No. 2021-1969

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

UNIVERSITY OF MASSACHUSETTS, CARMEL LABORATORIES, LLC,

Plaintiffs-Appellants,

v.

L'ORÉAL S.A., L'ORÉAL USA, INC.,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Delaware
No. 1:17-cv-868, Hon. Colm F. Connolly

NONCONFIDENTIAL REPLY BRIEF OF APPELLANTS UNIVERSITY OF MASSACHUSETTS AND CARMEL LABORATORIES, LLC

Justin A. Nelson
SUSMAN GODFREY LLP
1000 Louisiana, Suite 5100
Houston, TX 77002
(713) 651-9366 (telephone)
(617) 456-8100 (fax)

Tamar Lusztig
Beatrice C. Franklin
SUSMAN GODFREY LLP
1301 Avenue of the Americas
32nd Floor
New York, NY 10019

Jeffrey A. Lamken
Counsel of Record
Caleb Hayes-Deats
MOLOLAMKEN LLP
The Watergate, Suite 500
600 New Hampshire Avenue, N.W.
Washington, D.C. 20037
(202) 556-2000 (telephone)
(202) 556-2001 (fax)
jlamken@mololamken.com

Lauren F. Dayton
MOLOLAMKEN LLP
430 Park Avenue, 6th Floor
New York, NY 10012

Counsel for University of Massachusetts and Carmel Laboratories, LLC

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 Appellants University of Massachusetts and Carmel Laboratories, LLC

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: 11/29/2021

Signature: /s/ Jeffrey A. Lamken

Name: Jeffrey A. Lamken

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
University of Massachusetts	None	Not applicable
Carmel Laboratories LLC	None	Teresian Carmelites, Inc.

☐ 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

Farnan LLP	Susman Godfrey LLP	Foley & Lardner LLP
Brian Farnan	William Carmody	Matthew Lowrie
Michael Farnan	Davida Brook	Nicholas Carullo

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

I. The Patents' Numerical Requirements and Express Definition Make the "Amount Effective To Enhance" Limitation Definite.....2

A. The Patents Specify the "Amount Effective".....3

B. The Patents Provide Definiteness by Defining "Enhancement of Skin Condition".....8

C. L'Oréal Ignores Material Fact Disputes.....12

II. L'Oréal's Alternative Arguments Lack Merit.....16

A. L'Oréal's Argument About Measuring Penetration to Dermal Cells Lacks Merit 16

B. Defendants' Twice-Rejected Construction Ignores the Claims' Unambiguous Language.....21

1. The Recited Adenosine Concentration Is the Amount "Applied to the Dermal Cells".....22

2. The Specification Supports the District Court's Construction.....25

3. Prosecution History Provides No Support for L'Oréal's Construction.....27

III. The Court Has Personal Jurisdiction Over L'Oréal S.A. 30

A. This Court's Precedents Support Jurisdiction.....30

B. Discovery Confirmed Personal Jurisdiction.....32

CONCLUSION.....34

CONFIDENTIAL MATERIAL OMITTED

This brief redacts material that Defendants-Appellees designated as confidential under the protective order entered by the district court. The material omitted includes information about a contract between L'Oréal S.A. and L'Oréal USA, Inc. The redacted material appears on pages 31 and 33.

TABLE OF AUTHORITIES

Page(s)

CASES

Abbott Lab'ys v. Baxter Pharm. Prods.,
334 F.3d 1274 (Fed. Cir. 2003) 6

Alcon Research, Ltd. v. Apotex, Inc.,
687 F.3d 1362 (Fed. Cir. 2012) 6

Am. Axle & Mfg. v. Neapco Holdings,
967 F.3d 1285 (Fed. Cir. 2020) 6

Astrazeneca AB, Aktiebolaget Hassle, KBO-E, Inc. v. Mut. Pharm. Co.,
384 F.3d 1333 (Fed. Cir. 2004) 26

Ball Metal Beverage Container Corp. v. Crown Packaging Tech.,
838 F. App'x 538 (Fed. Cir. 2020) 18, 21

BASF Corp. v. Johnson Matthey Inc.,
875 F.3d 1360 (Fed. Cir. 2017) 9, 16, 17

In re Baxter Int'l,
678 F.3d 1357 (Fed. Cir. 2012) 11

Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.,
320 F.3d 1339 (Fed. Cir. 2003) 12, 15, 17

Bristol-Myers Squibb Co. v. Ben Venue Lab'ys, Inc.,
246 F.3d 1368 (Fed. Cir. 2001) 6, 24

CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG,
224 F.3d 1308 (Fed. Cir. 2000) 26

Celgard, LLC v. SK Innovation Co.,
792 F.3d 1373 (Fed. Cir. 2015) 33

Compagnie Des Bauxites de Guinee v. L'Union Atlantique S.A. d'Assurances,
723 F.2d 357 (3d Cir. 1983) 32

Datamize, LLC v. Plumtree Software, Inc.,
417 F.3d 1342 (Fed. Cir. 2005) 11

DDR Holdings v. Hotels.com, L.P.,
773 F.3d 1245 (Fed. Cir. 2014) 13, 14

Dow Chem. Co. v. Nova Chems. Corp. (Canada),
803 F.3d 620 (Fed. Cir. 2015) 18

Ecolab, Inc., v. FMC Corp.,
569 F.3d 1335 (Fed. Cir. 2009) 29

Eibel Process Co. v. Minn. & Ont. Paper Co.,
261 U.S. 45 (1923).....9

Eli Lilly & Co. v. Teva Pharm. Int'l GmbH,
8 F.4th 1331 (Fed. Cir. 2021) 6, 7, 24

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

Glaxo Grp. Ltd. v. TorPharm, Inc.,
153 F.3d 1366 (Fed. Cir. 1998) 16

Guangdong Alison Hi-Tech Co. v. ITC,
936 F.3d 1353 (Fed. Cir. 2019) 12, 15

Hamilton Beach Brands v. f'real Foods,
908 F.3d 1328 (Fed. Cir. 2018) 22

Honeywell Int'l v. ITC,
341 F.3d 1332 (Fed. Cir. 2003) 18

HZNP Meds. LLC v. Actavis Lab'ys. UT, Inc.,
940 F.3d 680 (Fed. Cir. 2019) 8, 18

In re Inland Steel Co.,
265 F.3d 1354 (Fed. Cir. 2001) 6

Intellectual Ventures I LLC v. T-Mobile USA,
902 F.3d 1372 (Fed. Cir. 2018) 11

Intelligent Automation Design, LLC v. Zimmer Biomet CMF & Thoracic, LLC,
799 F. App'x 847 (Fed. Cir. 2020) 14

Interstate Circuit, Inc. v. United States,
306 U.S. 208 (1939).....21

Interval Licensing LLC v. AOL, Inc.,
766 F.3d 1364 (Fed. Cir. 2014) 11

Merial Ltd. v. Cipla Ltd.,
681 F.3d 1283 (Fed. Cir. 2012) 6

MIT v. Shire Pharms.,
839 F.3d 1111 (Fed. Cir. 2016) 27, 28

Nautilus, Inc. v. Biosig Instruments, Inc.,
572 U.S. 898 (2014).....8, 15

Nelson v. Adams USA, Inc.,
529 U.S. 460 (2000).....13

Nevro Corp. v. Boston Sci. Corp.,
955 F.3d 35 (Fed. Cir. 2020) 18, 19

Nuance Commc'ns, Inc. v. Abbyy Software House,
626 F.3d 1222 (Fed. Cir. 2010) 30, 31, 33

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

Salazar v. Procter & Gamble Co.,
414 F.3d 1342 (Fed. Cir. 2005) 28

Sonix Tech. Co. v. Publ'ns Int'l, Ltd.,
844 F.3d 1370 (Fed. Cir. 2017) .....*passim*

Synthes (U.S.A.) v. G.M. Dos Reis Jr. Ind. Com. De Equip. Medico,
563 F.3d 1285 (Fed. Cir. 2009) 31

Takeda Pharm. Co. Ltd. v. Zydus Pharm. USA,
743 F.3d 1359 (Fed. Cir. 2014) 13, 17, 18, 21

Teva Pharms. USA v. Sandoz, Inc.,
789 F.3d 1335 (Fed. Cir. 2015) 18

Thorner v. Sony Comput. Ent. Am.,
669 F.3d 1362 (Fed. Cir. 2012) 28

TriMed, Inc. v. Stryker Corp.,
608 F.3d 1333 (Fed. Cir. 2010) 12

STATUTES

Fed. R. App. P. 10(a) 33

Fed. R. Civ. P. 15 34

Fed. R. Civ. P. 54(b) 34

OTHER AUTHORITIES

Elise A. Olsen et al., *Tretinoin Emollient Cream: A New Therapy for Photodamaged Skin,*
26 J. AM. ACAD. DERMATOL. 215 (1992) 15, 16

INTRODUCTION

L'Oréal offers no credible defense of the indefiniteness ruling below. The patents-in-suit claim specific, numerical concentrations of adenosine shown by the specification to be "effective to enhance the condition of skin," as the patents define that phrase. The patents' express definition of skin enhancement—a "***noticeable decrease in the amount of*** wrinkling" or other specified conditions—also provides definiteness. Skilled artisans can apply that definition, which rests on observable criteria. At the very least, reasonable jurors could conclude that L'Oréal failed to prove indefiniteness by clear-and-convincing evidence, given UMass's extensive proof and the patents' guidance.

Abandoning the district court's primary rationale, L'Oréal now argues that the patents' numerical concentrations cannot be the "effective" amounts because they are "ratios." This Court regularly permits inventors to express "effective amounts" as concentrations and ratios. L'Oréal urges that the patents' definition is insufficient because skilled artisans can use "subjective evaluations" to identify "noticeable decrease[s] in the amount" of listed skin conditions. The patents, however, permit only "subjective evaluations" well-known in dermatological arts. L'Oréal's own skilled artisans apply such evaluations to observe decreases in the amount of wrinkles. And L'Oréal's evidence of supposedly inconsistent results is incorrect; it

nowhere approaches being so compelling that no reasonable juror could find it less than clear-and-convincing.

L'Oréal devotes more than half its brief to alternative bases for affirmance. The district court did not address those issues, and this Court need not either. Insofar as L'Oréal argues there is no reliable way to determine the "adenosine concentration applied to the dermal cells"—because adenosine must penetrate through skin's outer layers to reach the dermis—ample evidence showed skilled artisans had a well-established method for analyzing effective-ingredient penetration. L'Oréal's arguments about ***application*** of that method misunderstand the facts and cannot prove indefiniteness as a matter of law. And L'Oréal's twice-rejected claim construction—rebuffed below and by the PTAB—is not grounds for affirmance and is wrong regardless. Reversal on personal jurisdiction is warranted as well.

I. THE PATENTS' NUMERICAL REQUIREMENTS AND EXPRESS DEFINITION MAKE THE "AMOUNT EFFECTIVE TO ENHANCE" LIMITATION DEFINITE

The patents-in-suit provide reasonable certainty about the "amount[s] effective to enhance the condition of the skin" by specifying ***numerical concentrations*** that meet that standard. UMass.Br.34-42. They recite a ***definition*** of "enhancement" that establishes an "objective baseline" skilled artisans can apply using observable criteria. *Id.* at 42-52. And L'Oréal improperly asks the Court to resolve disputed factual issues.

A. The Patents Specify the "Amount Effective"

L'Oréal asks the Court to read claim 1's "amount effective to enhance the condition of the skin" requirement in a vacuum. But claim 1 itself specifically recites the "effective" amounts: It specifies applying particular concentrations—10^{-4} M to 10^{-7} M for the '327 Patent, and 10^{-3} M to 10^{-7} M for the '513 Patent—to dermal cells. As UMass explained, moreover, "effective amount" is a "common and generally acceptable term," which is "not ambiguous or indefinite" if skilled artisans can "determine the specific amounts without undue experimentation." UMass.Br.32-33 (quoting *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003)). Here, skilled artisans can determine effective amounts without experimentation.

The patents' "experimental work" shows the recited concentrations' effectiveness. UMass.Br.35 (citing Appx69-71(6:14-9:50)); *see* Appx67(1:40-41). The specification declares the "therapeutically effective amount of adenosine . . . is preferably 10^{-3} M to 10^{-7} M." Appx67(2:13-16). Because the specification labels the claimed numerical concentrations "effective to enhance," and proves them to be so, ***no*** experimentation is necessary, much less "undue" experimentation. The effective amount could not be more definite. *Geneva*, 349 F.3d at 1383-84.

1. Rather than defend the district court's primary rationale, L'Oréal attacks it. At claim construction, the district court understood the patented composition

applied "topically," to skin's surface, contains more adenosine than the concentration "applied to the dermal cells." Appx3720(57:1-24); Appx8-9. That understanding followed from agreed scientific fact: Only some adenosine applied to the epidermis will penetrate to the dermal layer. Appx2877(¶17); Appx14934. For the recited concentration to reach and be "applied to the dermal cells," the topical composition needs additional adenosine that does not penetrate.

Addressing indefiniteness, the district court denied that the specified concentrations are the amounts effective to enhance because, it ruled, the "enhancement limitation" addresses the adenosine in the composition, not the amount applied to dermal cells. That was error. *See* UMass.Br.38-42. Claim 1's "wherein" clause shows that the recited numerical adenosine concentrations to be applied to dermal cells "'relate[] back to and clarif[y] what is required'" by the enhancement limitation. UMass.Br.36-37; *see* Appx3720(57:14-19). Far from responding, L'Oréal agrees with UMass: Claim 1's "wherein" clause, it declares, links the recited adenosine concentrations to the earlier recited "amount effective to enhance." L'Oréal.Br.48.

2. The district court posited indefiniteness by finding that the "amount effective" was an unspecified adenosine concentration in the topical composition, different from the recited concentration applied to dermal cells. Appx9-10. Rather than defend that rationale, L'Oréal attacks its premise, arguing that the adenosine

concentration in the composition is the concentration applied to dermal cells. A "composition has one adenosine concentration (mol/L)," L'Oréal declares, "not lesser 'included' concentrations." L'Oréal.Br.25. But the district court correctly rejected that construction of claim 1 as impossible. *See* pp. 23-24, *infra*. The amount "applied to the dermal cells" cannot be the amount applied topically to the epidermis because, as the parties agreed below, only a portion of the adenosine applied to the epidermis penetrates to the dermis. Appx2877(¶17); Appx14934. The "topically applied" composition thus must contain ***additional*** adenosine (which does not penetrate). UMass.Br.41. L'Oréal never explains why its construction would not impose a requirement skilled artisans would regard as impossible. That L'Oréal can defend the district court's indefiniteness judgment only by attacking its claim construction underscores the judgment's indefensibility. And L'Oréal's attack on claim construction is meritless, as set forth pp. 21-29, *infra*.

The district court, moreover, agreed with UMass that claim 1's use of "comprising" signals that the "composition" can include additional adenosine. Appx9-10; Appx3719-3721; p. 24, *infra*. L'Oréal accuses the district court of "doublespeak" that transforms "comprising" into a "weasel word." L'Oréal.Br.25. But L'Oréal offers only rhetoric to support its assertion that "comprising" cannot allow skilled artisans to include the recited amount of adenosine in the composition,

plus more (and other ingredients) to ensure the recited concentration is delivered and applied to dermal cells. *See* UMass.Br.39-40 (citing Appx69(5:13-16)).

3. L'Oréal insists that the recited adenosine ***concentrations*** cannot be amounts "effective to enhance." L'Oréal.Br.22-23. A "molar 'concentration,'" L'Oréal asserts, is a "ratio," not an "amount." L'Oréal never raised that argument below, Appx11794-11810; Appx18823-18834, thus waiving it, *Am. Axle & Mfg. v. Neapco Holdings*, 967 F.3d 1285, 1301 (Fed. Cir. 2020). The argument fails regardless.

This Court regularly allows inventors to define ratios and concentrations as "effective amounts." *See Alcon Research, Ltd. v. Apotex, Inc.*, 687 F.3d 1362, 1367 (Fed. Cir. 2012) ("olopatadine concentrations constitute a 'therapeutically effective amount'"); *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1301 (Fed. Cir. 2012) ("concentrations" that constitute "synergistically effective amounts"); *see Eli Lilly & Co. v. Teva Pharm. Int'l GmbH*, 8 F.4th 1331, 1343 (Fed. Cir. 2021) ("3 μg/kg"); *Bristol-Myers Squibb Co. v. Ben Venue Lab'ys, Inc.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001) ("135 mg/m2"); *Abbott Lab'ys v. Baxter Pharm. Prods.*, 334 F.3d 1274, 1279 (Fed. Cir. 2003) ("effective amount" in parts per million); *In re Inland Steel Co.*, 265 F.3d 1354, 1363-64 (Fed. Cir. 2001) ("concentration of 0.005%"). That makes sense. Effectiveness may depend on concentration. Acting as their own lexicographers, inventors can express effective amounts as molar concentrations. Appx67(2:13-16).

L'Oréal errs in urging that the recited concentrations are not effective amounts because "effective amount" refers to a "functional result"—effectiveness—not a "specific concentration." L'Oréal.Br.21-22. The specification proves the recited concentrations are sufficient to achieve the "functional result." Appx70-71(7:49-9:50). The patents further state that the "therapeutically effective amount of adenosine . . . is preferably 10^{-3} M to 10^{-7} M." Appx67(2:13-16). L'Oréal attempts to dismiss that language as a "descriptive," "subject complement[ ]," which identifies "characteristics of effective amounts." L'Oréal.Br.23. But the concentrations that claim 1 recites are not "characteristics" of an effective amount. They are recited as the effective amounts. *See* p. 3, *supra*. Those concentrations' effectiveness is confirmed by the specification, L'Oréal's expert, Appx2883-2884; Appx13511, L'Oréal's independent experiments, Appx4276-4277, and L'Oréal's advertisements for infringing products, Appx15176-15178.

4. Finally, L'Oréal insists that accepting the recited concentrations as "amounts effective to enhance" would "eliminate the skin-enhancement requirement." L'Oréal.Br.20-21.[1] The fact that the same adenosine concentration can

[1] L'Oréal regards the preamble as "separately limiting," L'Oréal.Br.24, a conclusion the district court never reached. But L'Oréal's citation held only that a preamble identified the effective amount's "intended purpose." *Eli Lilly*, 8 F.4th at 1342-43. Here, the preamble at most identifies the claimed method's intended purpose—enhancement under the patents' definition. Appx71(10:18-21).

satisfy two limitations—the recited numerical range and "effective amount"—does not "render claim language superfluous." L'Oréal.Br.20. Each limitation imposes distinct requirements. *HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 692 (Fed. Cir. 2019). The numerical concentrations focus on quantities, not properties. The effective amount limitation focuses on the effectiveness of the claimed amounts. UMass.Br.52 n.13. Failure to satisfy either limitation prevents infringement. Applying less than the recited amount to the dermis would not infringe, even if effective; and applying the recited amount would not infringe if not administered through the topical composition or if proved insufficient to be medically effective. That the limitations overlap is unsurprising given the patents' insight about the recited concentrations' effectiveness, UMass.Br.38, and the additions of clarifying language at the PTO's request, *see* Appx2708 (wherein clause); Appx2686 (preamble); pp. 27-28, *infra*.

B. The Patents Provide Definiteness by Defining "Enhancement of Skin Condition"

The patents' definition of "enhancement of skin condition" independently provides such certainty as is reasonable given the art. UMass.Br.42-52; *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). The patents state that "'enhancement of skin condition' ***means*** a ***noticeable decrease in the amount of*** wrinkling," or other listed skin conditions. Appx67 (2:35-37) (emphasis added). That language provides "an objective baseline" for interpreting the claim. *Sonix*

Tech. Co. v. Publ'ns Int'l, Ltd., 844 F.3d 1370, 1378 (Fed. Cir. 2017). Skilled artisans can discern whether a "noticeable decrease" in "amount" has occurred—*i.e.* whether there is less than before. UMass.Br.43-44. The patents identify "[m]ethods of measuring improvements in skin condition [that] are well known in the art." Appx69(5:48-49). And they offer a specific example of "enhancement" under the patents' definition, a "statistically significant decline" in "skin topography measurements." *Id.*(5:54-6:4). This Court and the Supreme Court have repeatedly upheld patents that provide ***less*** information. *See, e.g.*, *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1366 (Fed. Cir. 2017); UMass.Br.48-52.

L'Oréal attacks the definition as indefinite, opining that "there are no standards to determine what observable phenomena constitute a 'decrease.'" L'Oréal.Br.31. But the patents specifically describe measurements "well known in the art" and cite academic articles applying them. Appx69(5:48-50). L'Oréal has no difficulty applying those methods to determine whether its products with adenosine cause a "noticeable decrease in the amount of wrinkling" and other conditions: It markets them for that exact effect, UMass.Br.15-16, 53-54; *see Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45, 65-66 (1923), while under FTC injunction not to make misrepresentations, Appx22513-22517.[2]

[2] L'Oréal invokes hypothetical line-drawing concerns, such as "more, but shallower, wrinkling." L'Oréal.Br.31. But L'Oréal never suggests skilled artisans confront

L'Oréal retreats to the district court's position that the specification "***directs*** that 'noticeable decrease' can be assessed" using "***subjective evaluations***." L'Oréal.Br.27-28. But the patents limit permissible "subjective evaluations" to those "well known in the art." Appx69(5:48-52). They state that "***[m]ethods*** of measuring improvements in skin condition are ***well known in the art***, . . . and ***can include*** subjective evaluations." *Id.* (emphasis added). Permissible "subjective evaluations" thus are only those "include[d]" in methods "well known in the art." L'Oréal nowhere denies that visual examinations of "noticeable" skin conditions are an accepted part of dermatology. UMass.Br.45-47. That skilled artisans sometimes evaluate decreases through such "subjective" observations using specific criteria hardly indicts the art's definiteness. L'Oréal's scientists apply subjective evaluations when assessing reductions in wrinkles and other conditions. Appx15176-15178; Appx15518-15536. So does virtually every cosmetics producer. Because the evaluations described in the specification are "standard measurement method[s]" skilled artisans can apply, claim 1 is definite. *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1376 (Fed. Cir. 2017).

---

such hypotheticals, or that its products generate such results. Regardless, skilled artisans could "compare" them to the patents' "examples and criteria" when applying the patents' definition. *Sonix*, 844 F.3d at 1379.

L'Oréal cites cases like *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014), that hold claims indefinite where they "depend[] on the preferences of . . . particular user[s]." L'Oréal.Br.26-27. Whether an amount "decrease[s]," however, is a measurable phenomenon: It depends on quantity, not preference.[3] This Court has distinguished L'Oréal's cases when considering claim language that, like that here, sets forth specific criteria. *Sonix*, 844 F.3d at 1378. *Sonix* held that "visually negligible" does not turn on "a person's tastes or opinion," but instead "what can be seen by the normal human eye," providing "an objective baseline" for interpreting the claims. *Id.* So too with "noticeable decrease in the amount." Appx67(2:36).[4]

L'Oréal argues that the specification in *Sonix* provided more details on "visually negligible." L'Oréal.Br.27. But the *Sonix* defendants "criticize[d]" that specification for "low level of detail" and "subjectiv[ity]." 844 F.3d at 1379. This Court "disagree[d]," citing the specification's "examples" and "criteria." *Id.* Here

---

[3] *Interval Licensing* involved the undefined phrase "unobtrusive manner that does not distract a user." 766 F.3d at 1372. The patent offered no assessment method, leaving user-distraction dependent on individual "preferences" and "circumstances." *Id.* at 1371-73; *see Intellectual Ventures I LLC v. T-Mobile USA*, 902 F.3d 1372, 1381 (Fed. Cir. 2018) ("quality of service requirements," described in patent as a "relative term, finding different meanings for different users"); *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005) (invalidating "aesthetically pleasing" as "completely dependent on a person's subjective opinion").

[4] Contrary to L'Oréal's suggestion (at 29), UMass did not need to "specifically name" *Sonix* below. *In re Baxter Int'l*, 678 F.3d 1357, 1362 (Fed. Cir. 2012).

too, the specification identifies measurement methods "well known in the art" and provides specific examples of application. Appx69(5:48-6:4). Moreover, as in *Sonix*, prosecution history and "other actions" demonstrate that skilled artisans understand the term. 844 F.3d at 1379-80. The PTO accepted the patents' definition of enhancement. Appx2686; Appx2693-2699; Appx14587. And L'Oréal repeatedly applies the methods it now assails to identify "noticeable decrease[s] in the amount of wrinkling" and other conditions.

Myriad cases confirm what L'Oréal's conduct demonstrates—that the patents' definition of enhancement provides reasonable certainty. UMass.Br.49-52. While L'Oréal relegates most of this Court's post-*Nautilus* indefiniteness precedents to a footnote, proffering distinctions based on assertions about "purely subjective assessments" and the "intrinsic record," L'Oréal.Br.32-33 n.13, those precedents reject the very arguments L'Oréal advances, *see, e.g.*, *Guangdong Alison Hi-Tech Co. v. ITC*, 936 F.3d 1353, 1363 (Fed. Cir. 2019).

C. L'Oréal Ignores Material Fact Disputes

Summary judgment was improper for another reason: A reasonable juror could reject L'Oréal's arguments as less than clear-and-convincing. *TriMed, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1340 (Fed. Cir. 2010). L'Oréal does not deny that "heavy" burden applies. *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1353 (Fed. Cir. 2003). And it offers no defense of the district

court's erroneous statement that it could overlook "conflicting expert testimony" at summary judgment to decide the matter itself. Appx5; UMass.Br.55.

In district court, UMass's expert explained that skilled artisans "would have understood" the specifications' definition of enhancement; she identified "well-established standards for determining skin improvement"; and she explained those standards would not be expected to produce conflicting results. UMass.Br.54-55 (citing Appx14314 & n.165). A reasonable jury could agree.[5]

L'Oréal itself determined, using methods accepted in the art, that its products "improve skin condition and in particular combat lines." Appx266; Appx4276-4277. L'Oréal repeatedly applied those well-established standards to 130 infringing products, touting studies showing that those products "diminish the appearance" of "wrinkles and fine lines." UMass.Br.15-16, 53-54; *see DDR Holdings v. Hotels.com, L.P.*, 773 F.3d 1245, 1260-61 (Fed. Cir. 2014). Clearly, L'Oréal has no difficulty determining whether its products meet the limitation.

L'Oréal responds that its infringing products contain "***ingredients besides adenosine***." L'Oréal.Br.35 n.15. But the question is not which ingredient causes

---

[5] Contrary to L'Oréal's assertions, L'Oréal.Br.35-36, UMass made these same arguments below, Appx15085-15086; *see Nelson v. Adams USA, Inc.*, 529 U.S. 460, 469-70 (2000). L'Oréal's semantic complaints about the word "correlation," L'Oréal.Br.36, ignore authority upholding definiteness based on a "high degree of correlation," *see Takeda Pharm. Co. Ltd. v. Zydus Pharm. USA*, 743 F.3d 1359, 1367 (Fed. Cir. 2014).

skin "enhancement." It is whether artisans can apply the patents' definition of enhancement with reasonable certainty. L'Oréal's repeated assertion that infringing products "diminish the appearance" of "wrinkles and fine lines" defies its contention that it cannot determine whether compositions cause a "noticeable decrease in the amount of wrinkling." Appx67(2:35-40). Nor can L'Oréal distinguish *DDR Holdings* by arguing that advertisements there proved a claim term had "'established meaning.'" L'Oréal.Br.35n.15. L'Oréal uses well-known methods to measure whether its products decrease the amount of wrinkling—the very terms it now attacks as indefinite—and publicizes the results. Far from "overrid[ing]" the specification, *id.*, L'Oréal's conduct confirms that L'Oréal and skilled artisans easily understand.

The jury was not required to accept the contrary testimony of L'Oréal's expert, Dr. Kasting, as clear-and-convincing. *Intelligent Automation Design, LLC v. Zimmer Biomet CMF & Thoracic, LLC*, 799 F. App'x 847, 853 (Fed. Cir. 2020). Far from disputing that adenosine compositions lack observable effects, Dr. Kasting urges that adenosine has "been known and demonstrated" to have those effects for "a long time." Appx13511(43:19-25). Nor does he dispute that the patents' experimental evidence establishes the benefits of applying the recited concentrations to dermal cells. Appx2883-2884.

Dr. Kasting instead attacks every measurement method—the ***art***—contending that even ***objective*** methods have "yielded conflicting information." L'Oréal.Br.33-34 (quoting Appx12331-12335). The district court never accepted that testimony, and for good reason. Attacks on the art defy the Supreme Court's instruction to consider definiteness with "regard to [patents'] subject-matter." *Nautilus*, 572 U.S. at 910; *see* UMass.Br.47-48.

Moreover, L'Oréal's proof at most posits that ***some*** methods, for ***other*** compositions, might yield ***some*** unspecified conflict. That has no bearing on whether the patents-in-suit are definite. *Guangdong*, 936 F.3d at 1363; *Presidio*, 875 F.3d at 1377. L'Oréal protests that it has "no burden to prove exactly how often" results will conflict. L'Oréal.Br.36. But the lack of ***any*** identified conflict ***within the context of the patented invention*** precludes L'Oréal from meeting the "heavy burden" of producing proof that no reasonable jury could reject as less than clear-and-convincing. *Boehringer*, 320 F.3d at 1353.

L'Oréal's attacks could at most raise a jury issue—if they were not incorrect. Miscasting one study, L'Oréal urges that patients and skilled artisans found improvement rates of 60% and 32%, respectively, after applying 0.001% of active ingredient tretinoin. L'Oréal.Br.34&n.14. But L'Oréal omits a key fact. Comparing those findings to control groups—as the art requires—showed ***neither*** result "significantly different" from a placebo. *See* Elise A. Olsen *et al.*, *Tretinoin*

Emollient Cream: A New Therapy for Photodamaged Skin, 26 J. AM. ACAD. DERMATOL. 215, 217, 221, 223 (1992). Under recognized standards, patients' and skilled artisans' observations yielded consistent results: A 0.001% dose of tretinoin produced no statistically significant change in observed skin conditions. *Id.*

II. L'ORÉAL'S ALTERNATIVE ARGUMENTS LACK MERIT

Unable to defend the decision below, L'Oréal devotes over half its argument to alternative grounds. Neither supports affirmance.

A. L'Oréal's Argument About Measuring Penetration to Dermal Cells Lacks Merit

L'Oréal urges that requiring the recited concentrations to be "applied to the dermal cells" renders the patents indefinite because skilled artisans cannot determine the adenosine concentrations that reach skin's dermal layer. L'Oréal.Br.36-45. This fact-intensive argument was not "passed upon by the trial court," and this Court need not address it. *Glaxo Grp. Ltd. v. TorPharm, Inc.*, 153 F.3d 1366, 1371 (Fed. Cir. 1998).

1. According to L'Oréal, "intrinsic evidence discloses no . . . testing methodology" for measuring whether the recited adenosine concentration reaches—and is thus "applied to"—dermal cells. L'Oréal.Br.39. But "mere observation of information not 'recited' does not answer the question whether" skilled artisans "would *need* . . . measurement information to understand." *BASF*, 875 F.3d at 1366. Here, they would understand—and jurors would not be compelled to accept

L'Oréal's position as clear-and-convincing. At the priority date, "[c]ommon methods for determining the dermal penetration of a topically applied composition were widely used," and skilled artisans "generally agreed" on parameters for such testing. Appx15038-15039; Appx15340-15341. The "most common technique" was the "gold standard 'Franz cell' diffusion test," "widely accepted and used" since 1970. Appx15340-15341; Appx12327. Because it reliably predicts whether a "target dose" penetrates to the dermis, the FDA accepts it when approving "transdermal pharmaceutical compositions." Appx15039; *see* Appx12698(176:2-11).

A reasonable jury could easily conclude that skilled artisans do not need to be told about an FDA-approved method "widely accepted" since 1970. *See BASF*, 875 F.3d at 1366; *Presidio*, 875 F.3d at 1376. This Court has found definiteness despite "several possible ways to measure," where the patent "does not specify" any. *Takeda Pharm. Co. v. Zydus Pharms. USA*, 743 F.3d 1359, 1366 (Fed. Cir. 2014). L'Oréal does not even approach showing every reasonable juror would be compelled to find indefiniteness by clear-and-convincing proof. *Boehringer*, 320 F.3d at 1353.

2. L'Oréal attacks the "gold standard" Franz cell-diffusion test, arguing that using "different acceptable parameters" will affect measurements. L'Oréal.Br.39-45. The argument fails legally and factually.

Legally, the "'mere possibility of different results from different measurement techniques' does not render a claim indefinite." *Ball Metal Beverage Container Corp. v. Crown Packaging Tech.*, 838 F. App'x 538, 542 (Fed. Cir. 2020). Indefiniteness is shown only where measurement methods are ***so*** different that products "may infringe the claim under one method" but not another. *Id.*; *Takeda*, 743 F.3d at 1366-67. Disputes about "proper application" of a ***single methodology*** are "***not*** disputes about whether the patent claims are indefinite," but about infringement. *Presidio*, 875 F.3d at 1377 (emphasis added). Otherwise, conflicting proof ***on infringement*** would be "incontrovertible evidence of indefiniteness." L'Oréal.Br.44. This Court has rejected any such suggestion. *Nevro Corp. v. Boston Sci. Corp.*, 955 F.3d 35, 39 (Fed. Cir. 2020); *Presidio*, 875 F.3d at 1377.

L'Oréal invokes cases involving multiple measurement methods, where results left "no question" that choice of method "could affect whether or not a given product infringes." *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 803 F.3d 620, 631-34 (Fed. Cir. 2015) ("four methods"); *Teva Pharms. USA v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015) (three measures that "typically yield a different result"); *see HZNP*, 940 F.3d at 697-98 ("Two tests" with no "consistent results"); *Honeywell Int'l v. ITC*, 341 F.3d 1332, 1335-36 (Fed. Cir. 2003) ("four" inconsistent methods). L'Oréal's arguments, by contrast, concern applying a single, well-known measurement method.

Such arguments do not show indefiniteness. Under this Court's "post-*Nautilus* cases," claims are not indefinite if skilled artisans "would know how to utilize a standard measurement method . . . to make the necessary measurement." *Presidio*, 875 F.3d at 1376. UMass showed that skilled artisans know how to use FDA-accepted Franz cell-diffusion testing, a "standard measurement method," to make the "necessary measurement." Appx15340-15341; Appx14241. That the parties may dispute "infringement" under Franz cell-diffusion on a "case-by-case basis" is irrelevant; the method's acceptance provides skilled artisans "reasonable certainty." *Nevro*, 955 F.3d at 39; *Presidio*, 875 F.3d at 1377.

Factually, L'Oréal errs in asserting that "Plaintiffs' own infringement testing" applying Franz cell-diffusion shows "materially different, outcome-determinative results." L'Oréal.Br.43-44. As UMass explained below, the results L'Oréal characterizes as "below 10^{-7} M," and thus non-infringing, *id.*, were recorded as zero by UMass expert Dr. Edward Kisak for a different reason, Appx12400; Appx12433. While cell-diffusion testing L'Oréal products, Dr. Kisak ran control tests on identical skin samples "not dosed with any formulation." Appx12400. When his comparisons revealed "excessive background noise" or anomalies that prevented a reading "representative of the rate of adenosine delivery," Dr. Kisak recorded findings as zero "out of an abundance of caution." Appx12400; Appx12433. What L'Oréal mischaracterizes as "incontrovertible evidence of indefiniteness," L'Oréal.Br.44,

would be understood by skilled artisans as a result recorded as a null because it does not reflect the true "rate of adenosine delivery," Appx12400; Appx12703 (200:10-14). L'Oréal's suggestion that Dr. Kisak initially "failed to show infringement" and "reran the test," L'Oréal.Br.43-44, is thus false. Where testing ***actually*** showed an accused product did not infringe, *e.g.*, Appx12412 (concentrations around 10^{-9} M for individual product), UMass dropped its claims.

L'Oréal acknowledges the dispute over the meaning of Dr. Kisak's entries only in a footnote, denigrating his testimony as "unsupported assertions." L'Oréal.Br.44-45 n.22. But L'Oréal's challenge to Dr. Kisak's credibility is a classic jury issue. Far from being "unsupported," Dr. Kisak's opinions were explained in his report and confirmed by documentation. Appx12400; Appx12433; Appx12705-12706 (202:23-203:10). L'Oréal's argument thus improperly asks this Court to replace the jury by resolving fact disputes in its favor. L'Oréal's disputes about the methodology's "proper application" in "individual" cases do not prove indefiniteness regardless. *Presidio*, 875 F.3d at 1377. Indeed, skilled artisans do not rely on any individual result, instead using statistical tools to exclude outliers and calculate reliable averages. Appx12400.

Finally, L'Oréal invokes testimony from the inventor and UMass's expert about different "***factors that could affect the results***." L'Oréal.Br.42-43. But that testimony still concerns application of a single method, *see* pp. 18-19, *supra*, and

nowhere suggests that putative differences materially affect claim scope, *Ball Metal*, 838 F. App'x at 542; *Takeda*, 743 F.3d at 1366-67. And UMass offered contrary proof that skilled artisans "generally agreed" on parameters for cell-diffusion testing. Appx15038-15039. If L'Oréal, a sophisticated cosmetics company, believed it could manipulate Franz cell-diffusion testing to produce "materially different, outcome-determinative results," L'Oréal.Br.43, surely it would have at least produced its own testing to show that or non-infringement. But L'Oréal did no infringement testing at all. A reasonable jury could consider proof L'Oréal ***failed*** to provide. *Interstate Circuit, Inc. v. United States*, 306 U.S. 208, 226 (1939). Indeed, its "[s]ilence" is "evidence of the most convincing character." *Id.*

B. Defendants' Twice-Rejected Construction Ignores the Claims' Unambiguous Language

L'Oréal's claim construction argument is worse still. L'Oréal.Br.45-58. Because the district court rejected L'Oréal's construction, the parties never developed a record regarding infringement under it. L'Oréal invokes a footnote in UMass's opening brief. L'Oréal.Br.46. But that footnote did not concede the contents of 130 different products. L'Oréal's construction is wrong regardless, as the district court and PTAB both held.

1. *The Recited Adenosine Concentration Is the Amount "Applied to the Dermal Cells"*

Claim 1 recites "***topically applying to the skin a composition*** comprising a concentration of adenosine[,] . . . ***wherein*** the ***adenosine concentration applied to the dermal cells***" falls within specified ranges. Appx71(10:21-26) (emphasis added). That language is clear. It calls for a "composition" to be applied "topically" to "the skin," but recites a specified "adenosine ***concentration applied to the dermal cells***." The PTAB and the district court agreed that claim 1 explicitly distinguishes the composition applied topically to the epidermis from the concentration applied to dermal cells—making it "very, very clear" that the ***recited concentration*** is applied ***to dermal cells***, not the skin's surface. Appx3720-3721(57:1-58:2); Appx2806; Appx2844.

In this court, L'Oréal repeats its twice-rejected contention that the recited adenosine concentration describes the composition applied to skin—not the concentration that reaches the dermal layer. But "different claim terms . . . should have different meanings." *Hamilton Beach Brands v. f'real Foods*, 908 F.3d 1328, 1340 (Fed. Cir. 2018). Claim 1 specifies a "composition" that is "topically appl[ied] to the skin," *i.e.*, spread on the epidermis. Appx2844; UMass.Br.6. By contrast, the recited "adenosine concentration" must be "applied to the dermal cells," by penetrating skin's outer layers. Appx2844; *see* UMass.Br.6-7; Appx69(5:11-16). "[T]he meaning of claim 1 is clear: adenosine is first topically applied to the

epidermal layer of the skin and, only after it penetrates this outer skin layer, is a specific concentration (10^{-4} M to 10^{-7} M) of the adenosine 'applied' to the dermal cells." Appx2844; *see* Appx3720-3721(57:1-58:10)); Appx2806.

L'Oréal offers no genuine response. It argues that "apply" encompasses "close proximity." L'Oréal.Br.46-47. But L'Oréal ignores that claim 1 describes "applying" the "composition," on one hand, and "applying" the "adenosine concentration," on the other, to two *distinct* areas. Appx71(10:21-26). Had the inventors intended that the "adenosine concentration" merely come into "close proximity" to dermal cells the moment the "composition" is "topically" applied to surface skin, L'Oréal.Br.46-47, they would not have separately required "application" of specified concentrations "to the dermal cells." L'Oréal, moreover, rewrites the claim to apply the recited concentration to "***skin containing the*** dermal cells," L'Oréal.Br.46 (emphasis added); Appx2559, which is not what the claim says. L'Oréal's need to ***add*** language to the claim contradicts its plea for "ordinary meaning." L'Oréal.Br.46.

L'Oréal's construction would be absurd to skilled artisans. Because skin's outer layers act as a barrier, skilled artisans would not equate "topical" application with application "to the dermal cells." L'Oréal's expert conceded that the "amount of a compound applied to the skin is greater than the amount that permeates to a particular layer within the skin, often by large amounts." Appx2877(¶17);

Appx14934. Much of the topically applied adenosine thus will not even come into "close proximity" with dermal cells (any more than if spread on a rubber glove). L'Oréal's proposed construction is thus impossible: The same adenosine concentration cannot be "applied" both "topically" and "to the dermal cells" as L'Oréal demands.

L'Oréal's reliance on claim 1's articles and "wherein" clause, L'Oréal.Br.47-48, is misplaced. While the adenosine concentration "applied to the dermal cells" originates in the composition, UMass.Br.36-37, the composition includes additional adenosine that does not penetrate to dermal cells, *see* pp. 3-5, *supra*. Claim 1 thus uses the term "comprising" to indicate that the composition includes, but is not limited to, the recited adenosine concentration. UMass.Br.40-41. The articles and "wherein" clause simply reflect these points, UMass.Br.36, as the district court observed, Appx3720(57:10-24); *see* pp. 5-6, *supra*.[6]

Finally, L'Oréal argues that identifying the "concentration applied to the dermal cells" would require a "***completely different metric***." L'Oréal.Br.49. As explained above (at 6), pharmaceutical patents frequently define "effective amounts" using concentrations or ratios. *E.g.*, *Eli Lilly*, 8 F.4th at 1343 ("3 μg/kg"); *Bristol-*

[6] L'Oréal's arguments about the patents' dependent claims, L'Oréal.Br.49, likewise fail. Each dependent claim recites a narrower range of the concentration applied ***to dermal cells***. Appx71(10:18-33).

Myers Squibb, 246 F.3d at 1375 ("135 mg/m2"). A patent claiming a ratio as an "effective amount" need not specify two different metrics, because skilled artisans can determine "effective amount" based on that ratio. Here, skilled artisans can determine the amount of adenosine that should be included in the topical "composition," so the right concentration reaches dermal cells, based on diffusion calculations. UMass.Br.39-40; Appx69(5:13-16). L'Oréal did just that. It confirmed the patents' teaching that "10 μM" is an effective adenosine concentration, Appx4276-4277, and then used that information to determine the adenosine quantities its products should include.

2. *The Specification Supports the District Court's Construction*

The specification likewise shows that the "inventors contemplated dermal cells receiving the recited concentration of adenosine," as the PTAB and district court found. Appx2807; Appx3721(58:8-16). The specification's opening lines distinguish skin's "surface layer, known as the epidermis," from "a deeper connective tissue layer, known as the dermis." Appx67(1:19-20). The specification identifies a "variety of methods" for "enhanc[ing]" the "penetration of the adenosine into skin tissue." Appx69(5:10-24). And it discloses experiments showing the beneficial effects of applying claimed adenosine concentrations directly to dermal cells. Appx69-71(6:15-9:50).

L'Oréal argues that, while the disclosed experiments specify amounts applied to dermal cells, Appx70(7:50-9:50), the claims inexplicably require those same amounts to be applied only to a surface layer, the epidermis—when much of the topically applied adenosine will not reach dermal cells, *see* pp. 23-24, *supra*. Under L'Oréal's construction, the specification describes the effect of adenosine concentrations of 10^{-3} M to 10^{-7} M on dermal cells, but claims compositions that cannot transmit those quantities to dermal cells. That makes no sense. *Astrazeneca AB, Aktiebolaget Hassle, KBO-E, Inc. v. Mut. Pharm. Co.*, 384 F.3d 1333, 1337 (Fed. Cir. 2004).

L'Oréal invokes the specification's general observations that "***skin*** . . . ***contain[s] the dermal cell[s]***," and the composition "includ[es]" the recited adenosine concentration. L'Oréal.Br.51-52. But the PTAB found those general observations "provide little guidance with respect to the fundamental question." Appx2808. To prevail, L'Oréal must prove that "topically" applied to skin and "applied to dermal cells" are equivalent—not that skin includes a lower, dermal layer. *CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000). But the two are not interchangeable. *See* pp. 22-24, *supra*. Nor is there a requirement that the "composition" exclude additional adenosine beyond the recited concentration. L'Oréal cites nothing from the specification to

support those supposed requirements; the specification shows the opposite. *See* Appx2807; Appx3721(58:8-16).

3. *Prosecution History Provides No Support for L'Oréal's Construction*

A party invoking prosecution history to limit a claim "bears the burden of proving . . . a 'clear and unmistakable' disclaimer." *MIT v. Shire Pharms.*, 839 F.3d 1111, 1119 (Fed. Cir. 2016). The district court and PTAB correctly found no such disclaimer here. Appx3721(58:4-7); Appx2808-2810.

The prosecution history confirms that "applied to the dermal cells" means what it says. The inventors' initial proposals for what became claim 1 of the '327 Patent recited neither specific concentration ranges nor application to dermal cells. Appx2684-2686; *see* Appx2675. The PTO rejected the inventors' first amended proposal over prior-art references disclosing specified amounts of adenosine in compositions, rather than applied to dermal cells. Appx2695-2696, Appx2709-2720. In response, the inventors amended claim 1 to add the "wherein" clause reciting ***both*** numerical molar concentrations and application "to the dermal cells." Appx2708. The inventors also submitted experiments showing that, contrary to prior-art claims, the recited adenosine concentrations did not cause cell proliferation when applied to dermal cells. Appx2721-2723. L'Oréal focuses on the addition of numerical concentrations, L'Oréal.Br.54-55, but the simultaneous addition of ref-

erences to "dermal cells" and experimental evidence show the inventors understood those numerical concentrations operate at the dermal layer.

Later events confirmed that the recited adenosine concentrations must be "applied to the dermal cells." The '327 Patent's Notice of Allowability erroneously characterized the claims as reciting applying the claimed concentrations "to the skin." Appx2727. The inventors could have said nothing in response without disavowing claim scope. *Salazar v. Procter & Gamble Co*., 414 F.3d 1342, 1345 (Fed. Cir. 2005). But they "expressly corrected" the error, Appx2809, clarifying that the "claimed concentration of adenosine is applied to the dermal cells," not generically to skin, Appx2729. That is the opposite of a "clear and unmistakable disclaimer," *MIT*, 839 F.3d at 1119, as the district court and PTAB found, Appx3721(58:4-7); Appx2808-2810.[7] L'Oréal's insistence that the inventors' response "parroted" claim language, L'Oréal.Br.57, overlooks that the inventors could have said nothing. L'Oréal nowhere even approaches its "exacting" burden of showing "clear disavowal." *Thorner v. Sony Comput. Ent. Am.*, 669 F.3d 1362, 1366 (Fed. Cir. 2012).

L'Oréal's contention that the inventors' initial proposals described a "composition ***applied to the skin***," L'Oréal.Br.53-54, ignores the later changes and the

[7] L'Oréal urges that the inventors failed to expressly correct the '513 Patent's notice. But they had no obligation to do so. *Salazar*, 414 F.3d at 1345.

claims' current text. Regardless, the specification submitted with the initial proposal already distinguished between skin layers, and recited experiments applying the claimed adenosine ranges directly to dermal cells. Appx2665-2673; *see* pp. 25-27, *supra*. Nor is L'Oréal correct that the inventors distinguished prior art solely as "***compositions*** having higher adenosine concentrations." L'Oréal.Br.55. As the PTAB found, the inventors proved that the prior art's teachings were "not supported by reality" because they described cell proliferation the inventors proved would not occur under the patented method. Appx2846 (citing Appx2724). And the requirement that the recited concentrations be "applied to the dermal cells" separately distinguished prior art. Appx2813.[8]

L'Oréal's selective reliance on other prosecution statements, L'Oréal.Br.55-58, disregards this Court's teaching that an "isolated statement" does not "disclaim subject matter" if the "history as a whole" demonstrates "no clear and unmistakable disclaimer," *Ecolab, Inc., v. FMC Corp*., 569 F.3d 1335, 1342 (Fed. Cir. 2009). Here, the complete history unequivocally demonstrates the inventors' focus on applying the recited concentrations to the dermal cells. *See* pp. 27-28, *supra*.

[8] L'Oréal's suggestion that UMass misdescribed the prior art's treatment of the dermis, L'Oréal.Br.8 n.5, contradicts the PTAB's express finding, Appx2813.

III. THE COURT HAS PERSONAL JURISDICTION OVER L'ORÉAL S.A.

UMass's evidence established personal jurisdiction over L'Oréal S.A. or, at least, the need for jurisdictional discovery. L'Oréal effectively asserts that foreign corporations can litigate personal jurisdiction on a record they alone create, no matter how incomplete or misleading.

A. This Court's Precedents Support Jurisdiction

UMass provided evidence showing that L'Oréal S.A. "direct[ed] the activities of L'Oréal all over the world," Appx624, and designated L'Oréal USA's predecessor its "agent," Appx693. L'Oréal S.A. developed infringing products, Appx1073-1077; sought a U.S. patent to cover them, Appx263-269; and entered "written intra-company agreements" with L'Oréal USA to sell those products in the U.S., Appx553. It was L'Oréal S.A. that responded to UMass's U.S. infringement allegations. Appx1160-1170; Appx1098-1155. Under *Nuance Communications, Inc. v. Abbyy Software House*, 626 F.3d 1222 (Fed. Cir. 2010), that evidence—showing L'Oréal S.A. participated in actions giving rise to infringement—is sufficient to establish jurisdiction. *Id.* at 1231-32.

L'Oréal cannot defeat jurisdiction by attacking UMass's evidence and touting its own. L'Oréal.Br.60-63. Absent "discovery and a record on jurisdiction," "all factual disputes" must be resolved in UMass's favor. *Nuance*, 626 F.3d at 1231. Allegations must be "taken as true" unless "directly controverted." *Id.* While

MATERIAL REDACTED

L'Oréal still invokes a declaration, discredited by later discovery, *see* pp. 32-33, *infra*, that declaration does not "directly controvert[]" UMass's allegations. The declaration's conclusory assertion that L'Oréal USA "operates independently" from L'Oréal S.A. has no bearing on the issue of agency, which presumes independence and focuses instead on control. The declaration, moreover, never addresses L'Oréal S.A.'s development of the infringing products and its rights to control formulation and direct U.S. activities under its "written intracompany agreements." Appx551-554. Resolving factual disputes against UMass without discovery was error. Appx44-45.

L'Oréal's contention that *Nuance* rests on the defendant's "***own infringing acts***," L'Oréal.Br.63, is unpersuasive. Those acts consisted of exporting infringing software under license to an affiliate operated by the same "consolidated Global Management Team." *Nuance*, 626 F.3d at 1231-32. L'Oréal S.A. did the same: It developed, controlled, and licensed the formulations for U.S. sale and had the right to direct U.S. activities. UMass.Br.59-63. Nor is it relevant that the foreign defendant in *Nuance* was entitled to 95% of profits, L'Oréal.Br.63, while L'Oréal S.A.'s term was term. The question is whether L'Oréal S.A. "purposefully directed activities" to the U.S., not its share of proceeds. *Nuance*, 626 F.3d at 1231-32. This Court has found purposeful direction based on mere display of sample products at a U.S. conference. *Synthes (U.S.A.) v. G.M. Dos Reis Jr. Ind. Com. De Equip. Medico*,

563 F.3d 1285, 1289, 1298 (Fed. Cir. 2009). L'Oréal S.A did far more. L'Oréal's remaining citations, L'Oréal.Br.60-63, involve defendants with fewer U.S. contacts.

Finally, L'Oréal's preservation argument, L'Oréal.Br.59-60, is incorrect. UMass objected that the magistrate judge's report "brushed aside" evidence that L'Oréal S.A. is "designing and developing" accused products for L'Oréal USA to "manufacture[ ] and distribute[ ]" in the U.S. Appx21. UMass advances that exact argument now. UMass.Br.59-60; *see* pp. 30-31, *supra*.

B. Discovery Confirmed Personal Jurisdiction

L'Oréal does not dispute that a "total stranger to a corporation should not be required" to litigate personal jurisdiction "on affidavits without the benefit of full discovery." *Compagnie Des Bauxites de Guinee v. L'Union Atlantique S.A. d'Assurances*, 723 F.2d 357, 362 (3d Cir. 1983). This case shows why. Merits discovery confirmed each of UMass's jurisdictional allegations. UMass.Br.62-63. It showed the affidavit L'Oréal submitted, Appx551-554—on which the magistrate judge relied, Appx44-47—omitted critical information demonstrating L'Oréal S.A.'s control over the content and sale of accused products, Appx3935-3958; UMass.Br.62-63.

L'Oréal resorts to half-truths. It asserts that the license agreement "does not mention adenosine or the accused products." L'Oréal.Br.64. But L'Oréal nowhere disputes the agreement ***covers*** the accused products: L'Oréal conceded that

MATERIAL REDACTED

agreement covers "scope ." Appx11647(138:22-139:4); *see* Appx3940. L'Oréal argues that its "ingredient sheets . . . do not suggest that L'Oréal S.A. controlled L'Oréal USA's decision to use particular formulations." L'Oréal.Br.64-65. But the license agreement requires L'Oréal USA to "contract term " L'Oréal S.A. . Appx3944; *see* Appx3941 (" term ").

Celgard, LLC v. SK Innovation Co., *see* L'Oréal.Br.64, supports jurisdiction. 792 F.3d 1373, 1379 (Fed. Cir. 2015). Under *Celgard*, licenses do not establish "agency" if the "defendant did not exercise control over the licensees." *Id.* L'Oréal S.A. exercises control. The license agreement gives it the "contract terms ," , and , Appx3945; *see* Appx3942-3943, precisely as UMass alleged, UMass.Br.59-60. UMass's allegations "specifically questioned" L'Oréal S.A.'s "control" over L'Oréal USA, and the "veracity of . . . declarants' statements" based on "seemingly contradictory statements." *Nuance*, 626 F.3d at 1236. Failure to permit jurisdictional discovery in the face of such disputes was a prejudicial abuse of discretion. *Id.*

L'Oréal invites the Court to turn a blind eye. L'Oréal.Br.64-65. But this Court may consider documents L'Oréal produced after the district court's decision, UMass.Br.63-64 (citing *Werner v. Werner*, 267 F.3d 288, 294-97 (3d Cir. 2001)), all part of the record on appeal, Fed. R. App. P. 10(a). These documents disprove L'Oréal assertions on which the district court relied. On this record, jurisdiction

over L'Oréal S.A. was established; the Court should so hold. At a minimum, the Court should vacate and remand so the district court can resolve that issue or determine whether additional discovery is warranted.[9]

CONCLUSION

The district court's judgment should be reversed.

November 29, 2021

Respectfully submitted,

/s/ Jeffrey A. Lamken

Justin A. Nelson
SUSMAN GODFREY LLP
1000 Louisiana, Suite 5100
Houston, TX 77002
(713) 651-9366 (telephone)
(617) 456-8100 (fax)

Tamar Lusztig
Beatrice C. Franklin
SUSMAN GODFREY LLP
1301 Avenue of the Americas
32nd Floor
New York, NY 10019

Jeffrey A. Lamken
Counsel of Record
Caleb Hayes-Deats
MOLOLAMKEN LLP
The Watergate, Suite 500
600 New Hampshire Avenue, N.W.
Washington, D.C. 20037
(202) 556-2000 (telephone)
(202) 556-2001 (fax)
jlamken@mololamken.com

Lauren F. Dayton
MOLOLAMKEN LLP
430 Park Avenue, 6th Floor
New York, NY 10012

[9] L'Oréal wrongly suggests UMass needed to seek relief under Fed. R. Civ. P. 15 or 54(b). L'Oréal.Br.65. Neither applies. UMass need not amend under Rule 15 to argue discovery confirmed existing allegations. And Rule 54(b) imposed no obligation to seek reconsideration of the dismissal order.

FORM 31. Certificate of Confidential Material **Form 31**
July 2020

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF CONFIDENTIAL MATERIAL

Case Number: 2021-1969

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

Instructions: When computing a confidential word count, Fed. Cir. R. 25.1(d)(1)(C) applies the following exclusions:

- Only count each unique word or number once (repeated uses of the same word do not count more than once).
- For a responsive filing, do not count words marked confidential for the first time in the preceding filing.

The limitations of Fed. Cir. R. 25.1(d)(1) do not apply to appendices; attachments; exhibits; and addenda. *See* Fed. Cir. R. 25.1(d)(1)(D).

The foregoing document contains 15 number of unique words (including numbers) marked confidential.

☑ This number does not exceed the maximum of 15 words permitted by Fed. Cir. R. 25.1(d)(1)(A).

☐ This number does not exceed the maximum of 50 words permitted by Fed. Cir. R. 25.1(d)(1)(B) for cases under 19 U.S.C. § 1516a or 28 U.S.C. § 1491(b).

☐ This number exceeds the maximum permitted by Federal Circuit Rule 25.1(d)(1), and the filing is accompanied by a motion to waive the confidentiality requirements.

Date: 11/29/2021

Signature: /s/ Jeffrey A. Lamken

Name: Jeffrey A. Lamken

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'Oréal 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 6,988 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: 11/29/2021

Signature: /s/ Jeffrey A. Lamken

Name: Jeffrey A. Lamken

FORM 30. Certificate of Service **Form 30**
July 2020

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF SERVICE

Case Number 2021-1969

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

NOTE: Proof of service is only required when the rules specify that service must be accomplished outside the court's electronic filing system. See Fed. R. App. P. 25(d); Fed. Cir. R. 25(e). Attach additional pages as needed.

I certify that I served a copy of the foregoing filing on 11/29/2021

by ☐ U.S. Mail ☐ Hand Delivery ☑ Email ☐ Facsimile
☐ Other: _____

on the below individuals at the following locations.

Person Served	Service Location (Address, Facsimile, Email)
See attached.	

☑ Additional pages attached.

Date: 11/29/2021

Signature: /s/ Jeffrey A. Lamken

Name: Jeffrey A. Lamken

ADDENDUM – SERVICE LIST

The individuals listed below have consented to service by email.

Person Served	Service Location
Katherine F. Murray	kmurray@bgrfirm.com
Isaac S. Ashkenazi	isaacashkenazi@paulhastings.com
Eric W. Dittmann	ericdittmann@paulhastings.com
Stephen B. Kinnaird	stephenkinnaird@paulhastings.com
Naveen Modi	naveenmodi@paulhastings.com
Bruce M. Wexler	brucewexler@paulhastings.com