s/Eric W. Dittmann

Name: Eric W. Dittmann

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
L'Oréal S.A.		Nestlé S.A.
L'Oréal USA, Inc.		L'Oréal S.A.

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

Joseph E. Palys PAUL HASTINGS LLP	Frederick L. Cottrell, III RICHARDS, LAYTON & FINGER, P.A.	Dennis S. Ellis Browne George Ross O'Brien Annaguey & Ellis LLP
Robert Unikel PAUL HASTINGS LLP	Jason J. Rawnsley RICHARDS, LAYTON & FINGER, P.A.	Serli Polatoglu Browne George Ross O'Brien Annaguey & Ellis LLP
Blaine M. Hackman Formerly of PAUL HASTINGS LLP	Katharine L. Mowery RICHARDS, LAYTON & FINGER, P.A.	

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☑ None/Not Applicable ☐ Additional pages attached

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

TABLE OF CONTENTS

Page

INTRODUCTION 1
ISSUES PRESENTED 3
STATEMENT OF THE CASE 4
I. The Patents-in-Suit 4
A. The Skin-Enhancement Limitation 5
B. Plaintiffs' Fluidity with the Adenosine-Concentration Limitation 7
II. Proceedings Below 11
A. Personal Jurisdiction 12
B. Claim Construction 13
C. Summary Judgment of Indefiniteness 14
SUMMARY OF ARGUMENT 16
ARGUMENT 19
I. The Skin-Enhancement Limitation Is Indefinite 19
A. The Skin-Enhancement Limitation Is Limiting 20
B. The Skin-Enhancement Limitation Renders the Claims Indefinite 25
II. The Adenosine-Concentration Limitation Is Indefinite under the District Court's Construction 36
A. The Intrinsic Record Does Not Provide Guidance Regarding How to Determine the Claimed Results 38
B. Plaintiffs' Post-Hoc "Franz Cell Testing" Can Be Conducted in Many Different Ways 39
C. The Post-Hoc Methodologies Give Varying, Outcome-Determinative Results 42
III. Plaintiffs' Construction of the Adenosine-Concentration Limitation Is Wrong 45
A. The Claim Language Supports L'Oréal USA's Construction 46

TABLE OF CONTENTS
(continued)

Page

B. The Specification Supports L'Oréal USA's Construction 50

C. The Prosecution History Supports L'Oréal USA's Construction and, at a Minimum, Disclaims Plaintiffs' Construction.....53

IV. The District Court Correctly Dismissed L'Oréal S.A. for Lack of Personal Jurisdiction 59

A. L'Oréal S.A. Is Not Subject to Specific Personal Jurisdiction.....60

B. The District Court Did Not Abuse Its Discretion in Denying Jurisdictional Discovery.....63

CONCLUSION.....66

TABLE OF AUTHORITIES

Page(s)

Cases

ACCO Brands, Inc. v. Micro Sec. Devices, Inc.,
346 F.3d 1075 (Fed. Cir. 2003) 56, 57

Am. Standard Inc. v. Pfizer Inc.,
828 F.2d 734 (Fed. Cir. 1987) 29

Afshari v. Bear Archery, Inc.,
No. 12-13-KSF, 2012 WL 3027649 (E.D. Ky. July 24, 2012) 64

Amgen Inc. v. Coherus BioSciences, Inc.,
931 F.3d 1154 (Fed. Cir. 2019) 56

Asanov v. Gholson, Hicks & Nichols, P.A.,
209 F. App'x 139 (3d Cir. 2006) 62

BASF Corp. v. Johnson Matthey Inc.,
875 F.3d 1360 (Fed. Cir. 2017) 33

Biogen Idec, Inc. v. GlaxoSmithKline LLC,
713 F.3d 1090 (Fed. Cir. 2013) 53

Biogen, Inc. v. Berlex Labs., Inc.,
318 F. 3d 1132 (Fed. Cir. 2003) 57

Biosig Instruments, Inc. v. Nautilus, Inc.,
783 F.3d 1374 (Fed. Cir. 2015) 33

Brightwell v. Lehman,
637 F.3d 187 (3d Cir. 2011) 59

In re Capital Cities/ABC, Inc.'s Application for Access to Sealed Transcripts,
913 F.2d 89 (3d. Cir. 1990) 64

Celgard, LLC v. SK Innovation Co.,
792 F.3d 1373 (Fed. Cir. 2015) 59, 60, 64

TABLE OF AUTHORITIES
(continued)

Page(s)

Checkpoint Sys., Inc. v. ITC,
54 F.3d 756 (Fed. Cir. 1995) 35

In re Cruciferous Sprout Litig.,
301 F.3d 1343 (Fed. Cir. 2002) 24

Datamize, LLC v. Plumtree Software, Inc.,
417 F.3d 1342 (Fed. Cir. 2005) 19, 26, 27, 33

DDR Holdings, LLC v. Hotels.com, L.P.,
773 F.3d 1245 (Fed. Cir. 2014) 35

Dow Chem. Co. v. Nova Chems. Corp. (Canada),
803 F.3d 620 (Fed. Cir. 2015) 20, 26, 37, 45

Durel Corp. v. Osram Sylvania Inc.,
256 F.3d 1298 (Fed. Cir. 2001) 46

Eibel Process Co. v. Minnesota & Ontario Paper Co.,
261 U.S. 45 (1923).....32

Eli Lilly & Co. v. Teva Pharms. Int'l GmbH,
8 F.4th 1331 (Fed. Cir. 2021) 24

Engel Indus., Inc. v. Lockformer Co.,
96 F.3d 1398 (Fed. Cir. 1996) 53

Eurofins Pharma US Holdings v. Bioalliance Pharma SA,
623 F.3d 147 (3d Cir. 2010) 63

Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp., LLC,
879 F.3d 1332 (Fed. Cir. 2018) 33

Forest Labs., Inc. v. Teva Pharms. USA, Inc.,
716 F. App'x 987 (Fed. Cir. 2017) 37, 39, 41

Fresenius USA, Inc. v. Baxter Int'l, Inc.,
582 F.3d 1288 (Fed. Cir. 2009) 35

TABLE OF AUTHORITIES
(continued)

Page(s)

Geneva Pharms., Inc. v. GlaxoSmithKline PLC,
349 F.3d 1373 (Fed. Cir. 2003) 23

Griffin v. Bertina,
285 F.3d 1029 (Fed. Cir. 2002) 48

Guangdong Alison Hi-Tech Co. v. ITC,
936 F.3d 1353 (Fed. Cir. 2019) 33

Honeywell Int'l, Inc. v. ITC,
341 F.3d 1332 (Fed. Cir. 2003) 38, 41

HZNP Meds. LLC v. Actavis Labs. UT, Inc.,
940 F.3d 680 (Fed. Cir. 2019) 20, 38, 45

Intellectual Ventures I LLC v. T-Mobile USA, Inc.,
902 F.3d 1372 (Fed. Cir. 2018) 26

Interval Licensing LLC v. AOL, Inc.,
766 F.3d 1364 (Fed. Cir. 2014) 19, 26, 27, 31, 33, 38

King Pharms., Inc. v. Eon Labs, Inc.,
616 F.3d 1267 (Fed. Cir. 2010) 36, 37

London v. Carson Pirie Scott & Co.,
946 F.2d 1534 (Fed. Cir. 1991) 36

Nautilus, Inc. v. Biosig Instruments, Inc.,
572 U.S. 898 (2014).....*passim*

Nespresso USA, Inc. v. Ethical Coffee Co.,
263 F. Supp. 3d 498 (D. Del. 2017).....61, 62

NexLearn, LLC v. Allen Interactions, Inc.,
859 F.3d 1371 (Fed. Cir. 2017) 59

NTP, Inc. v. Research in Motion, Ltd.,
418 F.3d 1282 (Fed. Cir. 2005) 48

TABLE OF AUTHORITIES
(continued)

Page(s)

Nuance Commc'ns, Inc. v. Abbyy Software House,
626 F.3d 1222 (Fed. Cir. 2010) 63

Parallel Networks, LLC v. Abercrombie & Fitch Co.,
704 F.3d 958 (Fed. Cir. 2013) 45

Parker v. Learn the Skills Corp.,
219 F. App'x 187 (3d Cir. 2007) 64

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005) 22, 50

Presidio Components, Inc. v. Am. Tech. Ceramics Corp.,
875 F.3d 1369 (Fed. Cir. 2017) 33

Round Rock Research LLC v. Asustek Computer Inc.,
967 F. Supp. 2d 969 (D. Del. 2013).....61

Sonix Tech. Co. v. Publ'ns Int'l, Ltd.,
844 F.3d 1370 (Fed. Cir. 2017) 26, 27, 28, 30, 31

Spectrum Int'l, Inc. v. Sterilite Corp.,
164 F.3d 1372 (Fed. Cir. 1998) 25

Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.,
731 F.3d 1271 (Fed. Cir. 2013) 46

Teva Pharms. USA, Inc. v. Sandoz, Inc.,
789 F.3d 1335 (Fed. Cir. 2015) 38, 45

Tinnus Enters., LLC v. Telebrands Corp.,
733 F. App'x 1011 (Fed. Cir. 2018) 33

Touchcom, Inc. v. Bereskin & Parr,
574 F.3d 1403 (Fed. Cir. 2009) 62

Tuna Processors, Inc. v. Hawaii Int'l Seafood, Inc.,
327 F. App'x 204 (Fed. Cir. 2009) 48

TABLE OF AUTHORITIES
(continued)

Page(s)

Virnetx, Inc. v. Cisco Sys., Inc.,
767 F.3d 1308 (Fed. Cir. 2014) 52

Statutes

35 U.S.C. § 112 19

Other Authorities

Fed. R. Civ. P. 15 65

Fed. R. Civ. P. 54(b) 65

Grove et al., *Effects of Topical Retinoids on Photoaged Skin as Measured by Optical Profilometry*,
190 Methods in Enzymology 360 (1990) 30

Grove *et al.*, *Optical Profilometry: An Objective Method for Quantification of Facial Wrinkles*,
21 J. Am. Acad. Dermatol. 631 (1989).....28

Olsen *et al.*, *Tretinoin Emollient Cream: A New Therapy for Photodamaged Skin*, 26 J. Am. Acad. Dermatol. 216 (1992) 28, 29, 30, 34

Webster's Third New International Dictionary (2002 ed.).....50

STATEMENT OF RELATED CASES

No other appeals have been taken in this case, and counsel for Defendants-Appellees L'Oréal USA, Inc. and L'Oréal, S.A. are aware of no other cases pending in any court or agency that will directly affect, or be directly affected by, this Court's decision in the instant appeal.

INTRODUCTION

The central question on appeal is whether the asserted claims, all of which are directed to a "method for ***enhancing the condition of unbroken skin*** of a mammal" by "topically applying to the skin a composition comprising a concentration of adenosine in an amount effective ***to enhance the condition of the skin***," are indefinite.[1] The answer is "yes." Unlike most patents, the patents-in-suit expressly instruct that the scope of the amorphous term of degree "enhance" includes purely "subjective evaluations by the patient or a second party." Appx00069(5:48-52). The named inventor and Plaintiffs' Rule 30(b)(6) designee, Dr. James Dobson, confirmed this point in sworn deposition testimony, which Plaintiffs' expert did not dispute. The claims' boundaries thus depend on the unpredictable vagaries of an unspecified person's subjective opinion. And this uncertainty is only exacerbated by the fact that alternative methodologies for assessing skin enhancement produce conflicting, outcome-determinative results. The district court's judgment of indefiniteness accords with the Supreme Court's and this Court's precedent.

Unable to counter the patents' teachings and statements of their witnesses, Plaintiffs ask this Court to now rewrite the claims so as to erase most of the claim

[1] Unless otherwise noted, all emphases have been added and all internal citations, quotations, and modifications have been omitted.

language, eliminating any requirement that the composition "enhance" the condition of the skin—even though that language appears twice in the claim and was used during prosecution to distinguish prior art. Running from their own deliberately malleable claim language, Plaintiffs urge that the patents encompass ***any*** topical application to the skin of ***any*** composition with ***any*** concentration of adenosine in ***any*** amount, so long as by natural diffusion adenosine reaches ***any*** part of the "dermal layer" of the skin at the recited concentration ranges. That argument should be rejected, as should Plaintiffs' attempt to raise new—albeit futile—arguments and evidence in opposing the grant of summary judgment.

Plaintiffs' approach to the claims also supports affirmance on another, equally compelling indefiniteness ground that was fully briefed on summary judgment below. At Plaintiffs' urging, the patents' claimed concentration ranges were construed to refer not to the adenosine concentration in the topically applied composition, but rather the concentration "measured when the adenosine reached the dermal cells under the surface of the skin." Appx00003-00004. Although that construction is belied by the claim language, specification, and prosecution history, Plaintiffs relied on it to accuse approximately 130 L'Oréal USA products—which include adenosine in their compositions at ***the very same concentrations present in the prior art compositions distinguished during prosecution***—of infringement. The problem with this litigation-inspired position, however, is that the intrinsic

record does not provide any guidance regarding how to measure the adenosine that "reache[s] the dermal cells." And the undisputed record evidence established that there are many different ways to measure such adenosine concentrations—even when limited to Plaintiffs' preferred testing approach—which generate conflicting and outcome-determinative results, as confirmed by Plaintiffs' own testing. For this additional reason, the claims are indefinite.

Finally, to the extent Plaintiffs' litigation-inspired, adenosine-concentration construction were to be rejected, and that term properly construed to refer to the adenosine concentration in the composition, there would be no dispute that the accused products do not satisfy the claimed concentration ranges of the patents-in-suit. Correction of the claim construction would thus provide yet another, separate basis for resolving this case in L'Oréal USA's favor.

ISSUES PRESENTED

1. Whether the asserted claims are indefinite because the patents (i) call for purely subjective standards to evaluate skin enhancement and (ii) otherwise allow measurement methods that provide conflicting, outcome-determinative results.

2. Whether, under the district court's construction, the asserted claims are indefinite because multiple, acceptable ways of measuring the adenosine

concentration that "reache[s] the dermal cells" generate conflicting, outcome-determinative results.

3. Whether the claim phrase "the adenosine concentration applied to the dermal cells" should be construed to mean "the adenosine concentration applied to the skin containing the dermal cells."

4. Whether the district court properly ruled that it lacked personal jurisdiction over L'Oréal S.A. and denied jurisdictional discovery.

STATEMENT OF THE CASE

I. THE PATENTS-IN-SUIT

The patents-in-suit are U.S. Patent Nos. 6,423,327 ("the '327 patent") and 6,645,513 ("the '513 patent"), which share a common specification and expired three years ago. Claim 1 of the '513 patent is illustrative:

> A method for ***enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin***, without increasing dermal cell proliferation, the method comprising ***topically applying to the skin a composition comprising a concentration of adenosine in an amount effective to enhance the condition of the skin*** without increasing dermal cell proliferation, ***wherein the adenosine concentration applied to the dermal cells is 10^{-3} M to 10^{-7} M***.

Appx00081.[2] Thus, the claim is directed to a method for "enhancing the condition of unbroken skin of a mammal" that comprises, among other limitations, applying a composition containing adenosine in an amount "effective to enhance the condition of the skin" without the supposed deleterious effect of "increasing dermal cell proliferation" (the "skin-enhancement limitation").

The claims do not recite any particular numerical amount of adenosine to achieve this required function. The claims do, however, refer to an adenosine concentration range that is "applied to dermal cells" (the "adenosine-concentration limitation"). At Plaintiffs' urging, the district court construed this numerical concentration range to refer to the adenosine concentration that permeates through the skin and actually reaches the underlying "dermal cells" following topical application, rather than the adenosine concentration in the composition applied to the skin. Statement of the Case (II.B), *infra*.

A. The Skin-Enhancement Limitation

Although the claims are directed to a method of topically applying a composition for "enhancing" unbroken skin, the specification does not actually contain any (i) example of an actual composition that achieves this result or (ii) experimental data demonstrating "enhancement." The only experiments in the

[2] Claim 1 of the '327 patent is identical, except the concentration range is 10^{-4} M to 10^{-7} M. Appx00071.

patents involved *in vitro* petri dish studies with adenosine—not topically applying a composition to skin. Appx00069-00071(6:15-9:51).[3]

Without examples or data evidencing the effects of topical application of an adenosine-containing composition, the specification defines "enhancement of skin condition" as a "***noticeable decrease*** in the amount of wrinkling, roughness, dryness, laxity, sallowness, or pigmentary mottling in skin." Appx00067(2:35-37), Appx00069(5:45-48). The specification then declares that this assessment "can include subjective evaluations by the patient or a second party." Appx00069(5:50-51). Named inventor and Plaintiffs' 30(b)(6) designee, Dr. Dobson, confirmed that "a ***subject[ive] assessment*** of a diminution of fine lines and wrinkles or decrease in elasticity ***does satisfy*** or qualify as enhancing the condition of the skin, as [he] ***defined it in the patent***." Appx12561(135:4-18), Appx12553-12554(37:17-38:5), Appx12549-12554(33:9-38:5), Appx12601-12602.[4]

[3] Hereafter, references are provided only to the '327 patent.

[4] The specification discusses objective "skin topography measurements" as ***also*** permitted, but ***only*** with regard to "fine lines and wrinkles," Appx00069(5:52-58), Appx15085, PBr. 45, and not "roughness, dryness, or laxity of the skin," Appx00071(10:20). The specification also does not endorse any particular method of measuring skin enhancement, or otherwise indicate that the different available methods will provide consistent results. Appx00069(5:44-6), Appx12331-12335, Appx12379-12380.

Although Plaintiffs now contend that the enhancement claim language does not limit the claims, they took the contrary position during prosecution (and, indeed, *Markman* proceedings below, Appx18829, Appx19014-19016). Specifically, Applicants added the claim language "a method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin" and then relied on that requirement to distinguish certain prior art disclosing the topical application of adenosine to heal wounds (*i.e.*, broken skin). Appx02686, Appx02684, Appx02689, Appx12839-12841.

B. Plaintiffs' Fluidity with the Adenosine-Concentration Limitation

From at least 1971 onward, adenosine was recognized as suitable for use as a skin-cosmetic ingredient. Appx02877-02879, Appx12306, Appx15844-15845, Appx15912. The art taught that adenosine provided skin benefits by acting at the dermis. For example, the 1997 "DE107" patent application explained that adenosine addressed the "[l]oosening and formation of wrinkles in part due to the reduction and cross-linking of collagen and accumulation of glucosaminoglycans," which appear in the dermis. Appx12909, Appx12312, Appx15845. Similarly, the 1983 "Hartzshtark" reference demonstrated that adenosine increased skin firmness, disclosed that this "reflect[ed] the state of the ground substance" (*i.e.*, material found in the dermis), and hypothesized that this was caused by stimulating dermal

fibroblasts. Appx02917-02918, Appx15916, Appx15957-15958.[5] In addition, both prior art references used adenosine in compositions for topical delivery to the skin at the very same concentrations (*e.g.*, 0.1%) used in the L'Oréal USA products accused of infringement—which are the very same concentrations Plaintiffs expressly distinguished during prosecution. Appx12922-12925, Appx02917-02918, Appx15818, Appx12368, Appx02704-02705.

Indeed, by the mid-1990s, a number of well-known cosmetic companies, including Estée Lauder and Beiersdorf (which markets Nivea and Coppertone products, among others), disclosed adenosine-containing cosmetic skin creams. Appx15784, Appx15836-15839, Appx12908-12938. L'Oréal had likewise recognized by that time that adenosine and adenosine phosphate could be incorporated into anti-aging cosmetic compositions, Appx15789-15790, Appx16973, and, after further independent investigation, included adenosine in its products.

During prosecution, Plaintiffs argued that the adenosine concentrations in the topical compositions of their claims were lower than the prior art, and that these claimed lower concentrations would have been expected to cause unwanted "dermal cell proliferation." Appx02704-02705. Yet the inventors themselves

[5] Plaintiffs thus lack credibility in telling this Court that, "before the invention here, the only known 'site of action' for adenosine was the epidermis." PBr. 9.

admitted in deposition that no concentration of adenosine, to this day, has ever been shown to cause dermal cell proliferation, and that the prior art did not suggest that adenosine would cause dermal cell proliferation. Appx12556(93:12-95:12), Appx12616(102:9-20), Appx12621(107:14-22), Appx12624(110:10-24), Appx12639(169:16-22).[6]

Faced with this knowledge, and the fact that the accused L'Oréal USA products use prior-art adenosine concentrations, Plaintiffs pivoted in the district court by arguing that the claimed adenosine concentration ranges actually correspond to the concentrations that "reach[] the dermal cells" (as opposed to the composition concentrations). As explained in Argument Section II, this creates indefiniteness given the utter lack of guidance as to how to determine the adenosine concentration that "reache[s] the dermal cells" following application of a composition to the skin.

That litigation-inspired construction also contradicts the specification, which repeatedly teaches that the claimed adenosine concentration ranges refer to the concentration in the composition that is applied to the skin. The specification describes seven categories of purported "invention." Five of them involve "topically" administering a "therapeutically effective amount" of adenosine to

[6] Despite their assertions to the contrary, PBr. 8, Plaintiffs admitted that the prior art taught that the use of 0.1% adenosine is safe, Appx18857(¶22).

"skin" or "***skin … containing the dermal cell[s]***." Appx00067(1:42-2:8). This "therapeutically effective amount" is defined as "an amount that enhances skin condition when ***applied to skin***," Appx00067(2:38-40), and is disclosed to have a concentration of "preferably 10^{-3} M to 10^{-7} M, more preferably 10^{-3} M to 10^{-6} M, and most preferably about 10^{-4} M"—*i.e.*, the ***exact concentrations recited in the '513 patent claims***—in the "above-described [topical] methods." Appx00067(2:13-17). The only other category relevant to the asserted claims involves "***composition[s]*** including about 10^{-3} M to about 10^{-7} M adenosine" plus an angiogenesis factor. Appx00067(2:30-32).[7] Moreover, the specification does not mention any adenosine concentration that is based on a volume of dermis material (as opposed to a volume of solution), or measured at the dermis after topically applying a composition (much less how such a measurement would be performed).

This accords with the prosecution history, where Applicants represented (and the Examiner accepted) that the recited concentration ranges refer to adenosine composition concentrations. The original claims recited only such concentrations, and Applicants insisted that specifying that the recited concentration ranges (originally included only in dependent claims) are "applied to

[7] Another embodiment involves the *ex vivo* culturing of fibroblasts and is not covered by the claims at issue. Appx00067(2:9-12).

the dermal cells" added no new matter, citing in support the above-described specification passages directed to adenosine concentrations "applied to [the] skin containing the dermal cell[s]." Appx02684-02685, Appx02701-02702, Appx02708.

And contrary to the positions Plaintiffs now take in accusing L'Oréal USA's products of infringement, Applicants sought to distinguish prior art disclosing the ***same*** 0.1% adenosine concentration used in the accused products by stating that this prior art ***composition*** concentration was ***higher*** than the claimed ranges:

> Hartzshtark indicates … that the adenosine concentration effective to reduce indentation was 0.1% (3.8×10^{-3} M) …. The proposed amended claims would recite a ***maximum concentration*** of adenosine of 10^{-4} M.

Appx02705-02706. In allowing the claims, the Examiner explained that they "are directed to … administering adenosine at a concentration of 10^{-3} to 10^{-7} M [or 10^{-4} to 10^{-7} M] ***to the skin***, and the art of record utilizes ***concentrations much higher than claimed*** …." Appx02769, Appx02727. For both patents, Applicants agreed with the Examiner's reasoning (while also parroting back certain claim language, *see* Argument Section (III.C), *infra*). Appx02771, Appx02729.

II. PROCEEDINGS BELOW

Plaintiffs filed this action in 2017, accusing L'Oréal USA and its French parent, L'Oréal S.A., of selling an unspecified number of products that, when used, allegedly infringed the patents-in-suit. Appx00055-00060. Both the initial and

amended complaints identified only one specific product. Appx00055(¶34), Appx00234(¶34).

A. Personal Jurisdiction

L'Oréal S.A. moved to dismiss for, *inter alia*, lack of personal jurisdiction. In opposition, Plaintiffs argued only specific, not general, jurisdiction. Appx00557-00558. In the alternative, Plaintiffs sought jurisdictional discovery without identifying any specific matters on which discovery was needed. Appx00577-00578. In a thorough Report and Recommendation ("R&R") that methodically considered Plaintiffs' evidence, as well as L'Oréal S.A.'s evidence, the magistrate judge rejected Plaintiffs' agency and stream-of-commerce arguments (among others) as unfounded and "contradicted" by their "own proffered evidence," and denied jurisdictional discovery. Appx00039-00048.

Plaintiffs objected to the R&R's personal-jurisdiction ruling only on the agency question. Appx01251-01255. The district court ruled that the evidence, even if "viewed most favorably for Plaintiffs," did not establish that "L'Oréal S.A. exercised control over L'Oréal USA's manufacture and/or distribution of the Accused Products in the United States." Appx00021. The district court denied jurisdictional discovery because Plaintiffs "failed to suggest with reasonable particularity" that personal jurisdiction may exist. Appx00022.

B. Claim Construction

During *Markman*, the parties disputed the construction of the adenosine-concentration limitation. L'Oréal USA proposed a construction of "the adenosine concentration ***applied to the skin containing the dermal cells***." This construction was based on the claim language (including the use of the definite article "the" to refer back to the adenosine concentration "***appl[ied] to the skin***"), specification (describing, *inter alia*, "the invention" as applying the concentration ranges "to a region of ***skin … containing the dermal cell[s]***"), and prosecution history (where Plaintiffs distinguished the prior art based on composition concentrations and the Examiner allowed the claims because they were directed to "administering [the adenosine concentration range] ***to the skin***," Appx02727, Appx02769), as well as the uncontroverted expert declaration of Dr. Gerald Kasting (explaining, *inter alia*, that "dermal administration" means applied to the skin, Appx02872-02873).

The district court sided with Plaintiffs, ruling that the phrase at issue "has its plain and ordinary meaning without the need for further construction." Appx03739, Appx03719-03722. The court later declared this limitation "require[s] the concentration to be measured when the adenosine reached the dermal cells under the surface of the skin." Appx00003-00004.

C. Summary Judgment of Indefiniteness

Following discovery, including three rounds of expert reports, the parties cross-moved for summary judgment. L'Oréal USA argued that both the skin-enhancement and adenosine-concentration limitations rendered the claims indefinite.

With respect to the skin-enhancement limitation, L'Oréal USA demonstrated that the undisputed record evidence showed that it involves a purely subjective assessment, which was confirmed by inventor Dr. Dobson (Plaintiffs' Rule 30(b)(6) designee) and not disputed by Plaintiffs' expert, Dr. Bozena Michniak-Kohn. Appx11817-11818(¶¶7-10), Appx15138-15139(¶¶7-10), Appx18831, Appx12331-12335, Appx12477-12479. The undisputed evidence further showed that different methods for assessing skin enhancement can and do produce conflicting results such that a given product could be inside or outside the claimed range depending on the method used, with no specification guidance as to which method should be used. Appx12332-12335, Appx11818(¶12), Appx15139(¶12), Appx12379-12380.

The district court granted summary judgment of indefiniteness. Appx00001-00015. Keenly aware of Plaintiffs' previous reliance on the limitation, the court first rejected Plaintiffs' attempt "to collapse the skin enhancement limitation into the recited concentration range" and found that the skin-enhancement language

must be given effect. Appx00007-00010. The court then addressed the scope of this term, determining that "enhancement" involves a "purely subjective" assessment and thus "depends on the unpredictable vagaries of any one person's opinion." Appx00011. Indeed, the district court found that the specification "expressly confirm[ed] that the determination of whether the skin enhancement condition is satisfied can be made by purely subjective evaluations of one or more persons." Appx00012 (citing Appx00069(5:48-52)).

The district court further found no material dispute of fact because, in addition to the legally binding intrinsic record, Dr. Dobson testified that "a subjective assessment … does satisfy" the skin-enhancement limitation, Appx00013 (citing Appx12561) and Plaintiffs' expert "did not dispute in her expert reports that a subjective assessment may be used to determine whether the condition of the skin has been enhanced as required by the asserted claims." Appx00013-00014. As the district court recognized, this is "a paradigmatic example of indefiniteness." Appx00011.

Because all claims were indefinite on this basis, the district court did not reach the fully briefed, alternative ground of indefiniteness based on the adenosine-concentration limitation. *See* Argument Section (II), *infra*. The court entered final judgment invalidating all asserted claims on April 20, 2021, denying the parties' other motions as moot. Appx00017-00018.

SUMMARY OF ARGUMENT

I.A. The claims twice recite the requirement that the claimed methods must "enhance" the condition of the skin. The subjective and indeterminate scope of this requirement renders the claims indefinite. In contending otherwise, Plaintiffs ask the Court to disregard ***both*** instances of this claim language, and construe the claims to involve no more than topically applying an adenosine composition to the skin such that the adenosine diffuses into the dermis (however briefly) at an extraordinarily broad, multiple-orders-of-magnitude concentration range. Plaintiffs' reinterpretation also ignores the patents' lexicography defining "enhancement of skin condition" and "effective amount" in functional (and subjective) terms. And by seeking to define "***amount*** effective to enhance the condition of the skin"—in contravention of its plain meaning and the patent's express definition—as somehow referring solely to a "***concentration***," Plaintiffs ignore the specification's explanation that the former involves the quantity or dosage of adenosine applied, and not just the concentration. Finally, Plaintiffs disregard their reliance on the skin-enhancement limitation to distinguish prior art during prosecution.

I.B. Not only do the patents require an amorphous term of degree ("enhancing"), the specification expressly endorses subjective evaluations—without any guiding parameters—to determine skin enhancement, which the

inventor (and Plaintiffs' corporate designee) embraced and their expert did not contest. Making matters worse, the patents do not provide any examples of "enhanced" skin condition, or topical compositions that can achieve this effect. Even apart from the patents' embrace of subjective methods—which alone renders the claims indefinite—the manifold different tests for assessing skin enhancement produce interobserver discord and conflicting results. Plaintiffs' expert vaguely attempted to assert some limited correlation between unspecified metrics, but never addressed the fundamental absence of any basis by which a skilled artisan could reasonably determine the objective metes and bounds of the claims—and, indeed, acknowledged that a skilled artisan was free to choose whatever test they preferred.

II. The adenosine-concentration limitation, as construed by the district court at Plaintiffs' urging, equally renders the claims indefinite. The intrinsic record indisputably provides ***no*** guidance for determining the adenosine concentration that actually "reaches the dermal cells" following topical application. And the undisputed record evidence established that, even using Plaintiffs' preferred testing approach, there are still many ways of designing a test to attempt to make this determination. These variations can—and do—lead to conflicting results, such that the same use of the same product could be found to be inside or outside the claimed range depending on the parameters used. Indeed, Plaintiffs' own testing showed noninfringement for many accused products, but changing just

a single test parameter changed the outcome for the same products. The claims fail to "inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

III. This latter basis for indefiniteness is the direct result of Plaintiffs' misconstruction of the adenosine-concentration limitation in an attempt to cover the accused products. An ordinary artisan reading the specification would understand "applied to the dermal cells" to mean, as explained in the "Summary of the Invention," applied to the "skin … containing the dermal cell[s]." Appx00067(1:54-2:6). Indeed, L'Oréal USA's expert testified without dispute that an ordinary artisan would understand "dermal administration" to refer to application to the skin containing the dermal cells. This is consistent with the term "***the*** concentration" in the wherein clause at issue necessarily referring to the antecedent term "composition comprising ***a*** concentration of adenosine"—it does not introduce a brand-new concentration. And this is confirmed by the prosecution history, where Applicants (i) relied upon "applied to skin" language from the Summary of the Invention as support for this claim language and (ii) characterized their claims as referring to the concentrations applied to the skin in distinguishing prior-art skin creams based on their ***composition*** concentrations. The Examiner allowed the claims on that basis (which, to the extent there were any ambiguity

with respect to the ordinary meaning, would operate as a disclaimer of Plaintiffs' construction).

IV. Finally, the district court properly dismissed L'Oréal S.A. for lack of personal jurisdiction. Plaintiffs' evidence, even construed in its favor, does not establish *prima facie* that L'Oréal USA acted as L'Oréal S.A.'s agent or that the latter introduced the accused products in U.S. commerce. The district court also did not abuse its discretion in denying jurisdictional discovery, as Plaintiffs' self-contradictory evidence did not suggest that discovery would support jurisdiction.

ARGUMENT

I. THE SKIN-ENHANCEMENT LIMITATION IS INDEFINITE

A patent is invalid if it does not "particularly point[] out and distinctly claim[]" the invention. 35 U.S.C. § 112 ¶ 2. The patent claims, read in light of the intrinsic evidence, must "inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 572 U.S. at 901. As a result, "it is not enough … to identify ***some standard*** for measuring the scope of the" claim language, *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-71 (Fed. Cir. 2014) (emphasis in original), and claim meaning likewise cannot "depend on the unpredictable vagaries of any one person's opinion," *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350-51 (Fed. Cir. 2005) (affirming summary

judgment), *abrogated on other grounds by Nautilus*, 572 U.S. 898. Moreover, where there are "multiple methods" of evaluating a claim term that "lead[] to different results" and a lack of "guidance in the patent or the prosecution history as to which method should be used," the claim is indefinite. *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 803 F.3d 620, 634 (Fed. Cir. 2015).

A. The Skin-Enhancement Limitation Is Limiting

After having consistently treated the skin-enhancement limitation as a claim requirement, including during this litigation,[8] Plaintiffs reversed course and sought to defend against summary judgment by treating the vast majority of the claim language as mere surplusage. Plaintiffs attempt this sleight-of-hand by contending that "[t]he amount of adenosine effective to enhance the condition of the skin is … the recited numerical concentration range" in the claims' wherein clause. Second Corrected Confidential Opening Brief of Appellants ("PBr.") 35. The Court should reject this approach as contrary to basic claim construction principles and the intrinsic record.

First, claims should not be construed to render claim language superfluous. *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 692 (Fed. Cir. 2019). Yet Plaintiffs seek to eliminate the skin-enhancement requirement—which appears

[8] Appx01428-01434, Appx11819-11820(¶¶16-19), Appx02684, Appx02686, Appx02658, Appx02689, Appx12343-12344, Appx12905, Appx18829, Appx19004-19006, Appx19014-19015.

not once, but twice—in a single-step method claim comprising nine lines. The preamble recites "a method for ***enhancing the condition*** of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin …." Appx00071. The claim then proceeds to describe a "method comprising topically applying to the skin a composition comprising a concentration of adenosine ***in an amount effective to enhance the condition of the skin*** … wherein the adenosine concentration applied to the dermal cells is 10^{-4} M to 10^{-7} M." *Id.* Thus, the claim restricts the type of skin to be enhanced ("unbroken skin of a mammal"), the type of skin problem that must be reduced ("wrinkling, roughness, dryness, or laxity"), and the enhancement mechanism (topical application of an effective amount of "a composition comprising a concentration of adenosine"). Plaintiffs' improper proposal to treat claim language as meaningless would effectively result in the annotated claim below:

> A method ~~for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin, without increasing dermal cell proliferation, the method~~ comprising topically applying to the skin a composition comprising a concentration of adenosine ~~in an amount effective to enhance the condition of the skin without increasing dermal cell proliferation,~~ wherein the adenosine concentration applied to the dermal cells is 10^{-4} M to 10^{-7} M.

Second, Plaintiffs' construction, which requires only proof of any concentration falling within the broadly recited numerical range reaching the dermal cells, violates the patents' lexicography. A "'therapeutically effective

amount' of adenosine," which was equated with the claim term "amount effective" during prosecution, Appx02647, is defined as "an amount that enhances skin condition when applied to skin," Appx00067(2:38-40). Thus, the effective amount is determined by the recited functional result ("enhances skin condition"), not by any specific concentration.[9] And this functional result is in turn defined in the patents: "'enhancement of skin condition' means a noticeable decrease in the amount of wrinkling, roughness, dryness, laxity, sallowness, or pigmentary mottling in skin." Appx00067(2:35-37). Plaintiffs' construction is therefore contradicted not only by the claims, but also by "the single best guide to the meaning of a disputed term." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc).

Third, Plaintiffs ignore the readily apparent difference between an "amount" and a "concentration." A molar "concentration" is not an "amount"; it is a ratio of two amounts (*i.e.*, moles over liters). *See* Appx12380 (Plaintiffs' reading "ignores the distinction in the claim language between 'amount' and 'concentration'"). The specification confirms this distinction by referring only to topically applying therapeutically effective "amounts" of "a composition," or of "adenosine," to the skin. Appx00067(1:44-47) ("applying to the skin ***a composition*** including

[9] Were it otherwise, for example, 10^{-7} M adenosine could reach only the very top of the dermis for no more than a moment with no effect; but, according to Plaintiffs, that would constitute infringement. Appx18990-18992.

adenosine ***in an amount effective*** to enhance the condition of ***the skin***"), Appx00067(1:56-2:08, 2:38-40) (multiple references to topically administering a "therapeutically effective amount of adenosine [to the] skin"). The specification further explains that an effective amount is not just a function of concentration, but also of quantity: "***dosages*** for a ***therapeutically effective amount*** for topical application would be in the range of 100 ng to 10 mg per treated surface area per day." Appx00069(5:35-37). This is the accepted meaning of the common claim term "effective amount": a quantity or dosage that can achieve the intended result. *See Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003) (pre-*Nautilus*, cited by Plaintiffs).

Plaintiffs cite, but misread, the specification statement that "[t]he therapeutically effective amount of adenosine used in the above-described methods is preferably 10^{-3} M to 10^{-7} M, more preferably 10^{-3} M to 10^{-6} M, and most preferably about 10^{-4} M." Appx00067(2:13-16). This is not a definition of "therapeutically effective amount," as that term is expressly defined at column 2:38-40 and requires functional results (*supra* at 21-22). Grammatically, the above-referenced concentrations are subject complements that are descriptive, not definitional. They describe the adenosine concentrations that are "***prefer[red]***" characteristics of effective amounts of compositions applied to the skin.

Fourth, Plaintiffs overlook the claims' preamble, which, like most method-claim preambles, is separately limiting. *See Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1340-42 (Fed. Cir. 2021). This is particularly true here given that the preamble's enhancement requirement does not merely duplicate the body's skin-enhancement language, but rather imposes additional restrictions, namely: (i) the type of skin enhanced to "unbroken skin of a mammal," thereby excluding skin "healing" embodiments, Appx00067(1:49-53); and (ii) the particular manner of enhancement, *i.e.*, to only "wrinkling, roughness, dryness, or laxity," and not "sallowness" or "pigmentary mottling," as referenced in the specification, Appx00067(2:35-37).

In this regard, during (pre-*Nautilus*) prosecution, Applicants cancelled a pending claim and added a new claim with the preamble that limited the covered enhancements to the first four of the six conditions in the specification's express definition. Appx02684-02686, Appx00067(1:55). Applicants then relied on the skin-enhancement language to distinguish prior art, arguing that they "apply adenosine as a cosmetic approach to enhance the condition or complexion of the skin, whereas Cronstein describes a medical therapy for open wounds such as burns." Appx02689. The language is thus limiting. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1348 (Fed. Cir. 2002).

Fifth, the claims' use of "comprising" in the phrase "applying to the skin ***a composition comprising a concentration of adenosine*** in an amount effective to enhance the condition of the skin" does not support equating "***adenosine*** in an amount effective to enhance the condition of the skin" with the recited concentration ranges, as Plaintiffs propose. PBr. 35, 40-41. Plaintiffs attempt to distort the recited concentration ranges as referring only to a "component" of the compositional adenosine concentration that "also includes additional adenosine." PBr. 40. That is doublespeak. A composition has one adenosine concentration (mol/L), and not lesser "included" concentrations. The "comprising" term means simply that the composition is not limited to adenosine, but may include additional, different ingredients, as the specification recognizes, Appx00068(4:16-28). "'Comprising' is not a weasel word with which to abrogate claim limitations." *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998).

For each of these independent reasons, the claims require separate proof of the skin-enhancement limitation.

B. The Skin-Enhancement Limitation Renders the Claims Indefinite

The skin-enhancement limitation renders the asserted claims indefinite for at least two independent reasons. *First*, the intrinsic evidence endorses subjective assessments to determine skin enhancement, without providing guidance regarding

how to make those assessments. *See Interval Licensing*, 766 F.3d at 1371. An ordinary artisan thus cannot discern the claim scope without guessing the boundaries set by future subjective opinions of unspecified persons. *See Datamize*, 417 F.3d at 1350; Appx00014. *Second*, irrespective of subjectivity, there are multiple, conflicting methods of measuring skin characteristics, and the intrinsic evidence does not indicate which test(s) to use. A skilled artisan therefore cannot discern claim scope with "reasonable certainty." *Nautilus*, 572 U.S. at 901; *Dow Chem.*, 803 F.3d at 634.

1. The Patents' Embrace of Purely Subjective Methods Renders the Claims Indefinite

"[T]o enhance the condition of the skin" is a facially subjective term of degree. It is facially subjective because whether skin is "enhanced" is a matter of personal opinion. *See Datamize*, 417 F.3d at 1350. It is a term of degree because its bounds depend on the degree of change. *See, e.g.*, *Intellectual Ventures I LLC v. T-Mobile USA, Inc.*, 902 F.3d 1372, 1381 (Fed. Cir. 2018) (finding "optimizing [quality of service]" to be an "entirely subjective" term of degree). Consequently, for a claim with such a term to be definite, the intrinsic evidence must clarify its "objective boundaries" with reasonable certainty. *Interval Licensing*, 766 F.3d at 1370-71.

In discerning these boundaries, the specification is "key." *Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1378 (Fed. Cir. 2017). In *Interval Licensing*,

the Court found the "highly subjective" term "unobtrusive manner" to be indefinite where the specification, which contained only one example of an "unobtrusive" embodiment, provided insufficient objective guidance. 766 F.3d at 1371-74 (declining "to cull out a single 'e.g.' phrase from a lengthy written description to serve as the exclusive definition of a facially subjective claim term"). In *Datamize*, a claim to "aesthetically pleasing" computer interfaces was similarly indefinite, as the specification "did not contain any examples of an 'aesthetically pleasing' interface" or identify "what factors" should be considered, despite detailing "various elements" that might affect aesthetic pleasure. *Sonix*, 844 F.3d at 1377-79 (citing *Datamize*, 417 F.3d at 1352). In *Sonix*, the Court found "visually negligible" to be definite only because the specification taught the "general exemplary design" as well as the express "requirements," and also included "two specific examples." 844 F.3d at 1378-79.

Here, the specification provides no skin-enhancement examples meeting the specification's definition, let alone enhancements resulting from topically applying adenosine compositions. Appx12331-12332. Instead, the specification defines "enhancement of skin condition" as "a noticeable decrease"—***another facially subjective term of degree***—"in the amount of wrinkling, roughness, dryness, laxity, sallowness, or pigmentary mottling in skin," Appx00067(2:35-37), the first four of which are claimed as enhancements, Appx00071(10:19-20). And the

specification ***expressly directs*** that "noticeable decrease" can be assessed "subjective[ly]":

> Methods of measuring improvements in skin condition are well known in the art (see, e.g., Olsen et al., J. Amer. Acad. Dermatol. 26:215-24, 1992) [("*Olsen*")] and ***can include subjective evaluations by the patient or a second party***, e.g., a treating physician.

Appx00069(5:48-54). The specification provides no "guidance" or "specific examples." *Sonix*, 844 F.3d at 1379.[10]

There is no genuine dispute that the patents embrace subjective measures. Citing the deposition testimony of Dr. Dobson, a named inventor and Plaintiffs' Rule 30(b)(6) designee, the district court correctly found that skin enhancement involves "purely subjective" assessments. Appx00013. Dr. Dobson agreed that "***a subjective assessment*** of a diminution of fine lines and wrinkles or decrease in elasticity ***does satisfy*** or qualify as enhancing the condition of the skin, as [he] defined it in the patent." *Id*. (quoting Appx12561(135:4-18)), Appx11818(¶10), Appx15139(¶10), Appx12331-12332(¶258), *see also* Appx11817(¶¶5-8),

[10] As discussed below (at 31-32), although the specification then provides that "[o]bjective methods ***can*** include skin topography measurements, such as those described in Grove et al., J. Amer. Acad. Dermatol. 21:631-37 (1989)," it does not require their use in any circumstance, including for "fine lines and wrinkles." Appx00069(5:52-58). Nor are the claims at issue so limited, and Plaintiffs have not contended otherwise.

Appx15138-15139(¶¶5-8).[11] The district court also found that Plaintiffs' "expert, Dr. Bozena Michniak-Kohn, did not dispute in her expert reports that a subjective assessment may be used to determine whether the condition of the skin has been enhanced as required by the asserted claims." Appx00013-00014, Appx11818(¶9), Appx15139(¶9), Appx12479(¶186).

Plaintiffs argue that "subjective evaluation," as used in the patents, involves "human perception," but not "opinions" or "value judgment[s]." PBr. 46-48. Plaintiffs' and their expert did not take this position below, and Plaintiffs improperly try to rely on three articles outside the summary-judgment record, *see* PBr. at 12-13, 46-47, which this Court should not consider (even if cited in the specification or an expert report), *see Am. Standard Inc. v. Pfizer Inc.*, 828 F.2d 734, 746 (Fed. Cir. 1987).

Regardless, these articles show the opposite. The Olsen reference, for instance, asked patients whether their skin was "much improved, somewhat improved, the same or worse" after a course of treatment; investigators assessed responses as "excellent (much improved), good (improved), fair (slightly improved), or poor (no change or worse)." Olsen *et al*., *Tretinoin Emollient*

[11] Contrary to Plaintiffs' assertion (PBr. 24 n.7, 45, 56), Dr. Dobson's testimony squarely addressed "enhancing the condition of the skin, as [he] ***defined it in the patent***." Appx12561(135:4-18).

Cream: A New Therapy for Photodamaged Skin, 26 J. Am. Acad. Dermatol. 215 (1992) at 216. The Grove authors likewise discussed ratings such as "much improved," "somewhat improved," and "same or worse." Grove *et al*., *Effects of Topical Retinoids on Photoaged Skin as Measured by Optical Profilometry*, 190 Methods in Enzymology 360 (1990) at 368. Such judgments necessarily rely on the evaluator's (and patient's) opinion. Moreover, the specification distinguishes *Olsen*'s methods from the separately identified "subjective evaluations." Appx00069 (5:48-52). Regardless, quoting extensive scholarship from the relevant period, L'Oréal USA's expert noted the "inconsistencies" that "plagued" studies relying on subjective assessments governed by grading scales, including "unacceptable variability" due to differences between evaluators. Appx12332-12335. Plaintiffs did not contradict this evidence.[12] Appx11818(¶11), Appx15139(¶11) (citing Appx12479(¶186)).

Plaintiffs erroneously argue that "noticeable decrease" is necessarily an objective term similar to the "visually negligible" limitation approved in *Sonix*: "Noticeable 'involves what can be seen by the normal human eye,' thus providing 'an objective baseline through which to interpret the claims.'" PBr. 43-44 (quoting *Sonix*, 844 F.3d at 1378). Unlike *Sonix*, the claims do not specify a particular

[12] The context of these articles was not, of course, determining whether a particular product infringes a patent claim or not, subjecting a party to damages claims.

sensory test, and the nature of the observation is different; a visual versus a tactile test may yield different results as to, for example, decreases in roughness, dryness, or laxity. *See* Appx12333-12334 (discussing problematic "highly subjective" visual and tactile tests for dryness). And there are no standards to determine what observable phenomena constitute a "decrease." There is no discussion regarding, for example, whether (i) more, but shallower, wrinkling or (ii) more pronounced roughness in a smaller area constitutes a decrease. Nor is there any reliable basis by which different observers might notice a change in the pattern of wrinkles, roughness, dryness, or laxity and register it as a decrease; an improvement that is "noticeable" to one patient may not be noticeable to another or to a "second party," but the patents permit any of those evaluations. Appx00069(5:50-51). Whether an improvement is "noticeable" necessarily also depends on a person's "attentiveness" and "mental state at a given moment"—one factor that distinguished the indefinite claim in *Interval Licensing* from the definite claim in *Sonix*. *See Sonix*, 844 F.3d at 1378.

Plaintiffs point to the specification's description of "skin-topography measurements" as ***one*** objective measure. PBr. 45. But the specification describes the cited method as applying to assessing "fine lines and wrinkles," Appx00069(5:57), and neither Plaintiffs nor their expert have contended that this is the sole test to be used to assess the skin-enhancement limitation in the asserted

claims. Moreover, Plaintiffs' reliance on a computer-imaging test of skin topography, Appx00069(5:60-6:4), also contradicts Plaintiffs' proposed definition of a "noticeable decrease" as one that is "seen by the normal human eye." PBr. 44. In any event, neither the specification nor the claims at issue requires an objective assessment; subjective assessments can be used instead. Appx00069(5:57); *accord* Appx12561 (Dr. Dobson admitting that the claims cover subjective assessments of decreased wrinkling).

None of Plaintiffs' counterarguments carries the day. Plaintiffs argue that the specification's embrace of subjective methods "describes the art, not the patents." PBr. 45. Not true; the specification is specifically explicating how to apply its skin "enhancement" definition. Appx00069(5:44-52). Nor is there record support for Plaintiffs' suggestion that the art reserves subjective evaluation for cases where enhancement is indisputable. PBr. 45. And the ability to visually identify the overall ***presence*** of skin conditions, PBr. 47-48, does not suggest any "accepted criteria," PBr. 48, for determining a noticeable ***decrease*** in wrinkling, roughness, dryness, or laxity.[13] Because this "term of degree" involves "the

[13] Contrary to Plaintiffs' claims, PBr. 50-52, this case is not like *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923). In *Eibel*, an ordinary artisan could discern from context what constituted the claimed "high" or "substantial elevation" of a papermaking machine wire by what achieved the intended result (*i.e.*, increasing processing speed while removing bubbles and disturbances in the stock). *Id.* at 50, 65-66. Here, the question of degree requires measuring the functional result itself, without additional contextual factors, and the

unrestrained, subjective opinion of a particular individual," which leads to a lack of concordance among different observers on skin-condition changes, it is indefinite. *See Datamize*, 417 F.3d at 1350-53; *Interval Licensing*, 766 F.3d at 1371.

2. The Multiplicity of Potential Tests Renders the Claims Indefinite

The incorporation of purely subjective methodologies for assessing skin enhancement is a sufficient, independent basis for finding indefiniteness. But the asserted claims are also indefinite because the multiple available alternative methodologies, including those described in the patent as objective, can and do produce conflicting results. Appx12331-12335, Appx12379-12380. Expert testimony and technical literature established that "no standard scale is widely used" to measure skin enhancement; for example, there are more than 100 skin-

---

evaluator is not necessarily a skilled artisan, but can be "the patient or a second party" making a "subjective" assessment. Appx00069(5:50-51). Plaintiffs' remaining cases are equally inapposite because they do not concern patent statements expressly endorsing purely subjective assessments or unrebutted evidence of conflicting test results, and otherwise addressed intrinsic records that, for example, disclosed multiple embodiments (including exemplary infringing and noninfringing products), pertinent test results, and/or specific criteria for ascertaining the scope of the claims. *See, e.g.*, *Guangdong Alison Hi-Tech Co. v. ITC*, 936 F.3d 1353, 1360-63 (Fed. Cir. 2019); *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp., LLC*, 879 F.3d 1332, 1345-47 (Fed. Cir. 2018); *Tinnus Enters., LLC v. Telebrands Corp.*, 733 F. App'x 1011, 1018-22 (Fed. Cir. 2018) (non-precedential); *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1366-67 (Fed. Cir. 2017); *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1375-77 (Fed. Cir. 2017); *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1382-84 (Fed. Cir. 2015).

aging scales, most of which lack validity and reliability, leading to lack of both repeatability and interobserver agreement on skin-condition differences. Appx12332-12335. "Studies using objective measurements on facial skin have been rare and yielded conflicting information." *Id*.

Plaintiffs' expert admitted that, at the time of patent filing, available tests included "objective clinical evaluation scales or tests such as TEWL studies, ultrasounds, other imaging, skin impressions, or biopsies, or some combination of the above," Appx12478, and "there continue to be numerous different ways to assess skin conditions," Appx12479. L'Oréal USA's expert pointed out that even *Olsen*—the very study cited in the specification as methodologically exemplary, *see* Appx00069(5:49-50)—reported conflicting assessments from medical professionals and patients. Appx12332-12333 ("None of the results for the subjects' self-assessment [of global response] were statistically significant and the results did not match the investigators' evaluations.").[14] Plaintiffs did not dispute that different methods can yield conflicting results. In fact, Dr. Dobson agreed that, "depending on the tests that you use, a formulation can show an improvement in wrinkling in one test but no improvement in wrinkling in the other test for that

[14] In one treatment group of 75 patients, the expert rater determined that 32% of patients had shown an improvement, while a full 60% of the patients felt that their own skin had improved. *Compare Olsen* at 217 tbl.II *with id*. at 221 tbl.V.

same formulation," and "the same thing would be true for roughness." Appx12577(171:1-15). Nor did Plaintiffs' expert contradict this testimony. Appx12477-12480.[15] Indeed, in opposing summary judgment on this ground, Plaintiffs cited only a ***single paragraph*** from Dr. Michniak-Kohn's report, which is entirely non-responsive regarding this issue (as were Plaintiffs' specification and *Markman* transcript citations). *Compare* Appx11818(¶¶11-14) *with* Appx15139-15140(¶¶11-14), Appx12479(¶186), Appx15085-15086.

Contrary to Plaintiffs' claim (PBr. 54-58)—which they did ***not*** raise in summary judgment briefing, Appx15139-15140(¶¶11-14), and thus waived on appeal, *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1295-96 (Fed. Cir. 2009)[16]—Dr. Michniak-Kohn's assertion that "comparative studies have shown

[15] Plaintiffs discuss how L'Oréal USA tests its own products or advertises them to consumers, PBr. 53, but neither says anything about how a skilled artisan would perceive the outer boundaries of the skin-enhancement limitation ***in the context of the patents-in-suit***. Nor are advertisements about a cosmetic product—containing ***multiple ingredients besides adenosine***—probative of a patent claim directing that adenosine must enhance the skin. Plaintiffs' attempt (PBr. 53) to derive a general rule concerning a defendant's advertising from *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014), is misguided. That case involved a "look and feel" claim term having an "established meaning" in the art of e-commerce systems (*e.g.*, logos and other website elements), as evidenced by, for example, the defendant's advertising. 773 F.3d at 1260-61. *DDR* did not establish that a defendant's advertising can override the specification's express endorsement of purely subjective assessments.

[16] Faulting the district court for not considering arguments Plaintiffs failed to raise is remarkable only for its chutzpah. *Cf. Checkpoint Sys., Inc. v. ITC*, 54 F.3d 756, 763 n.7 (Fed. Cir. 1995).

correlation between assessments performed using different metrics," Appx12478(¶185), creates no genuine issue of fact regarding indefiniteness. Claims must give the public "fair notice of … the metes and bounds of the claimed invention" to avoid infringement. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). The existence of some unspecified degree of correlation between certain tests does not establish a definite standard for determining the line between infringement and noninfringement, and thus the claims do not "inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus,* 572 U.S. at 901. For the same reason, L'Oréal USA had no burden to prove exactly how often the results of different tests would conflict, PBr. 57 n.15; the question is the reasonable certainty of the standard. And L'Oréal USA's evidence, summarized above, showed that these differences are significant. Indeed, Dr. Michniak-Kohn's concession that "the asserted patents provide flexibility for the skilled artisan to select the desired assessment standard," Appx12479, underscores the lack of reasonable certainty. The district court properly granted summary judgment of indefiniteness.

II. THE ADENOSINE-CONCENTRATION LIMITATION IS INDEFINITE UNDER THE DISTRICT COURT'S CONSTRUCTION

On appeal, this Court is "not limited to a district court's stated reasons for invalidating claims and can affirm a grant of summary judgment on any ground supported by the record and adequately raised below." *King Pharms., Inc. v. Eon*

Labs, Inc., 616 F.3d 1267, 1278 (Fed. Cir. 2010). As construed by the district court, at Plaintiffs' urging, the claim language "wherein the adenosine concentration applied to the dermal cells is 10^{-4} M to 10^{-7} M [or "10^{-3} M to 10^{-7} M"]" is also indefinite. This provides a separate, independent basis for affirmance.

It is undisputed that the intrinsic record does not provide ***any*** guidance regarding how to determine the adenosine concentration that actually reaches the dermal cells following topical application. And the undisputed record evidence establishes that—even focusing solely on the single type of testing advocated by Plaintiffs—there are multiple methods for attempting to make this determination, which can (and in fact do) lead to conflicting results such that the use of a given product may be found to be inside or outside the claimed range depending on the testing method. In such situations, this Court has consistently held claims invalid as indefinite. *See, e.g.*, *Forest Labs., Inc. v. Teva Pharms. USA, Inc*., 716 F. App'x 987, 994 (Fed. Cir. 2017) (non-precedential) (following "precedents" finding indefiniteness where "different techniques for [quantity] measurements are known in the art and some produce infringing results and others not, the intrinsic evidence does not adequately specify the technique or techniques to use, and extrinsic evidence does not show that a relevant skilled artisan would know what technique or techniques to use"); *Dow Chem.*, 803 F.3d at 634 (holding claim indefinite where "multiple methods" of evaluating claim term "lead[] to different results"

given lack of "guidance in the patent or the prosecution history as to which method should be used"); *Honeywell Int'l, Inc. v. ITC*, 341 F.3d 1332, 1335-36, 1339-40 (Fed. Cir. 2003) (claims requiring a "melting point elevation" within particular numerical ranges to be determined using differential scanning calorimetry indefinite where sample could be prepared in multiple ways that materially affected the results without guidance in the intrinsic record).[17]

A. The Intrinsic Record Does Not Provide Guidance Regarding How to Determine the Claimed Results

The district court construed the adenosine-concentration limitation as referring to the adenosine concentration that "reache[s] the dermal cells" following topical application to the skin. Appx00003-00004. So construed, the question then becomes how to determine whether this limitation is met, *i.e.*, the standard for assessing the claimed concentration. *See Nautilus*, 572 U.S. at 909 ("[A] patent must … appris[e] the public of what is still open to them.").[18]

---

[17] *See also HZNP Meds.*, 940 F.3d at 698 (holding claims indefinite where claimed parameter could be assessed using two tests that "do not provide consistent results"); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015) (claim term "molecular weight" was indefinite where "each of these measures is calculated in a different way and would typically yield a different result for a given polymer sample").

[18] Contrary to Plaintiffs' arguments below, the claims' recitation of a specific concentration range is not sufficient to satisfy the definiteness requirement, especially in view of the case law cited above. *See, e.g.*, *Interval Licensing*, 766 F.3d at 1371 (even where claim terms "can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition

It is undisputed that the intrinsic evidence discloses no information regarding how to ascertain this value, including any testing methodology. Appx11770(¶5), Appx12326-12327, Appx12378(¶100), Appx15026(¶5). While the specification generally recognizes that adenosine may penetrate the skin, Appx00069(5:10-23), Dr. Dobson admitted that the patents do "not discuss how to measure the concentration of adenosine that reaches the dermal layer after topical application of a composition containing adenosine," Appx12578(176:5-12), Appx12579(177:4-8), Appx12550-12552(34:8-18, 35:9-21, 36:4-17), Appx12601-12602. Plaintiffs' expert, Dr. Michniak-Kohn, likewise agreed that the patents do not "mention anything about how to measure the concentration of the adenosine that reaches the dermis after topical application." Appx12761-12762(80:14-22, 81:18-20). The intrinsic record is thus entirely silent about how to determine the claimed concentration values following topical application.

B. Plaintiffs' Post-Hoc "Franz Cell Testing" Can Be Conducted in Many Different Ways

In defending against indefiniteness, Plaintiffs relied on "*in vitro* permeation testing" (also known as "Franz cell testing"), Appx12474-12475(¶174), which is not mentioned in the patents-in-suit, Appx15026(¶8). In such tests, a piece of skin (such as cadaver or surgically-excised, and taken from various parts of the body) is

---

into meaningfully precise claim scope"); *Forest Labs.*, 716 F. App'x at 994 (numerical ratio found indefinite).

mounted to an apparatus called a "diffusion cell," a composition (as well as potentially other materials) is applied to the skin for a period of time, and the extent of the composition's permeation through the different layers of the skin (or into the receptor fluid at the bottom of the cell) is measured. Appx12461-12462.

As Plaintiffs' own testing expert, Dr. Edward Kisak, admitted, "there is no single way to do an in vitro permeation test to study the distribution of cosmetic products in the skin." Appx12662-12665(43:15-22), Appx12327-12331(¶¶250-56). Plaintiffs' other expert, Dr. Michniak-Kohn, likewise conceded that "different methods for conducting [*in vitro*] penetration studies were available to a skilled artisan in 1997-1998." Appx12476(¶177). Similarly, Dr. Dobson testified that there are "many variations of Franz Cell diffusion systems," including with respect to test parameters. Appx12580-12585.

These admissions, and the evidence discussed herein, expose as unsupported Plaintiffs' assertion on appeal that *in vitro* permeation testing was a "specific method[] for measuring 'dermal penetration,'" PBr. 26 n.8, which mirrors arguments it made below—in an attempt to stave off indefiniteness—that this is a single, "standardized" testing method that "a POSITA would know to use," Appx14993-14994, Appx15026-15030 (citing Appx15038-15039, Appx12392,

Appx12579-12580(177:22-178:6).[19] To the contrary, it is undisputed that a scientist conducting *in vitro* permeation testing can choose among the different acceptable parameters, *e.g.*, different kinds of skin samples, diffusion cell types, and materials ("tracers") for labeling the adenosine for measurement. Appx11771(¶¶10-11), Appx12476(¶177), Appx12662-12665, Appx12581-12582, Appx12327-12331(¶¶250-55), Appx15027(¶¶10-11). The tested skin may: (i) be from a cadaver or surgically excised tissue (and stored under different conditions, including fresh or frozen); (ii) have different thicknesses and come from different parts of the body (*e.g.*, abdomen, back, breast, or arms); and (iii) have different qualities depending on the donor's gender, race, and age. Appx11771-11772(¶12), Appx12327-12330, Appx12622-12655, Appx12582, Appx12764-12766, Appx15027(¶12). Likewise, the diffusion cell can have different designs, including configuration (*e.g.*, static or flow-through) and materials (*e.g.*, glass, Teflon, stainless steel, or plastic), and the amount of applied dose, the duration of exposure, and the type of tracer molecule can all vary. Appx11772(¶13),

[19] At most, Plaintiffs' evidence showed that *in vitro* permeation testing is a general type of testing with many acceptable variations. Regardless, this Court has held (both *pre-* and *post-Nautilus*) that, even when there is one type of measurement method relevant to the claims, they are indefinite when, as here, the variation allowed by method parameters generate results inside and outside the claims without sufficient guidance in the intrinsic record. *See, e.g.*, *Forest Labs.*, 716 F. App'x at 994; *Honeywell Int'l*, 341 F.3d at 1335-36, 1339-40.

Appx12328-12331(¶¶251-55), Appx12664-12665, Appx12581-12582, Appx12585, Appx15027(¶13).

Indeed, Dr. Michniak-Kohn acknowledged that there are at least "several valid options for determining the adenosine concentration," Appx12476, and even within Plaintiffs' preferred categories of parameters, there is discretion in selecting "human skin samples," "diffusion cells," and "labeled molecules," among other parameters, Appx12376-12377, Appx12328-12331. There is thus a large number of variables involved in conducting Franz cell testing, which, as discussed below, significantly impact the results in outcome-determinative ways. *Compare* Appx11772(¶14), Appx12328-12331(¶¶251-55), Appx12375-12378(¶¶98-99), Appx12584-12585, Appx12596-12597, Appx12764-12768 *with* Appx15028(¶14) (citing Appx15050-15051).

C. The Post-Hoc Methodologies Give Varying, Outcome-Determinative Results

As Dr. Dobson, who also served as Plaintiffs' 30(b)(6) designee on the "testing" and "evaluation" of the "concentration of topically applied adenosine" that "reaches the dermal cell layer," testified: "The operator, the type of tissue used, the conditions under which the apparatus was utilized, the temperature, the pressure exerted to the top chamber. ***All those are factors that could affect the results***." Appx12596-12597(348:2-349:8), Appx12551-12552(35:25-36:17),

Appx12602, Appx15028(¶15). Dr. Dobson further testified that such differences "would be ***statistically significant***." Appx12596-12597(348:2-349:8).

Similarly, it is undisputed that, for each excised-skin sample used, there is donor-to-donor variability, and the donor's age, gender, and race as well as the body location from which the skin is taken will significantly affect its permeability. Appx11773(¶16).[20] In addition, both Dr. Dobson and Dr. Michniak-Kohn acknowledged that the amount of product applied and the duration of skin exposure to the composition will affect the adenosine concentration permeating the skin. Appx12585(193:5-24), Appx12766-12768(88:15-22, 112:22-113:3), Appx12331. Nor did Dr. Michniak-Kohn dispute the opinions of Dr. Kasting, L'Oréal USA's expert, that varying these parameters will significantly affect the results. *Compare* Appx12328-12331(¶¶251-55), Appx12375-12377(¶¶98-99), *with* Appx12473-12477(¶¶169-80).

Indeed, Plaintiffs' own infringement testing shows that varying even a single permissible testing parameter generates materially different, outcome-determinative results. When Plaintiffs first ran certain of their tests for this litigation, they failed to show infringement for many accused products, returning

[20] Although Plaintiffs argued that the cited evidence did not "support" this fact, Appx15028(¶16), the unrebutted evidence refutes Plaintiffs' position, Appx12329-12330(¶¶253-54), Appx12584(192:1-10), Appx12764-12766(86:12-15, 87:10-14. 87:20-88:14).

results that were below 10^{-7} M. *See* Appx12377-12378(¶ 99 & n.63), Appx12382-12388.[21] When they altered the donor tissue sample and reran the test, however, they claimed to obtain results for the same product above 10^{-7} M. *Id.*, Appx11773-11774(¶¶19-20). As Plaintiffs' own testing expert admitted,

> depending on the skin donor used, the ***same L'Oréal product*** may be found to deliver a concentration of adenosine to the dermis of ***greater than 10 to the minus 7 molar or less than 10 to the minus 7 molar.***

Appx12704(201:7-14), Appx12703(200:15-25), Appx12695(167:13-24), Appx12696-12697(174:24-175:5). This is incontrovertible evidence of indefiniteness.

Moreover, it is undisputed that the results for individual replicates of a given test involving the same skin donor often varied substantially, such that some were above 10^{-7} M and others were below. Appx12708, Appx12407-12409, Appx12377-12378(¶99 & n.64). Nevertheless, Plaintiffs accused these products of infringement. Thus, depending on the tissue sample used, the same product may be found to infringe or not infringe under Plaintiffs' proposed methodology.[22]

---

[21] Plaintiffs presented no evidence disputing the accuracy of Kasting Appendix D, which identifies examples where Plaintiffs' test results suggest that a given product was both within or outside the claimed ranges. Appx15029(¶21), Appx18971-18975(218:16-222:3).

[22] At summary judgment, Plaintiffs sought to minimize these differences by arguing that some samples were "overly 'noisy'" and so recorded as zeros. Appx14995-14996, Appx15029(¶¶19-20) (citing Appx12400, Appx12433, Appx12676-12677). Yet Dr. Kisak provided no underlying evidence of "noise" in

Particularly given its complete silence regarding methodology, the intrinsic record does not reasonably inform how to measure the adenosine concentration that "reache[s] the dermal cells." *See, e.g.*, *Dow Chem.*, 803 F.3d at 634 ("Neither the patent claims nor the specification here discusses the four methods or provides any guidance as to which method should be used or even whether the possible universe of methods is limited to these four methods."); *see also HZNP Meds.*, 940 F.3d at 698; *Teva Pharms.*, 789 F.3d at 1341.[23]

III. PLAINTIFFS' CONSTRUCTION OF THE ADENOSINE-CONCENTRATION LIMITATION IS WRONG

Given indefiniteness, this Court need not review Plaintiffs' arguments regarding the district court's construction of the adenosine-concentration limitation

---

connection with his reports, Appx12705(202:15-22), Appx19253(n.4), and unsupported assertions do not create a genuine issue of material fact, *see Parallel Networks, LLC v. Abercrombie & Fitch Co.*, 704 F.3d 958, 970 (Fed. Cir. 2013). And Dr. Kisak's reports attributed the zero values to "a signal too low to be accurately analyzed," not only noise. Appx12400, Appx12433. Moreover, the intrinsic record does not provide guidance regarding how to account for this supposed "noise." Regardless, Dr. Kisak's testing returned certain non-zero results that were both inside and outside the claimed ranges, and Plaintiffs do not claim that these differences were due to noise. Appx12387 (No. 118).

[23] At the district court, Plaintiffs sought to distinguish these cases by claiming they "involve a functional limitation," but that is incorrect; all involved physical parameters to be measured. *See Dow Chem.*, 803 F.3d at 624 nn.2-3 (polymer composition having "a slope of strain hardening coefficient greater than or equal to 1.3"); *Teva Pharms.*, 789 F.3d at 1338 ("copolymer-1 having a *molecular weight of about 5 to 9 kilodaltons*") (emphasis in original); *HZNP Meds.*, 940 F.3d at 697-98 ("better drying rate").

in this appeal. *See, e.g.*, PBr. 20-21, 40. Nonetheless, because claim construction is an issue of law that supports a judgment of noninfringement, PBr. 20 n.6 (conceding that "the adenosine in [L'Oréal USA's] topical compositions exceeds 10^{-3} M"),[24] and would obviate the second ground of indefiniteness, L'Oréal USA demonstrates below that the adenosine-concentration limitation should be construed to mean "the adenosine concentration applied to the skin containing the dermal cells."

A. The Claim Language Supports L'Oréal USA's Construction

First, the claims recite the step of "topically ***applying*** to the skin a composition comprising ***a concentration of adenosine*** in an amount effective … ***wherein the adenosine concentration applied*** to the dermal cells is 10^{-4} M to 10^{-7} M." Appx00071(10:20-21). The ordinary meaning of "apply" is "to bring into physical contact with ***or close proximity to***," and thus encompasses direct and indirect application. Appx02845. Indeed, dependent claim 10 recites such indirect

[24] *See, e.g.*, *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1305 (Fed. Cir. 2001) (reversing summary judgment of literal infringement under correct claim construction adopted on appeal and also finding no doctrine-of-equivalents infringement, even though issue was not raised below); *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1280 (Fed. Cir. 2013) (granting summary judgment of infringement based on undisputed facts, despite such relief not being requested below). Plaintiffs did not (and could not, in view of their prosecution amendments and arguments) pursue any equivalence-based infringement theory below.

topical application by using an adenosine-containing transdermal patch that is in turn "contacting … the skin." Appx00071(10:45-47).

As a result, adenosine may be "applied" (brought into close proximity) to the dermal cells by applying the adenosine composition to the skin containing those dermal cells, consistent with L'Oréal USA's construction. This is fully consistent with the ***only*** record evidence from the perspective of a person of ordinary skill in the art. Appx02872-02873 (Dr. Kasting explaining that "dermal administration" in the cosmetic arts means applied to the skin); *see also* Appx02873-02877, Appx02881-02883. In fact, Plaintiffs conceded in *inter partes* review proceedings involving the patents-in-suit that adenosine "compositions are 'preferably [***applied to the dermal cells***] ***by topical routes***," Appx02864 (alteration in original)—i.e., they equated the "applied to the dermal cells" claim language with topical application to the skin.[25]

Second, the claims use "a" to introduce the adenosine concentration ***in the composition***. The subsequent reference to "***the*** adenosine concentration applied to the dermal cells" refers back to, and specifies in numerical terms, the adenosine

[25] This understanding of "applied to the dermal cells" as referencing the adenosine's ultimate site of action (*i.e.*, the dermal cells) is also consistent with the claims' identification of that site of action immediately preceding the adenosine-concentration limitation. Appx00071(10:20-21) (referring to "without increasing ***dermal cell*** proliferation").

concentration in the composition that is applied to the skin containing the dermal cells. *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1306 (Fed. Cir. 2005) ("[I]t is a rule of law well established that the definite article 'the' particularizes the subject which it precedes."), *abrogation on other grounds recognized in Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1047 (Fed. Cir. 2016). Claims do not use a "definite article" to accomplish "the introduction of a new element" (here, a different concentration); this is the province of an indefinite article. *See Tuna Processors, Inc. v. Hawaii Int'l Seafood, Inc.*, 327 F. App'x 204, 210 (Fed. Cir. 2009) (non-precedential).

Third, "wherein" clauses "relate back to and clarify what is required by the [claim]." *Griffin v. Bertina*, 285 F.3d 1029, 1033 (Fed. Cir. 2002). Here, the wherein clause relates back to the prior clause, and explains that topically ***applying*** (a gerund) the composition comprising "***a*** concentration of adenosine" to the skin means that "***the*** adenosine concentration" (*i.e.*, the same concentration) is "***applied*** to the dermal cells" (past participle). In fact, Plaintiffs concede that "the 'wherein' clause" at issue in this case "gives 'meaning' to the prior" claim language. PBr. 36-37.[26]

[26] Plaintiffs mistakenly contend, however, that "the ***concentration***" somehow refers back to "an amount effective," as opposed to "a ***concentration***." Plaintiffs' repeated reliance on the district court's "referring back" analysis, PBr. 22, 37, 42, which they take out of context, is also misguided for this reason.

Fourth, the dependent claims confirm this common-sense understanding of the terms. Dependent claim 3 of each patent-in-suit recites "[t]he method of claim 1, wherein the adenosine concentration is 10^{-4} M to 10^{-6} M" ('327 patent) or "10^{-3} M to 10^{-6} M" ('513 patent). Appx00071(10:30-31), Appx00081-00082(10:29-30). Plaintiffs' construction renders the dependent claims unintelligible, as it would be unclear whether the dependent claim concentrations refer to the adenosine in the composition or what "reaches the dermal cell layer." Only L'Oréal USA's construction avoids this problem.

Plaintiffs' construction, on the other hand, defies the claim language and rewrites the phrase "***applied*** to the dermal cells." The ordinary meaning of "applied" (*see supra* at 46-47) is not "measured when … reached," and nothing in the claims or specification redefines that term. Making matters worse, Plaintiffs assert this second concentration term refers to not only a separate measurement, but also a ***completely different metric*** from the first concentration term (mol/L of dermis, as opposed to mol/L of composition). Appx12437. In other words, Plaintiffs' construction defines the same word—"concentration"—to mean mol/L of composition in the first part of the claim, and then mol/L of dermis in the second.[27] A concentration, by definition, is part of a solution (or

[27] Like their improper conflation of "concentration" and "amount," Plaintiffs' construction—"reaches" the "dermal layer" (Appx02559; PBr. 39)—also ignores the distinction between "dermal cells" and the dermis ("a deeper connective tissue

mixture/dispersion), *see, e.g.*, Webster's Third New International Dictionary (2002 ed.) at 469, and a concentration is only "applied" by applying the solution comprising that concentration to an object of interest. At a minimum, a definite article referring back to an antecedent term ("the concentration") does not introduce a completely new concentration metric. *Supra* at 47-48. Plaintiffs' construction simply cannot be reconciled with the claim language.

B. The Specification Supports L'Oréal USA's Construction

The specification "is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315. The specification does not mention ***any*** adenosine concentration "measured" when reaching the dermal cells (or dermal layer), including after topically applying a composition. And it never mentions any concentration measured as the amount of adenosine per volume of dermis. Instead, the patents refer ***only*** to the concentration of adenosine within an applied solution or composition. *See* Appx00067 (2:13-16, 2:30-34) (10^{-3} to 10^{-7} M topically applied compositions), Appx00068 (3:1-3), Appx00070-00071(8:48-

layer" of the skin, Appx00067(1:20)), Appx02885, Appx02871-02872. A skilled artisan would understand the term "dermal cells" to refer to cells that form part of, and are scattered throughout, the dermis (which includes substances that are not "cells"), Appx02871-02872, and measurement of adenosine concentrations ***within*** the dermis is not by any stretch "appl[ying]" adenosine concentrations to "the dermal cells."

9:51) (10^{-4} to 10^{-6} M solutions applied to cultured dermal fibroblasts). Plaintiffs have no specification support whatsoever for their construction.

By contrast, the specification confirms that the recited concentration ranges refer to the adenosine concentration in the composition applied to "***skin … containing the dermal cell[s]***." Appx00067(1:54-2:6). The "Summary of the Invention" of the patents-in-suit, for example, describes seven categories of purported "invention":

- Five involve "topically applying … therapeutically effective" adenosine concentrations—disclosed to be "preferably 10^{-3} M to 10^{-7} M, [and] more preferably 10^{-4} M to 10^{-6} M"—to "skin" or the "***skin … containing the dermal cell[s]***." Appx00067(1:42-2:8).[28]
- Another involves a "***composition*** including about 10^{-3} M to about 10^{-7} M adenosine" and an "angiogenesis factor." Appx00067(2:30-34).
- The last involves culturing fibroblasts "ex vivo" in adenosine and then reintroducing the fibroblasts into the mammal, which is not covered by the claims at issue. Appx00067(2:9-13).

[28] As explained above (at 9-10), the specification expressly identifies the adenosine concentrations in the "therapeutically effective amount[s]" that are "used in the[se topical] methods" to be "preferably 10^{-3} M to 10^{-7} M, [and] more preferably 10^{-4} M to 10^{-6} M," Appx00067(2:13-16), and defines "therapeutically effective amount" in terms of adenosine that is "applied to skin," Appx00067(2:38-40), Appx02882-02885.

That all six categories of "the invention" relevant to the asserted claims require the ***precise*** numerical concentration ranges set forth in those claims to be applied to the "skin … containing the dermal cells" confirms the correctness of L'Oréal USA's construction. *See, e.g.*, *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1318 (Fed. Cir. 2014) ("The fact that the Summary of the Invention gives primacy to these attributes strongly indicates [the proper claim construction].").

The specification also confirms that the claimed methods involve only one type of adenosine concentration (*i.e.*, the composition concentration). To stimulate DNA and protein synthesis and increased fibroblast cell size, the specification refers to (with minimal variation in wording) "topically administering a ***composition*** including a therapeutically effective amount of adenosine to a region of ***skin*** of the mammal ***containing the dermal cell***, wherein addition of the adenosine does not cause proliferation of the dermal cell." Appx00067(2:1-7, 1:54-65). Thus, in applying a composition comprising an adenosine concentration to skin containing dermal cells, the concentration is "applied to the dermal cells."

Finally, consistent with the claim language, *supra* at 46-47, the specification underscores that adenosine can be "appli[ed]" directly or indirectly: "adenosine may be applied directly and mechanically rubbed into the skin. Alternatively, adenosine or adenosine analogs may be incorporated into a transdermal patch that is applied to the skin." Appx00069(5:16-19). In sum, the specification repeatedly

makes clear that the claimed concentration ranges are applied to the skin containing dermal cells.

C. The Prosecution History Supports L'Oréal USA's Construction and, at a Minimum, Disclaims Plaintiffs' Construction

"[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention," and also "whether the inventor limited the invention in the course of prosecution" through a "clear and unmistakable disavowal." *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1094-95 (Fed. Cir. 2013). The prosecution history is "especially important" where, as here, "there is particular prior art that the applicant is trying to distinguish." *Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398, 1405 (Fed. Cir. 1996). The prosecution history eliminates any potential ambiguity regarding claim meaning, and indeed disclaims Plaintiffs' construction.

1. The '327 Patent Prosecution History

Claim 1's predecessor (claim 70) had the exact same language, except it did not contain the "wherein" clause reciting the adenosine-concentration range. Appx02684. Instead, dependent claim 72 recited "[t]he method of claim 70, where in the adenosine concentration is 10^{-4} M to 10^{-6} M." Appx02684. Thus, original claim 70 recited a single adenosine concentration in the composition ***applied to the skin***, with claim 72 identifying the numerical range of that concentration (10^{-4} M to

10^{-6} M). That concentration is ***moles per liter of composition***, not per liter of dermis, and would not be measured when the adenosine "reaches the dermal cells."

Applicants emphasized that claim 70 covered applications to the skin of compositions comprising adenosine in a therapeutically effective amount, and that "claims to specific concentrations are supported by the original claims and in the application, e.g., at page 3, lines 15-18." Appx02685. That passage became Column 2:13-17, and states: "The therapeutically effective amount of adenosine used in the above-described [topically administered] methods is preferably 10^{-3} M to 10^{-7} M, more preferably 10^{-4} M to 10^{-6} M, and most preferably about 10^{-4}M." Appx02657, Appx00067(2:13-17). Plaintiffs concede that this is the specification support for the "wherein clause," PBr. 34, which confirms that the adenosine-concentration limitation recites the concentration in compositions applied to the skin containing dermal cells.

Claim 1 took its final form by amendment to overcome a prior-art rejection. Specifically, Applicants added "wherein the adenosine concentration applied to the dermal cells is 10^{-4} M to 10^{-6} M"—*i.e.*, the same concentration range in dependent claim 72—to then-pending claim 70. Appx02701, Appx02708. Despite including the new phrase "applied to the dermal cells,"[29] Applicants explained that "[t]his

[29] Although this language was new, it tracks the site of action of the adenosine identified elsewhere in the claim (*i.e.*, the topically applied adenosine has the

amendment would ***add no new matter***, as it merely includes a range of concentrations of adenosine recited in the dependent claims and in the specification at page 3, lines 15-18," Appx02702, which, as noted immediately above, are the same composition concentrations that appear in the claims. Those concentrations, Applicants emphasized, were "based on the application of certain concentrations of adenosine ***to the skin*** to achieve certain results." Appx02702. Thus, Applicants affirmatively represented to the Examiner that the "wherein" clause recited adenosine concentrations of the composition previously set forth in the dependent claims, not some different concentration measured at the dermal cells. Plaintiffs should be estopped from arguing otherwise.

Indeed, Applicants proceeded to rely on the recited ranges to distinguish prior art ***compositions*** having higher adenosine concentrations. For example, Applicants acknowledged that the Hartzshtark reference disclosed a composition with an adenosine concentration effective to reduce skin indentation of 3.8×10^{-3} M (*i.e.*, 0.1%), but argued that "[t]he proposed amended claims would recite a maximum concentration of adenosine of 10^{-4} M." Appx02705-02706. "Thus," according to Applicants, "Hartzshtark does not anticipate claim 70 as amended." *Id.* Applicants similarly distinguished DE107 as disclosing

---

required effect while not "increasing dermal cell proliferation") before the amendment. Appx02708.

compositions having "a relatively high concentration of 0.1% adenosine." Appx02704.

Thus, Applicants characterized the adenosine-concentration limitation as reciting adenosine concentrations in skin-treatment ***compositions*** to distinguish the prior art. Irrespective of whether Plaintiffs set forth other alleged distinctions,[30] each "separate argument[]" is relevant to claim scope. *Amgen Inc. v. Coherus BioSciences, Inc.*, 931 F.3d 1154, 1159-60 (Fed. Cir. 2019).[31]

As a result, in its Reasons for Allowance, the PTO stated that the "[i]nstant claims are directed to … administering adenosine at ***a concentration of 10^{-4} to 10^{-7} M, to the skin***. The prior art of record teaches administering adenosine to skin for treating aging. However, the art of record utilizes concentrations much higher than claimed …." Appx02727. Both the PTO and Applicants understood the claimed concentration range to refer to the adenosine concentration in the composition applied "to the skin," and distinguished the prior art accordingly. *See ACCO*

[30] Applicant discussed whether the "higher" prior art composition concentrations would have been taught to result in "dermal cell proliferation," asserting that no such proliferation occurred at the "lower," claimed composition concentrations. Appx02704-02705. In litigation, it was revealed that no prior art disclosed "dermal cell proliferation," and Plaintiffs never pursued any patentability theory relating to this claim limitation below. *Supra* at 8-9, Appx14898-14899.

[31] Contrary to Plaintiffs' assertion (PBr. 14), the rejection of a L'Oréal patent application over the '327 patent was overcome by pointing out that the latter disclosed ***composition*** concentrations below 0.1%.

Brands, Inc. v. Micro Sec. Devices, Inc., 346 F.3d 1075, 1079 (Fed. Cir. 2003) (relying on Reasons for Allowance in construing claim).

Significantly, in its Comments on Statement of Reasons for Allowance, Applicants did not contest this ground, commenting that "the claims are allowable ***for at least all of the reasons of record*** in Applicants' responses," and not just those cited by the Examiner. Appx02729. Applicants parroted back the claim language by "not[ing] that the claimed concentration of adenosine is applied to the dermal cells." *Id.* But they never contested the Examiner's finding—which they had urged, including by citing in support of this claim language the Summary of the Invention's disclosure of "therapeutically effective amount[s] of adenosine used in the above-described" topical applications "to skin … containing the dermal cell[s]," Appx02702 (citing Appx00067(2:13-17))—that the adenosine-concentration limitation refers to the concentration in the composition applied to the skin. Appx02729.[32] Applicants' repeated insistence that the claimed concentration values were the adenosine concentrations applied to the skin

[32] In the proceedings below, Plaintiffs focused on this response, asserting that it amounted to a correction. As explained above, that characterization is wrong, and in any event, Applicants' comments "do[] not, [and] indeed cannot, change the examiner's Reasons for Allowance." *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1139 (Fed. Cir. 2003). Moreover, Applicants did not include these remarks in prosecuting the '513 patent, discussed immediately below.

operates as a clear and unequivocal disclaimer of Plaintiffs' contrary position, and at a minimum resolves any ambiguity in the claim language.

2. The '513 Patent Prosecution History

Applicants made similar representations in securing the '513 patent, including that the adenosine-concentration limitation was supported by the originally filed claims (which were limited to an adenosine concentration in a composition applied to the skin or *ex vivo* methods) and the concentration ranges disclosed in the specification for such compositions. Appx02760-02762. They also distinguished prior art ("Borstel") as not teaching "what amount to apply to skin." Appx02765. Here, too, the Examiner allowed the patent to issue because, *inter alia*, the "[i]nstant claims are directed to a method of … administering adenosine ***at a concentration of 10^{-3} M to 10^{-7} M, to the skin***. The closest prior art of record teaches administering adenosine ***in skin care compositions***. However, the art of record utilizes ***concentrations much higher than claimed*** …." Appx02769.

Once again, Applicant affirmatively agreed with these reasons, this time not even mentioning the "applied to the dermal cells" claim language. Appx02771. The prosecution history flatly contradicts Plaintiffs' claim construction.

IV. THE DISTRICT COURT CORRECTLY DISMISSED L'ORÉAL S.A. FOR LACK OF PERSONAL JURISDICTION

Plaintiffs bear the burden of making a *prima facie* showing of personal jurisdiction. *NexLearn, LLC v. Allen Interactions, Inc.*, 859 F.3d 1371, 1375 (Fed. Cir. 2017). Plaintiffs asserted only specific, not general, jurisdiction over L'Oréal S.A., Appx00558, which requires them to "affirmatively establish[]" that (i) L'Oréal S.A. "purposefully directed its activities at residents of the forum" and (ii) Plaintiffs' claims for patent infringement "arise[] out of or relate[] to" those alleged activities, before the burden shifts to L'Oréal S.A. to contest the fairness of jurisdiction. *Celgard, LLC v. SK Innovation Co.*, 792 F.3d 1373, 1377-78 (Fed. Cir. 2015).

Plaintiffs advanced a single theory of personal jurisdiction in objecting to the R&R: that "L'Oréal USA is L'Oréal S.A.'s agent for at least the purpose of designing, manufacturing, and selling Accused Adenosine Products in the United States and in Delaware." Appx01253, Appx00020. On appeal, however, Plaintiffs assert an unspecified theory based on a disparate collection of mischaracterized "facts" allegedly falling within this Court's precedent. Any challenge other than to the court's agency determination is thus reviewed for plain error. *See Brightwell v. Lehman*, 637 F.3d 187, 193 & n.7 (3d Cir. 2011).

A. L'Oréal S.A. Is Not Subject to Specific Personal Jurisdiction

Plaintiffs did not muster *prima facie* evidence that L'Oréal S.A controls L'Oréal USA with respect to its allegedly infringing acts or introduces the accused products in commerce in the United States. Indeed, Plaintiffs ignore the requisites of establishing personal jurisdiction under the only theory—agency—they properly preserved. *Celgard*, 792 F.3d at 1379 ("[T]he plaintiff must show that the defendant exercises control over the activities of the third-party."). L'Oréal S.A. is a French corporation that does not conduct business or have a physical presence in Delaware. Appx00552-00554, Appx00229(¶6). Its wholly owned subsidiary L'Oréal USA "observe[s] standard corporate formalities" and "maintains separate licensing and distribution contracts, manufactures and distributes its own products, has its own board of directors, issues separate financial statements, files separate tax returns, and maintains its own workforce [separate] from L'Oréal S.A.," as well as distinct marketing, advertising, customer relations, and research departments. Appx00552-00553. It does not act as L'Oréal S.A.'s agent in any capacity. *Id.* Indeed, as Plaintiffs acknowledge, ***L'Oréal USA, not L'Oréal S.A.***, is responsible for the actions from which their infringement claims arise—"manufactur[ing], market[ing], and sell[ing] the Accused Adenosine Products across the United States." Appx00234(¶33).

None of Plaintiffs' cited "evidence" (PBr. 59-60), even construed in its favor, establishes the contrary. The description of France as "the nerve centre" of the L'Oréal Group, Appx00692, Appx00624, is insignificant; every diversified multinational corporate group has a headquarters. Even less persuasive are historical statements that L'Oréal USA's predecessor, Cosmair, Inc., was designated a L'Oréal "exclusive agent" in 1953 and later acquired in 1994. Appx00693. That is not evidence of current agency, and the same document says that, while L'Oréal S.A. provides overall global coordination, "[t]he subsidiaries develop the Group's business activities in the country or region in which they are located" and "manufacture … and commerciali[z]e the products that ***they decide to sell on the market***." Appx00717.[33]

None of Plaintiffs' other evidence suffices. L'Oréal USA's status as a wholly owned subsidiary, Appx01040, does not establish jurisdiction. *Nespresso*, 263 F. Supp. 3d at 504; *Round Rock Research LLC v. Asustek Computer Inc.*, 967 F. Supp. 2d 969, 978 (D. Del. 2013). Nor does collaboration among global research centers, Appx01044, or the L'Oréal S.A.-L'Oréal USA intracompany agreement (discussed *infra*), support jurisdiction.

[33] *See Nespresso USA, Inc. v. Ethical Coffee Co.*, 263 F. Supp. 3d 498, 505 (D. Del. 2017) ("[S]etting the corporate policies and procedures for all subsidiaries is not sufficient evidence of agency.").

Similarly, Plaintiffs' citation of an unissued L'Oréal S.A. patent application (Appx00263-00269) and a published article by a L'Oréal S.A. scientist (Appx01073-01077)—neither of which mentions the accused products, and which predate their launch by years—does not suggest that L'Oréal S.A. is responsible for the manufacture, sale, and marketing of the accused products. *See Nespresso*, 263 F. Supp. 3d at 504 (ownership of patents covering accused products did not subject foreign patentee to personal jurisdiction).[34] It is similarly irrelevant that this article was then cited on a website owned by L'Oréal Paris—a ***L'Oréal USA*** brand—in connection with a generic ingredient entry concerning adenosine. Appx01070. Nor does the discussion of anti-aging research generally on loreal.com, A01090-1092, support jurisdiction.

The same is true of the response of a L'Oréal S.A. attorney to ***Plaintiffs' correspondence***. *See Asanov v. Gholson, Hicks & Nichols, P.A.*, 209 F. App'x 139, 142 (3d Cir. 2006) (non-precedential) ("[N]ormal incidents of legal representation … do not, by themselves, establish purposeful availment to support the assertion of personal jurisdiction."). ***Unrelated*** patent filings and lawsuits

[34] *Touchcom*, cited by Plaintiffs, is not to the contrary. There, the court found personal jurisdiction for a legal malpractice claim arising directly from a lawyer's filing of a deficient patent application. *See Touchcom, Inc. v. Bereskin & Parr*, 574 F.3d 1403, 1409 (Fed. Cir. 2009).

(Appx00300-00334, Appx01098-01155) are likewise irrelevant to specific jurisdiction.

Finally, *Nuance Communications, Inc. v. Abbyy Software House*, 626 F.3d 1222 (Fed. Cir. 2010), on which Plaintiffs principally rely (PBr. 59), is inapposite because the Court found personal jurisdiction over one defendant (Abbyy Production) ***based on its own infringing acts***; it imported the allegedly infringing software products into the United States, retained ownership of the products provided to a U.S. affiliate, and received 95% of the profits, all of which constituted "sufficient presence in the forum for importation under 35 U.S.C. § 271(a)." *Nuance*, 626 F.3d at 1233-34. The gossamer evidence here does not establish personal jurisdiction over L'Oréal S.A.

B. The District Court Did Not Abuse Its Discretion in Denying Jurisdictional Discovery

Jurisdictional discovery is warranted if the plaintiff "presents factual allegations that suggest with reasonable particularity the possible existence of the requisite contacts between the party and the forum." *Eurofins Pharma US Holdings v. Bioalliance Pharma SA*, 623 F.3d 147, 157 (3d Cir. 2010). "A plaintiff may not, however, undertake a fishing expedition based only upon bare allegations, under the guise of jurisdictional discovery." *Id*. Here, Plaintiffs have not made even a colorable *prima facie* showing that L'Oréal S.A. is subject to personal jurisdiction, or identified any specific issues for which jurisdictional

discovery would help, and their rehashing of these deficient allegations does not suffice. *See, e.g.*, *Parker v. Learn the Skills Corp.*, 219 F. App'x 187, 190 (3d Cir. 2007) (non-precedential) ("[G]eneralized allegations of defendants' contact with [the forum] are insufficient … to make out a prima facie case that could justify jurisdictional discovery.").

Plaintiffs attempt to rely on "later merits discovery" (PBr. 62), but courts do not "consider material on appeal that is outside of the district court record." *In re Capital Cities/ABC, Inc.'s Application for Access to Sealed Transcripts*, 913 F.2d 89, 96 (3d. Cir. 1990). Even if the Court were inclined to consider Plaintiffs' extra-record citations, they do not justify granting jurisdictional discovery because they do not support Plaintiffs' agency theory (or their inadequately preserved stream-of-commerce theory). The intracompany agreement (Appx03935-03958) on which Plaintiffs so heavily rely was entered into almost a decade ***before*** L'Oréal USA began selling products containing adenosine. *Compare* Appx03935, *with* PBr. 14-15. It does not mention adenosine or the accused products—let alone any products at all. It is a generic agreement that does not even identify any particular patents, Appx03935-03958, and does not support personal jurisdiction. *Celgard*, 792 F.3d at 1379; *Afshari v. Bear Archery, Inc.*, No. 12-13-KSF, 2012 WL 3027649, at *2 (E.D. Ky. July 24, 2012). Likewise, the ingredient sheets Plaintiffs cite do not suggest that L'Oréal S.A. controlled L'Oréal USA's decision

to use particular formulations or sell particular products in the United States. Appx03075, Appx03144-03157.

Finally, Plaintiffs cannot credibly claim that additional discovery is required to develop information surrounding the license agreement and the accused products' development. Plaintiffs already had the opportunity to question L'Oréal USA's witnesses about these specific documents and any related facts and circumstances, as shown by their own citations. If this information warranted further discovery, Plaintiffs had to ask the court to revisit its interlocutory decision (Fed. R. Civ. P. 54(b)) or seek leave to amend (Fed. R. Civ. P. 15). They did neither. Plaintiffs' attempted fishing expedition was correctly rejected.

CONCLUSION

The district court's judgment should be affirmed.

Dated: October 14, 2021

Respectfully Submitted,

/s/ Eric W. Dittmann
Eric W. Dittmann
Isaac S. Ashkenazi
Bruce M. Wexler
Nicholas A. Tymoczko
Karthik R. Kasaraneni
PAUL HASTINGS LLP
200 Park Ave.
New York, NY 10166
(212) 318-6000

Naveen Modi
Stephen B. Kinnaird
PAUL HASTINGS LLP
2050 M. Street NW
Washington, DC 20036
(202) 551-1700

Katherine F. Murray
BROWNE GEORGE ROSS O'BRIEN
ANNAGUEY & ELLIS LLP
2121 Avenue of the Stars, Suite 2800
Los Angeles, CA 90067
(310) 274-7100

Attorneys for Appellees L'Oréal S.A. and L'Oréal USA, Inc.

FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2021-1969

Short Case Caption: University of Massachusetts v. L'Oreal S.A.

Instructions: When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

☑ the filing has been prepared using a proportionally-spaced typeface and includes 13,983 words.

☐ the filing has been prepared using a monospaced typeface and includes _____ lines of text.

☐ the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Date: 10/14/2021

Signature: /s/Eric W. Dittmann

Name: Eric W. Dittmann