

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MOMENTIVE PERFORMANCE MATERIALS INC.,
Petitioner

v.

GRANT INDUSTRIES INC.,
Patent Owner

Case IPR2026-00498
U.S. Patent No. 12,337,057

DECLARATION OF BRENT SUMERLIN, PH.D.

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TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	MY BACKGROUND AND QUALIFICATIONS	2
III.	SUMMARY OF OPINIONS.....	6
IV.	DOCUMENTS CONSIDERED.....	8
V.	PERSON OF ORDINARY SKILL IN THE ART	13
VI.	LEGAL BASIS FOR MY ANALYSIS.....	14
	A. Claim Construction.....	14
	B. Prior Art.....	15
	C. Anticipation	15
	D. Written Description	16
	E. Incorporation by Reference	18
VII.	STATE OF THE ART BEFORE AUGUST 30, 2019	19
	A. By 2019, polyurethane chemistry and bio-based synthesis pathways were well known in the art.	19
	B. By 2019, cross-linking mechanisms and their effects on the properties of polyurethane elastomers were well understood in the art.....	23
	C. By 2019, bio-based polyurethane elastomers had seen longstanding and widespread use across medical, adhesive, and industrial applications.	25
VIII.	OVERVIEW OF THE PRIOR ART	29
	A. The '924 Publication (EX1007)	29
	B. Schüwer-573 (EX1008).....	31
IX.	THE '057 PATENT	32
	A. The '057 Patent Specification	33
	B. The '057 Patent Claims	34
	C. The '057 Patent Prosecution History	36
X.	CLAIM CONSTRUCTION	38
XI.	GROUND 1: THE '924 PUBLICATION ANTICIPATES CLAIMS 1-7 AND 13-17.....	38

A.	Claims 1-17 of the '057 patent are not entitled to a priority date earlier than December 14, 2022.....	39
1.	The “esterified dilinoleic acid” genus is not supported by the '015 provisional, the '968 provisional, nor the '831 application.	40
a.	The term “esterified dilinoleic acid” is extremely broad.	41
i.	The term “esterified dilinoleic acid” does not specify the type of alcohol used to esterify the dilinoleic acid.	41
ii.	The term “esterified dilinoleic acid” does not specify the resulting end-group functionality.	44
iii.	The term “esterified dilinoleic acid” does not place a limit on the degree of esterification present and the resulting molecular weight.	46
iv.	The term “esterified dilinoleic acid” does not place a limit on the amount of branching present.....	47
b.	The priority specifications disclose, at most, a species-level subset of the massive genus of “esterified dilinoleic acid.”	49
i.	The '831 application does not describe the full scope of “esterified dilinoleic acid.”	49
ii.	The '015 provisional does not describe the full scope of the “esterified dilinoleic acid.”	50
iii.	The '968 provisional does not describe the full scope of the “esterified dilinoleic acid” genus.....	51
iv.	The polyols disclosed in the priority specifications do not describe the full scope of the “esterified dilinoleic acid.”	52
v.	Nothing incorporated by reference in the priority specifications adds disclosure that might support the full scope.	52
2.	The “multi-functional crosslinker” genus is not supported by the '015 provisional, the '968 provisional, nor the '831 application.	54

a.	The term “multi-functional crosslinker,” when considered by itself, encompasses an immense genus of chemically distinct crosslinkers.	55
b.	The term “multi-functional crosslinker,” when considered in context with the polyester it interacts with, encompasses an immense genus of chemically distinct crosslinkers..	60
c.	The priority specifications disclose, at most, a single class of multi-functional crosslinker (polyisocyanate) within the broad “multi-functional crosslinker” genus.	61
i.	The ’831 application discloses only polyisocyanates, which does not support the full scope of the “multi-functional crosslinkers”.....	62
ii.	The ’015 provisional also discloses only polyisocyanates	64
iii.	The ’968 provisional likewise discloses only polyisocyanates	66
iv.	Nothing incorporated by reference in the priority specifications adds more disclosure that might support the full scope.	67
3.	None of dependent claims 2-17 sufficiently narrow the “multi-functional crosslinker” and “esterified dilinoleic acid” genera	69
a.	Claim 2.....	69
b.	Claims 3-6.....	70
c.	Claim 7.....	70
d.	Claims 8-17.....	71
B.	The ’924 publication anticipates claims 1-7 and 13-17.	71
1.	Claim 1: “A cross-linked elastomer comprising a reaction product of a polyester and a multi-functional crosslinker, wherein the polyester is an esterified dilinoleic acid or a branched C ₃₆ dicarboxylic acid/diol copolymer”	71
2.	Claim 2: “The cross-linked elastomer of claim 1, wherein the multi-functional crosslinker is polyisocyanate.”	74
3.	Claim 3: “The cross-linked elastomer of claim 1, wherein the diol is propanediol or butanediol.”	75

4.	Claim 4: “The cross-linked elastomer of claim 1, where in the polyester is greater than 60% by weight of the total weight of the cross-linked elastomer.”	76
5.	Claim 5: “The cross-linked elastomer of claim 1, where in the polyester is greater than 75% by weight of the total weight of the cross-linked elastomer.”	77
6.	Claim 6: “The cross-linked elastomer of claim 1, wherein the cross-linked elastomer is silicone-free.”	77
7.	Claim 7: “The cross-linked elastomer of claim 1, wherein the branched C ₃₆ dicarboxylic acid/diol copolymer is dilinoleic acid/propanediol copolymer or dilinoleic acid/butanediol copolymer.”	78
8.	Claim 13: “A gel composition comprising the cross-linked elastomer of claim 1 dispersed in a carrier fluid.”	78
9.	Claim 14: “The gel composition of claim 13, the cross-linked elastomer is in micronized form.”	81
10.	Claim 15: “The gel composition of claim 14, wherein the cross-linked elastomer in micronized form has a particle size from 1 to 100 microns.”	82
11.	Claim 16: “The gel composition of claim 15, wherein the particle size is less than 60 microns.”	82
12.	Claim 17: “The gel composition of claim 13, wherein the gel has a viscosity ranging from 15,000 cP to 1,000,000 cP.”	83
13.	The '924 publication is an enabling disclosure of a species of claims 1-7 and 13-17 of the '057 patent.	83
XII.	GROUND 2: SCHÜWER-573 ANTICIPATES CLAIMS 1-7.....	85
A.	Claim 1: “A cross-linked elastomer comprising a reaction product of a polyester and a multi-functional crosslinker, wherein the polyester is an esterified dilinoleic acid or a branched C ₃₆ dicarboxylic acid/diol copolymer”	86
B.	Claim 2: “The cross-linked elastomer of claim 1, wherein the multi-functional crosslinker is polyisocyanate.”	88
C.	Claim 3: “The cross-linked elastomer of claim 1, wherein the diol is propanediol or butanediol.”	88

D.	Claim 4: “The cross-linked elastomer of claim 1, where in the polyester is greater than 60% by weight of the total weight of the cross-linked elastomer.”.....	89
E.	Claim 5: “The cross-linked elastomer of claim 1, where in the polyester is greater than 75% by weight of the total weight of the cross-linked elastomer.”.....	90
F.	Claim 6: “The cross-linked elastomer of claim 1, wherein the cross-linked elastomer is silicone-free.”.....	91
G.	Claim 7: “The cross-linked elastomer of claim 1, wherein the branched C ₃₆ dicarboxylic acid/diol copolymer is dilinoleic acid/propanediol copolymer or dilinoleic acid/butanediol copolymer.”.....	92
H.	Schüwer-573 is an enabling disclosure of claims 1-7 of the '057 patent.	92
XIII.	CONCLUSION.....	95

I, Brent Sumerlin hereby declare as follows.

I. INTRODUCTION

1. I am over the age of eighteen and competent to make this declaration.

2. I have been retained as an expert witness on behalf of Momentive Performance Materials Inc. for the above-captioned *inter partes* review (IPR). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$650 per hour for consulting, document review, and drafting, \$750 per hour for depositions, and \$325 per hour for travel time.

3. I understand that this Declaration accompanies a petition for IPR involving U.S. Patent No. 12,337,057 (“the ’057 patent”) (EX1001), which resulted from U.S. Patent Application No. 18/066,105 (“the ’105 application”), filed on December 14, 2022. From the front page of the patent, I understand that the ’057 patent claims priority to U.S. Patent Application No. 16/992,831 (“the ’831 application”), filed on August 13, 2020, and the ’831 application claims priority to two provisional applications: (1) U.S. Provisional Application No. 62/976,015 (“the ’015 provisional”), filed on February 13, 2020; and (2) U.S. Provisional Application No. 62/893,968 (“the ’968 provisional”), filed on August 30, 2019. I understand that the ’057 patent alleges a priority date of August 30, 2019.

4. In preparing this Declaration, I have reviewed the ’057 patent and

each of the documents cited herein, in light of general knowledge in the art before August 30, 2019. In formulating my opinions, I have relied upon my experience, education, and knowledge in the relevant art. In formulating my opinions, I have also considered the viewpoint of a person of ordinary skill in the art (“POSA”) (i.e., a person of ordinary skill in the field of polymer chemistry, as defined further below in Section V) prior to August 30, 2019.

II. MY BACKGROUND AND QUALIFICATIONS

5. I am the George Bergen Butler Professor of Chemistry at the University of Florida (UF). I hold a Ph.D. in Polymer Science and Engineering from the University of Southern Mississippi. I also hold a B.S. in Textile Chemistry with a concentration in Polymer Chemistry from North Carolina State University. I am a member of the UF Health Cancer. I currently am a Fellow of the American Chemical Society (ACS), including Fellow of the Division of Polymer Chemistry (POLY) of the ACS, and a Fellow of the Royal Society of Chemistry. I am the Director of the George & Josephine Butler Polymer Research Laboratory and the Center for Macromolecular Science & Engineering at UF. My other active professional memberships include the UF Health Cancer Center, Nanoscience Institute for Medical and Engineering Technology (NIMET) at UF, the Division of Polymer Chemistry (POLY) of the ACS and the Division of Polymeric Materials Science & Engineering (PMSE) of the ACS.

6. I have extensive experience in polymer chemistry.
7. In 1998, I obtained a B.S. in Textile Chemistry with a concentration in Polymer Chemistry from North Carolina State University. Subsequently, I obtained a Ph.D. in Polymer Science and Engineering from the University of Southern Mississippi. During my Ph.D., I studied polymer synthesis, polymer characterization, and water-soluble polymers.
8. After obtaining my doctoral degree, I studied as a postdoctoral research associate and served as a Visiting Assistant Professor in the Department of Chemistry at Carnegie Mellon University. As a postdoctoral research fellow, I specialized in polymerization chemistry and reactions on polymers.
9. From 2005-2007, I worked as an Assistant Professor at Southern Methodist University (SMU). I was promoted to Harold Jeskey Trustee Assistant Professor in Chemistry at SMU in 2007, a role that I served until 2009, when I was promoted to Harold Jeskey Trustee Associate Professor with tenure in Chemistry at SMU. I held this position until 2012, after which, I became a tenured Associate Professor of Chemistry at UF from 2012-2015. I was then promoted to Professor of Chemistry at UF and held this position until 2017, when I was promoted to George Bergen Butler Professor of Chemistry at UF. I teach courses on Organic Chemistry, the Organic Chemistry of Polymers, and the Chemistry of High Polymers.

10. At UF, my research focuses on the application of organic chemistry to the design and study of polymers with precise structures and properties. My research includes developing new methods for controlled polymerization and post-polymerization modification, enabling access to macromolecules with tailored architectures and functions. My research also includes investigating depolymerization as a tool for understanding polymer stability and reactivity, with implications for recycling, sustainability, and subtractive manufacturing.

11. My research has led to over 250 peer-reviewed publications, over five books, and over 30 filed patent applications, of which the majority relates to polymer chemistry. As shown in my CV (EX1006), my publications on these topics include:

- Nathan D. Rosenmann, et al., “Prediction of Rheological Properties via Structure Elucidation of Solvated Hydrogels,” *Nature Materials* 2026, DOI: 10.1038/s41563-026-02491-z;
- Joshua D. Marquez, et al., “Latently Curable Ultra-High Molecular Weight Polymers as Dimensionally Stable Monoliths,” *Chemistry of Materials* 2025, 24, 9985-9992;
- Cabell B. Eades, et al., “Ultra-High Molecular Weight Polymer Synthesis via Aqueous Dispersion Polymerization,” *Chemical Science* 2025, 16, 5573-5578;

- Debabrata Konar, et al., “Functionalized Cyclic Polymers and Network Gels,” *Macromolecules* 2024, 57, 1779-1787; and
- Georg M. Scheutz, et al., “Gradient Copolymer Synthesis via Self-Assembly,” *ACS Macro Letters* 2023, 12, 454-461.

12. Over the course of my career, I have received a variety of awards and recognition. These include the Macro Group UK Medal for Outstanding Achievement (2026), IETI Krzysztof Matyjaszewski Award in Chemical Science & Materials Engineering (2025), Herman F. Mark Scholar Award (2024), UF Innovate Intellectual Property Certificate of Achievement (2023), Alfred P. Sloan Fellowship (2010), and NSF CAREER Award (2008).

13. I frequently perform peer review for academic journals, including as an Associate Editor of *ACS Macro Letters*, a Member of the Editorial Advisory Boards of the *Journal of the American Chemical Society*, *Aggregate*, *RSC Applied Polymers*, *Chemical Science*, *Chem*, *Matter*, *Journal of Polymer Science*, *Progress in Polymer Science*. I have previously served as a Member of the Editorial Board for *Polymer Chemistry* from 2010-2012 and as an Associate Editor of *Polymer Chemistry* from 2012-2015.

14. In addition to my educational training and professional and research experience, I have kept abreast of the field of polymer chemistry by reading scientific literature, conferring with colleagues in the field, and attending and

presenting lectures at scientific conferences. I or members of my group have presented at over 500 national or international conferences on topics including polymer chemistry. I have also served as Chair of the Gordon Research Conference on Polymers (2019).

III. SUMMARY OF OPINIONS

15. Generally speaking, the '057 patent is directed to silicone-free, bio-based polyurethane elastomer materials, and gel and cosmetic/personal care compositions containing those materials. EX1001, Abstract, 4:13-21. The claims recite, for example, “[a] cross-linked elastomer comprising a reaction product of a polyester and a multi-functional crosslinker, wherein the polyester is an esterified dilinoleic acid or a branched C₃₆ dicarboxylic acid/diol copolymer,” as well as cosmetic/personal care compositions and gel compositions incorporating that elastomer. EX1001, 24:1-48.

16. As explained in Section XI.A., it is my opinion that claims 1-7 and 13-17 are not entitled to a priority date earlier than December 14, 2022, because the priority applications do not provide written description support for the full scope of claim 1’s two broad genus limitations: “multi-functional crosslinker” and “esterified dilinoleic acid.” In particular, the priority applications do not disclose the term “multi-functional crosslinker.” Instead, they disclose the term “multifunctional, e.g. a tri-functional, polyurethane crosslinker.” This aligns with

the specification as a whole, which relates to polyurethane chemistry and discloses only a single multi-functional crosslinker species (polyisocyanates) without disclosing additional, structurally diverse species sufficient to support the breadth of the claimed genera. Similarly, the priority applications do not disclose “esterified dilinoleic acid.” Instead, they only disclose “dilinoleic acid” and provide only one or two closely related species (DAPD and, in some filings, DABD), without disclosing additional, structurally diverse species sufficient to support the breadth of the claimed genera.

17. Because claims 1-17 are not entitled to a priority date earlier than December 14, 2022, U.S. Patent Publication No. 2021/0059924 (“the ’924 publication”), published March 4, 2021, qualifies as prior art. As explained in Section XI.A, it is my opinion that the ’924 publication discloses an embodiment of each of claims 1-17, arranged as claimed. The ’924 publication provides detailed examples describing the synthesis of cross-linked polyurethane elastomer rubbers from identified reactants and catalysts under specified reaction conditions, followed by conversion of those elastomers into gels and further formulation into a variety of cosmetic and personal care product formats using disclosed carrier fluids and conventional cosmetic components.

18. As further explained in Section XI.A., it is also my opinion that the ’924 publication’s disclosure is enabling for the claimed polyurethane

elastomer embodiments addressed in this Declaration because it provides sufficient direction, including working examples and processing details, such that a POSA would not need to engage in undue experimentation to make and use the disclosed elastomer rubbers, gels, and formulated compositions described in the '924 publication.

19. Separately, as explained in Section XI.B., even assuming for the sake of argument that the claims were entitled to the earliest filing date of August 30, 2019, listed on the patent's face, it is my opinion that Schüwer-573, published April 1, 2015, discloses and enables embodiments meeting each limitation of claims 1-7, including cross-linked elastomer compositions formed from a polyester (polycondensate) derived from dimer fatty acid and a diol, and cross-linked using a polyisocyanate crosslinking agent, with detailed preparative examples and reaction conditions.

20. Accordingly, it is my opinion that claims 1-7 and 13-17 of the '057 patent are anticipated by the '924 publication, and claims 1-7 of the '057 patent are anticipated by Schüwer-573.

IV. DOCUMENTS CONSIDERED

21. In formulating my opinions, I have considered all the references and documents cited herein, including those listed below.

Exhibit No.	Description
1001	U.S. Patent No. 12,337,057 to Croom et al., issued June 24, 2025 (“the ’057 patent”)
1002	File History of U.S. Patent No. 12,337,057 B2 (“’057 Patent File History”)
1006	<i>Curriculum Vitae</i> of Brent Sumerlin, Ph.D.
1007	U.S. Patent Application Publication No. 2021/0059924 A1 to Croom et al., published March 4, 2021 (“the ’924 publication”)
1008	European Patent Application Publication No. EP 2853573 A1 to Schüwer et al., published April 1, 2015 (“Schüwer-573”)
1013	Liles et al., “Silicone Elastomeric Particles in Skin Care Applications,” Chapter 11 of <i>Polymeric Delivery of Therapeutics</i> , Morgan et al., eds. (2010) (“Liles”)
1015	Li, Y., “Bio-based poly(urethane urea) dispersions: chemistry, colloidal stabilization and properties,” Doctoral Dissertation, Technische Universiteit Eindhoven (2014) (“Li 2014”)
1016	Lligadas et al., “Plant Oils as Platform Chemicals for Polyurethane Synthesis: Current State-of-the-Art,” <i>Biomacromolecules</i> , 11:2825-2835 (2010) (“Lligadas”)
1017	Khanderay et al., “Fully biobased polyester polyols derived from renewable resources toward preparation of polyurethane and their application for coatings,” <i>Journal of Applied Polymer Science</i> , 47558 (2019) (“Khanderay”)
1019	U.S. Patent No. 9,815,939 B2 to Smits et al., issued November 14, 2017 (“the ’939 Patent”)
1020	European Patent Application Publication No. EP 2957611 A1 to Schüwer et al., published December 23, 2015 (“Schüwer-611”)
1031	U.S. Patent Application Publication No. 2010/0184635 A1 to Tollington et al., published July 22, 2010 (“Tollington-635”)

Exhibit No.	Description
1032	Akindoyo et al., “Polyurethane types, synthesis and applications – a review,” <i>RSC Advances</i> , 6:114453-114482 (2016) (“Akindoyo”)
1033	Berezkin et al., “Modern Polyurethanes: Overview of Structure Property Relationship,” Chapter 4 of <i>Polymers for Personal Care and Cosmetics</i> , Patil et al., eds. (2013) (“Berezkin”)
1034	Neff et al., “Renewable building blocks for polyurethanes,” <i>Physical Sciences Reviews</i> , 3(8) (June 2018) (“Neff”)
1035	“Amended Safety Assessment of Dialkyl Dimer Dilinoleates as Used in Cosmetics,” Tentative Amended Report for Public Comment, Cosmetic Ingredient Review (June 13, 2018) (“Cosmetic Ingredient Review”)
1036	Biermann et al., “Synthesis of alkyl-branched fatty acids,” <i>European Journal of Lipid Science and Technology</i> , 110:805-811 (2008) (“Biermann”)
1037	“Glossary of Basic Terms in Polymer Science,” <i>Pure and Applied Chemistry</i> , 68(12):2287-2311 (1996) (“IUPAC”)
1038	Corneillie et al., “PLA architectures: the role of branching,” <i>Polymer Chemistry</i> , 6:850-867 (2015) (“Corneillie”)
1039	Clemitson, I., <i>Castable Polyurethane Elastomers</i> (2008) (“Clemitson”)
1040	Qamar et al., “Mechanical and structural behavior of a swelling elastomer under compressive loading,” <i>Materials and Design</i> , 45:487-496 (2013) (“Qamar”)
1041	Ashrafizadeh et al., “Erosive and Abrasive Wear Resistance of Polyurethane Liners,” Chapter 6 of <i>Aspects of Polyurethanes</i> , Yilmaz, F., ed. (2017) (“Ashrafizadeh”)
1042	U.S. Patent No. 8,802,770 B2 to Meltzer et al., issued August 12, 2014 (“Meltzer-770”)

Exhibit No.	Description
1043	U.S. Patent Application Publication No. 2004/0228821 A1 to Sunkel et al., published November 18, 2004 (“Sunkel-821”)
1044	Japanese Unexamined Patent Publication No. 8-198744 to Matsuoka, published August 6, 1996, with certified English-language translation (“JP744”)
1045	Badri, K., “Biobased Polyurethane from Palm Kernel Oil-Based Polyol,” Chapter 20 of Aspects of Polyurethanes, Yilmaz, F., ed. (2017) (“Badri”)
1046	Ball et al., <i>Introduction to Chemistry: General, Organic, and Biological</i> (2011) (“Ball”)
1047	Ertl et al., “An algorithm to identify functional groups in organic molecules,” <i>Journal of Cheminformatics</i> , 9(1):1-7 (June 2017) (“Ertl”)
1048	Lau et al., “Tailoring degree of esterification and branching of poly(glycerol sebacate) by energy efficient microwave irradiation,” <i>Polymer Chemistry</i> , 8:3937-3947 (2017) (“Lau”)
1049	Zhang et al., “Migration studies and chemical characterization of low molecular weight cyclic polyester oligomers from food packaging lamination adhesives,” <i>Packaging Technology and Science</i> , 31:197-211 (2018) (“Zhang”)
1050	“Branched polymers: Synthetic subtlety,” <i>NPG Asia Materials</i> (2010) (“NPG”)
1051	Zhu et al., “Influence of Branching Architecture on Polymer Properties,” <i>Journal of Polymer Science Part B: Polymer Physics</i> , 49:1277-1286 (2011) (“Zhu”)
1052	U.S. Patent Application No. 16/992,831, filed August 13, 2020 (“the ’831 Application”)
1053	U.S. Provisional Application 62/976,015, filed February 13, 2020 (“the ’015 Provisional”)

Exhibit No.	Description
1054	U.S. Provisional Application 62/893,968, filed August 30, 2019 (“the ’968 Provisional”)
1055	U.S. Patent No. 8,222,363 B2 to Lin et al., issued July 17, 2012 (“the ’363 Patent”)
1056	Qin et al., “The effect of a renewable fatty acid derivatives based epoxy diluent on the curing kinetics and thermal properties of epoxy/anhydride systems,” <i>Thermochimica Acta</i> , 614:37-44 (2015) (“Qin”)
1057	Lei et al., “Study on the Soy Protein-Based Wood Adhesive Modified by Hydroxymethyl Phenol,” <i>Polymers</i> , 8(7):256-265 (2016) (“Lei”)
1058	Watts et al., “Segregation and crosslinking in urea formaldehyde/epoxy resins: a study by high-resolution XPS,” <i>Journal of Electron Spectroscopy and Related Phenomena</i> , 121:233-247 (2001) (“Watts”)
1059	Mequanint et al., “Nano-structure phosphorus-containing polyurethane dispersions: synthesis and crosslinking with melamine formaldehyde resin,” <i>Polymer</i> , 44:2631-2639 (2003) (“Mequanint”)
1060	Roesler et al., “Tris-3-(1-aziridino)propionates and their use in formulated products,” <i>Progress in Organic Coatings</i> , 50:1-27 (2004) (“Roesler”)
1061	Xia, Y. & Larock, R., “Castor-Oil-Based Waterborne Polyurethane Dispersions Cured with an Aziridine-Based Crosslinker,” <i>Macromol. Mater. Eng.</i> , 2011, 296, 703-709 (“Xia”)
1062	Kamjornsupamitr et al., “Development of hyperbranched crosslinkers from bio-derived platform molecules for the synthesis of epoxidised soybean oil based thermosets,” <i>RSC Advances</i> , 8:37267-37276 (2018) (“Kamjornsupamitr”)

Exhibit No.	Description
1064	Odian, G., Principles of Polymerization, Chapter 2, <i>John Wiley & Sons</i> (2004) (“Odian”)
1065	U.S. Patent No. 11,534,389 B2 to Croom et al., issued December 27, 2022 (“the ’389 Patent”)
1066	“Safety Assessment of Fatty Acids & Fatty Acid Salts as Used in Cosmetics,” Final Report, Cosmetic Ingredient Review (May 15, 2019) (“FDA”)
1067	“Raw Materials for Flexible Packaging: Fulfilling Your Specific Needs,” Covestro Deutschland AG Brochure (2015) (“Desmodur Brochure”)
1068	POLYSORB ID37 EXP- LAB 3822 Safety Data Sheet, Roquette Frere (March 2011) (“Polysorb Safety Data Sheet”)
1069	Jia et al., “Plasticizers Derived from Biomass Resources: A Short Review,” <i>Polymers</i> , 10(12):1303 (2018) (“Jia”)
1070	U.S. Patent Application Publication No. 2015/0050493 A1 to Yoshie et al., published February 19, 2015 (“Yoshie-493”)

V. PERSON OF ORDINARY SKILL IN THE ART

22. As an expert, I have offered opinions throughout this declaration from the perspective of a person of ordinary skill in the art (“POSA”). I understand that a POSA is a hypothetical person who is presumed to be aware of all pertinent art, who thinks along conventional wisdom in the art, and is a person of ordinary creativity. I also understand the level of a POSA is a prism or lens through which the prior art and the claimed invention are viewed.

23. A POSA in the field of the ’057 patent would have been familiar with

the scientific literature and skilled in laboratory techniques relevant to the synthesis, characterization, and formulation of elastomers and related polymers. Typically, a POSA would have had a Ph.D. degree in organic chemistry, chemical engineering, materials science, polymer science, polymer engineering, or a related discipline, with at least two years of experience in the field. A POSA may also have worked as part of a multidisciplinary team, drawing not only upon his or her own skills, but also upon specialized skills of others to solve technical problems in the field. Here, a formulation scientist having familiarity with cosmetic formulations and personal care products may have been part of the team.

VI. LEGAL BASIS FOR MY ANALYSIS

24. In formulating my opinions set forth in this Declaration, I applied the following legal principles:

A. Claim Construction

25. I understand that in an IPR, patent claim terms are given their ordinary and customary meaning as understood by a POSA at the time of the invention, in view of the patent's specification and its prosecution history—unless the patentee has acted as his own lexicographer. I understand that a patentee may act as his own lexicographer when providing definitions in the specification or prosecution history. For example, an inventor may clearly set forth a definition of the claim term in either the specification or prosecution history that is different

from the term's ordinary meaning.

26. I understand that claim 1 is the independent claim in the '057 patent, and that claims 2-17 are dependent claims depending directly or indirectly from claim 1. I understand that a dependent claim contains all limitations (i.e., elements) of the claim(s) from which it depends. Thus, I understand that claims 2-17 contain at least all of the limitations of claim 1.

B. Prior Art

27. I understand that whether a document is prior art to a patent claim depends upon the date of publication of the document and the priority date of the claim. I have also been informed that different claims in the same patent may have different priority dates depending upon when the subject matter of the claim was filed with the U.S. Patent and Trademark Office (USPTO). In other words, while a patent may claim priority to an earlier filed application, including a provisional application, each claim requires analysis to determine if it was disclosed in the earlier application and, therefore, entitled to the priority date of that earlier application.

C. Anticipation

28. I understand that a prior-art reference anticipates a claim if it discloses, either expressly or inherently, each and every element recited in the claim, arranged in the same manner as in the claims.

29. I understand that the anticipating reference must also enable a POSA to make an embodiment of the claimed invention without the need for undue experimentation in light of the general knowledge available in the art. The factors that I have considered in determining whether a reference discloses an embodiment of a claim in a sufficient manner such that a POSA could have made and used the claimed invention without undue experimentation include: the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the reference, the existence of working examples, and the quantity of experimentation needed to make or use an embodiment of the claims.

D. Written Description

30. I understand that a patent specification must convey clearly to a POSA that, as of the filing date sought, the inventor was in possession of the claimed invention. I also understand that possession does not mean physical possession and does not require making or testing the invention.

31. I further understand that this written description requirement must be applied in the context of the particular invention and the state of the knowledge in the art. In addition, I understand that a patent specification is written for a POSA and that such a hypothetical person presumably has all of the knowledge of the state of the art as of the patent's filing date, in addition to the knowledge provided

by the patent specification itself.

32. I understand that there is sufficient written description support when a POSA can visualize or recognize the identity of the full scope of the claimed subject matter and that the claimed subject matter need not be provided verbatim in a specification because a skilled artisan comes to the patent with knowledge in the art, and it is therefore unnecessary to spell out every detail of the invention in the specification for a skilled artisan to conclude that there is written description support.

33. I understand that assessing whether there is written description support for a genus claim in the chemical arts involves consideration of a number of factors, including (i) the nature and scope of the claims; (ii) existing knowledge in the particular field and extent and content of the prior art; (iii) maturity of the science of technology and scientific and technologic knowledge already in existence; (iv) predictability of the aspect at issue; and (v) scope of the invention at issue.

34. I further understand that a sufficient description of a genus requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus. Additionally, I understand that an adequate written description requires a precise

definition—such as by structure, formula, chemical name, physical properties, or other properties—of species falling within the genus sufficient to distinguish the genus from other materials.

35. It is also my understanding that a patent application may claim priority benefit to the filing date of one or more of the applicant's previously filed U.S. patent applications for claims that are supported in those previously filed applications by an adequate written description. It is my understanding that the date to which a particular claim is entitled to claim this benefit depends upon when the matter necessary to provide a written description of the claim was first disclosed in an application in the chain of priority. If an application in the chain of priority does not provide a written description of a claim, then that claim is not entitled to claim the benefit of the filing date of that priority application.

E. Incorporation by Reference

36. I have been advised that when a patent or patent application “incorporates by reference” another patent or publication, it is as if the portions of the patent or publication incorporated by reference are reproduced verbatim within the specification.

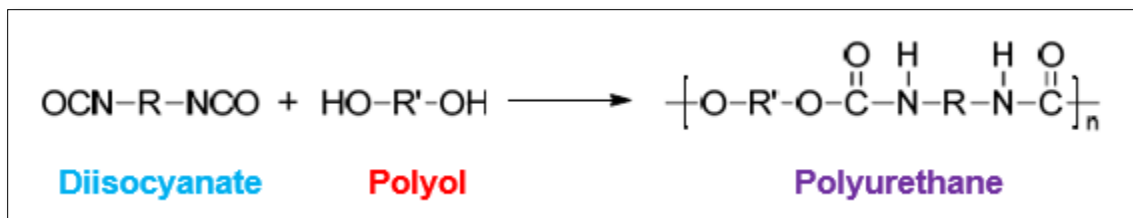
VII. STATE OF THE ART BEFORE AUGUST 30, 2019¹

A. By 2019, polyurethane chemistry and bio-based synthesis pathways were well known in the art.

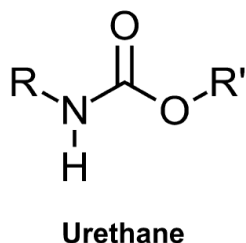
37. Polyurethanes (“PU”) are a major class of polymers. One category of polyurethanes is an elastomer. EX1032, 114454. As the name suggests, polyurethane elastomers are elastic (i.e., malleable) polymers. EX1032, 114454, 114459. Polyurethane elastomers are able to recover from stress and have a tolerance to high physical strains. EX1032, 114459.

38. Polyurethanes are typically synthesized from polyols and polyisocyanates (-NCO). An example of a polyurethane formed from a diisocyanate and a diol is depicted below. EX1015, 2; *see also* EX1032, 114455 (“Generally, PUs are often synthesized from the reaction between an isocyanate and polyol molecule in the presence of either a catalyst or ultraviolet light activation.”).

¹ Although I understand that the ’057 patent claims are not entitled to a priority date earlier than December 14, 2022, I nonetheless provide a summary of the state of the art as of August 30, 2019, the earliest filing date listed on the face page of the patent.



EX1015, 2 (annotated). In other words, the repeating units of the polyurethane are derived from the polyisocyanate and the polyol, linked together by a urethane group. The structure of the urethane group is shown below.



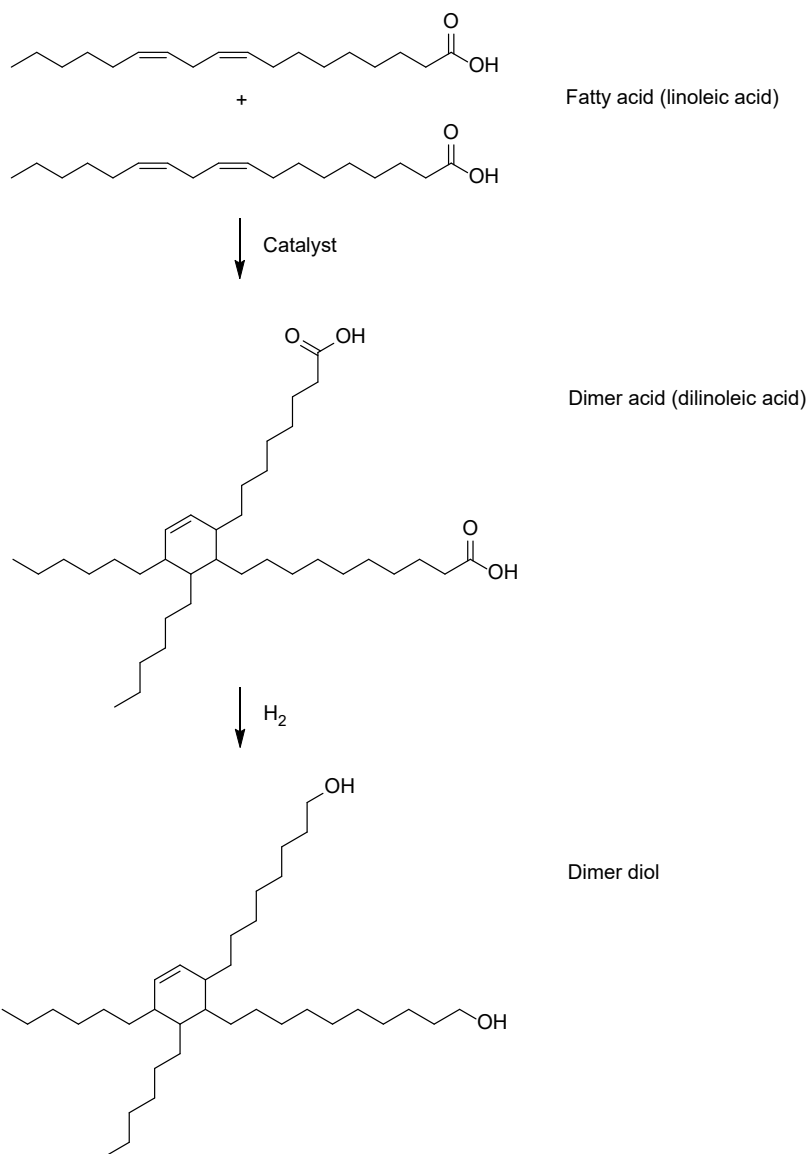
EX1033, 66 (cropped).

39. There has been “research interest in developing high-performance PU products from renewable resources” to obtain “more sustainable polymeric materials.” EX1015, 6; EX1017, 1. Polyurethanes prepared from renewable resources are known to “exhibit a number of excellent properties that are attributable to [their] hydrophobicity.” EX1016, 2825-26. Bio-based polyurethanes are typically formed when the polyol and/or the polyisocyanate used in their synthesis are obtained from renewable or natural sources such as vegetable oils or amino acids. EX1015, 6-7 (“[R]enewable polyurethanes [are] synthesized from vegetable oil-based polyols and diisocyanates, sugar-based polyols as well as

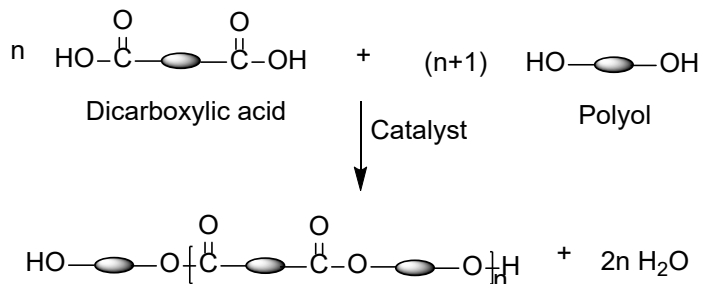
amino acid-based diisocyanates.” (internal citations omitted)). Linoleic acid and related fatty acids are obtained from vegetable oils and thus can be used to generate bio-based polyurethanes. EX1016, 2831; *see also* EX1017, 1.

40. To create a polyol from a fatty acid such as linoleic acid, multiple steps occur. First, the acid undergoes dimerization to form dimer acids.² *See, e.g.*, EX1034, 7; *see also* EX1035, 3. During the dimerization reaction, in addition to dimer acids, other byproducts are formed, including “varying amounts of trimer fatty acids (so-called ‘trimer’), oligomeric fatty acids, and residues of monomeric fatty acids (so-called ‘monomer’), or esters thereof.” EX1019, 4:31-36. As shown in the figure below, dimer acids have two long alkyl chains, also referred to as “branches.” *See* EX1036, Abstract (referring to “[a]lkyl-branched fatty compounds”). Dimer acids can be chemically reduced—typically by hydrogenation or other reduction methods—to convert the carboxylic acid groups into hydroxyl groups, resulting in a dimer diol, as shown in the figure below. *See* EX1016, 2831; *see also* EX1034, 7.

² The resultant dimer acid is a mixture of acyclic, monocyclic, and bicyclic compounds, with varying degrees of unsaturation. EX1035, 0002-3, FIG. 1.



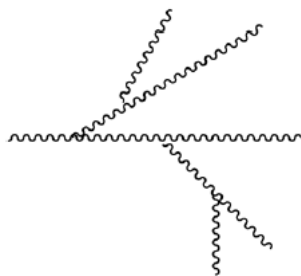
41. Alternatively, dimer acid is reacted with a diol to form a dimer acid/diol polyester that serves as a renewable polyester polyol. EX1032, 114462 (“Polyester polyols are derived from virgin raw materials and are often produced through the direct polyesterification of very pure diacids and glycols.”). This process is depicted below.



This polyester polyol can then be combined with polyisocyanates to synthesize cross-linked, bio-based polyurethanes. EX1015, 2; *see also* EX1032, 114455.

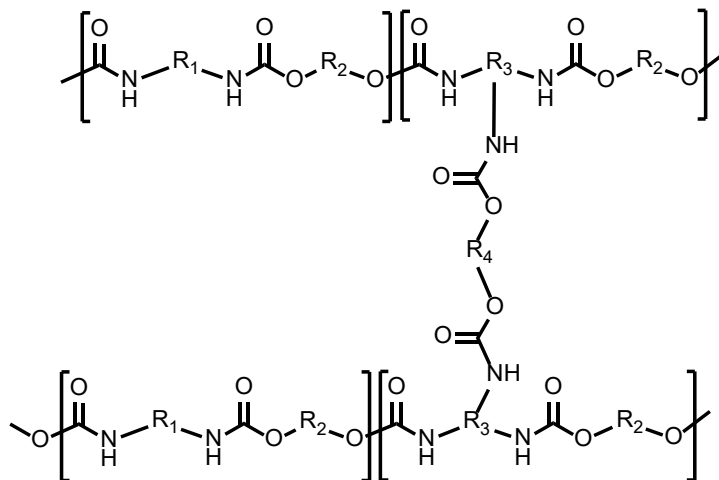
B. By 2019, cross-linking mechanisms and their effects on the properties of polyurethane elastomers were well understood in the art.

42. If a fraction of the polyol has a hydroxyl functionality greater than two, the resulting polyester formed from the reaction between the diacid and the polyol can be branched or cross-linked. A branched polymer includes a polymer in which a branch (i.e., an offshoot) extends from the main backbone of the polymer. EX1031, ¶[0049]; *see also* EX1037, 2297 (Definition 1.53).



EX1038, 853 (Table 2). The polymer can also be cross-linked, meaning that chemical bonds or bridges form between separate polymer backbones, producing an interconnected three-dimensional network. EX1031, ¶[0049].

43. When polyester polyols are reacted with polyisocyanates, the polyester chains are chemically joined into a three-dimensional network in the crosslinking process. EX1039, 218; *see also* EX1031, ¶¶[0049]-[0052].



44. The degree of crosslinking, often described in terms of cross-link density, affects the mechanical properties of an elastomer, including its modulus, tensile strength, elongation, and elastic recovery. Increasing the number of cross-links will also make the polyurethane more rigid, whereas millable polyurethanes “have a limited degree of cross-linking and low chain stiffness.” EX1039, 8. Introducing permanent covalent cross-links can improve the ability of a polyurethane elastomer to recover its original shape after deformation under compressive force. EX1039, 126-127. In other words, crosslinking can affect the material properties of the polyurethane elastomer.

C. By 2019, bio-based polyurethane elastomers had seen longstanding and widespread use across medical, adhesive, and industrial applications.

45. Owing to their tunable mechanical properties, including flexibility and rigidity, and their chemical resistance, polyurethane elastomers have long been recognized as a versatile and well-established class of elastomeric materials.

EX1015, 2. One such example of the versatility of elastomers is their ability to swell when interacting with fluids such as oil and water. *See* EX1040, 487. By absorbing either hydrocarbons or water, elastomers increase in volume and become softer, thereby affecting their volume, thickness, density, and hardness. *See* EX1040, 487; *see also* EX1041, 141; EX1042, 7:16-17. While at times, this swelling can lead to higher abrasive wear (EX1041, 141), swelling of elastomers can also be advantageous as it can lead to the formation of gels (EX1043, ¶[0004]) and can also be utilized to deliver therapeutic agents to the skin (EX1013, 217). Thus, polyurethane elastomers are widely applied in biomedical applications, building and construction applications, automotive, textiles, and in several other industries. EX1032, 114453.

46. By the 1990s, polyurethane elastomers were in use as flexible base films for percutaneous and transdermal drug delivery systems, where they provided a combination of softness, durability, and skin compatibility that was difficult to achieve with other polymers. For example, in 1996, Japanese Pub. No.

JPH08198744A (“JP744”) disclosed polyurethane elastomer films for use in transdermal medicinal patches. EX1044, Abstract. JP744 discloses that the polyurethane elastomers are formed from polyester polyols and diisocyanates, and the polyester polyols, in turn, are synthesized from dimer acids having 36 carbon atoms and a diol such as 1,4-butanediol. EX1044, ¶¶[0002]-[0010], Example 1. JP744 highlighted the benefits of the polyurethane elastomers, including their flexibility, chemical resistance, and suitability for skin-contact applications. EX1044, ¶[0005].

47. Schüwer-573 and European Patent Publication No. 2 957 611 (“Schüwer-611”) provide examples of biomedical and industrial uses of cross-linked polyurethane elastomers. These applications, which published in 2015, disclosed cross-linked polyurethane and polyester/polyurethane elastomer compositions for use in skin-friendly adhesives, medical tapes, patches, and a range of non-medical applications such as masking tapes, protective tapes, and temporary bonding of semiconductor elements. EX1008, ¶¶[0011], [0106]-[0117]; EX1020, ¶¶[0166]-[0178].

48. Schüwer-573 emphasized that its adhesive can be made “using as much as possible of biobased materials.” EX1008, ¶[0011]; *see also* EX1008, ¶¶[0090], [0099]. Schüwer-573 defined the term “bio-based” to “refer to substances derived from renewable starting materials (as opposed to mineral oil-

derived starting materials) by isolation and optionally one or more chemical transformations.” EX1008, ¶[0027]. The components of Schüwer-573’s polycondensate (polyester)³ includes at least one diacid and at least one diol. EX1008, ¶[0032]. Schüwer-573 describes its diacid in particular, as being a dimer of linoleic acid, which is bio-based. EX1008, ¶¶[0035]-[0037]. Schüwer-573 lists 1,4-butanediol as a preferred diol. EX1008, ¶[0042]. Schüwer-573 also describes crosslinking the polycondensate with a crosslinking agent that contains at least 2 isocyanate groups. EX1008, ¶¶[0070]-[0071]. In particular, Schüwer-573 discloses using “a commercially available aliphatic polyisocyanate crosslinking agent” under the trademark DESMODUR (also known as hexamethylene diisocyanate trimer). EX1008, ¶¶[0074], [0121], [0126]-[0127]; *see also* EX1067, 20. Thus, Schüwer-573 emphasized that its cross-linked polyurethane elastomers can be synthesized from dimerized linoleic acid, at least one diol, and a polyisocyanate crosslinker.

49. Schüwer-611 similarly emphasized that its adhesive can be made “using as much as possible of bio-based materials.” EX1020, ¶[0023], *see also*

³Polyesters are typically formed by step-growth condensation between hydroxyl-functional and carboxylic-acid-functional monomers, producing ester linkages and, upon further reaction, oligomeric or polymeric polyester species. EX1032, 114461; *see also* EX1045, 451, 459.

EX1020, ¶¶[0115], [0166]. Schüwer-611 defined the term “bio-based” to “refer to substances derived from renewable starting materials (as opposed to mineral oil-derived starting materials) by isolation and optionally one or more chemical transformations.” EX1020, ¶[0036]. The components of Schüwer-611’s polycondensate include a dicarboxylic acid and a diol. EX1020, ¶[0044]. Schüwer-611 describes its dimer acid, in particular, as being a dimer of a fatty acid, such as linoleic acid, which is a bio-based fatty acid. EX1020, ¶¶[0047]-[0048]. Schüwer-611 lists 1,4-butanediol as a preferred diol. EX1020, ¶[0054]. Schüwer-611 also described adding a crosslinking agent, including “isocyanate-based cross-linkers” or more specifically, polyisocyanates, such as DESMODUR. EX1020, ¶¶[0097], [0100]. Thus, Schüwer-611 emphasized that its cross-linked polyurethane elastomers can be synthesized from dimerized linoleic acid, at least one diol, and a polyisocyanate crosslinker.

50. In 2017, U.S. Patent 9,815,939 B2 (“the ’939 Patent”) described polyurethanes formulated as dispersions, coatings, adhesives, and elastomer compositions. EX1019, 1:15-20. According to the ’939 patent, these elastomer compositions “may be solid elastomers or microcellular elastomers.” EX1019, 12:5-7. The ’939 patent described “polyesters and polyurethanes made therefrom which may be formed from starting materials which may be biobased.” EX1019, 2:15-17. The polyurethanes described in the ’939 patent are “reaction product[s] of

a polyisocyanate and polyester, wherein said polyester is formed from a dimer fatty acid, a C₂ to C₄ diol, and a C₈ to C₁₆ dicarboxylic acid or C₆ to C₁₂ lactide.”

EX1019, 2:28-32. The '939 patent further describes that “[s]uitable dimer fatty acids are preferably derived from (i.e., are the dimer equivalents of) the dimerisation products of...linoleic acid.” EX1019, 4:18-21. The '939 patent describes suitable diols as including “straight chain aliphatic diols,” which include 1,3-propanediol and 1,4-butanediol. EX1019, 5:26-32. Thus, the '939 patent emphasizes that its polyurethane elastomers are derived from dimerized linoleic acid and a diol. Moreover, the '939 patent discloses that the polyisocyanate component is “preferably at least one isocyanate which has a functionality of at least 2.” EX1019, 8:41-46.

51. Accordingly, by 2019, cross-linked polyurethane elastomers made from dimerized fatty acid and a diol were a mature and widely adopted elastomer class, routinely used in medical, adhesive, and industrial applications due to their flexibility, chemical resistance, and ability to be tailored for specific end uses.

VIII. OVERVIEW OF THE PRIOR ART

A. The '924 Publication (EX1007)

52. U.S. Patent Publication No. 2021/0059924 (“the '924 publication”), entitled “Bio-Based and Biodegradable Elastomer for Cosmetic and Personal Care,” published on March 4, 2021. EX1007, 1. I understand that because claims

1-17 are entitled to a filing date of, at best, December 14, 2022, the '924 publication (the published application of the '831 parent application) qualifies as prior art.

53. The '924 publication discloses cross-linked polyurethane elastomer gels formed by reacting a polyester with a multi-functional polyisocyanate crosslinker. EX1007, ¶¶[0299]-[0303]. The polyester most commonly exemplified in the '924 publication is an esterified dilinoleic acid/propanediol copolymer ("DAPD"), which is a "branched C36 dicarboxylic acid/diol copolymer." EX1007, ¶¶[0298]-[0308]. The '924 publication also discloses an example using a dilinoleic acid/butanediol copolymer ("DABD"). EX1007, ¶¶[0298]-[0308]. The multi-functional polyisocyanate crosslinker is described as pentylene diisocyanate trimer, PDT. EX1007, ¶¶[0299]-[0303]. This reaction is carried out in the presence of a urethanes catalyst, yielding a silicone-free, bio-based elastomeric gel. EX1007, ¶[0299]. The polyester is present at 78% by weight of the elastomer-forming reactants. EX1007, ¶¶[0298]-[0299]. The elastomer is developed as a silicone alternative (EX1007, ¶[0006]), with none of the examples including silicone (EX1007, ¶¶[0299]-[0303]).

54. The '924 publication further discloses cosmetic and personal care compositions comprising the cross-linked elastomer and a carrier fluid. EX1007, ¶¶[0031]-[0032]. The '924 publication further discloses that the elastomer may be

incorporated into water-in-oil emulsions. EX1007, ¶[0311]. The elastomer is also disclosed in the '924 publication as being incorporated into foundations, lotions, creams, shampoos, serums, and lip care formulations. EX1007, ¶¶[0254], [0311]-[0316].

55. The '924 publication also describes forming gel compositions comprising the cross-linked elastomer and a carrier fluid. EX1007, ¶¶[0293]-[0295]. The gel composition is refined by milling to produce micronized elastomer particles in the 1–100 micron range, preferably less than 60 microns. EX1007, ¶[0017]. The gel described in the '924 publication has a viscosity ranging from 15,000 to 1,000,000 cP. EX1007, ¶ [0035].

B. Schüwer-573 (EX1008)

56. European Patent Application No. 13198936.0 to Schüwer, Nicolas et al., entitled, “Skin Friendly Adhesive,” was filed on December 20, 2013 and published on April 1, 2015 as EP2853573. (“Schüwer-573”) EX1008, 1. I understand that Schüwer-573 qualifies as prior art.

57. Schüwer-573 expressly discloses cross-linked elastomer compositions formed by reacting a polyester (polycondensate) with a multi-functional polyisocyanate crosslinker (e.g., DESMODUR N3600). EX1008, ¶¶[0032]-[0037], [0042], [0052], [0122], [0125]-[0126]. The polyester (polycondensate) is derived from a dimer of fatty acid (such as dilinoleic acid, including PRIPOL 1009 or

PRIPOL 1006) and a diol (such as 1,4-butanediol). EX1008, ¶¶[0032]-[0037], [0042], [0052]. An oil additive, such as a plasticizer and fatty acid esters of polyvalent alcohols, is also incorporated. EX1008, ¶¶[0078]-[0080], [0088]-[0097]. Schüwer-573 provides concrete examples using 1,4-butanediol as the diol, and in Preparative Example 5, the polyester is present at approximately 96% by weight of the elastomer-forming reactants. EX1008, ¶¶[0125]-[0126].

58. Schüwer-573 repeatedly emphasizes that the disclosed formulations are silicone-free, developed as alternatives to silicone adhesives, and none of the examples include silicone. EX1008, ¶¶[0009], [0122]-[0127]. Schüwer-573 also discloses that the disclosed elastomers are “preferably made by using as much as possible of biobased materials.” EX1008, ¶[0011]. Schüwer-573 further discloses that the cross-linked elastomer compositions are used in a wide range of applications, including skin-friendly medical tapes, patches, and drug delivery systems to deliver a broad array of active pharmaceutical ingredients, such as analgesics, anti-inflammatories, antibiotics, and hormones for topical or transdermal administration. EX1008, ¶¶[0106]-[0117].

IX. THE '057 PATENT

59. I understand from counsel that the '057 patent issued on June 24, 2025, from U.S. Pat. Appl. No. 18/066,105 (“the '105 application”), which was filed on December 14, 2022. From the front page of the patent, I understand that

the '057 patent claims priority to the '831 application, which was filed on August 13, 2020, and the '831 application claims priority to two provisional applications: (1) the '015 provisional, which was filed on February 13, 2020; and (2) the '968 provisional, which was filed on August 30, 2019.

A. The '057 Patent Specification

60. The '057 patent is generally directed to compositions and methods for preparing “polyester and polyurethane type feedstocks for use in cosmetics.”

EX1001, 1:17-20. Specifically, the '057 patent relates to a “biobased and biodegradable swellable, elastic non-ionic, nonaqueous material using a polyester linked between a multifunctional, e.g. a tri-functional, polyurethane crosslinker in a natural origin reaction solvent, which is also referred to herein as a cosmetic emollient, using a urethanation catalyst such as a bismuth catalyst.” EX1001, 3:29-35.

61. The '057 patent is also related to “gel compositions which contain a mixture of a cross-linked polyurethane elastomer rubber composition as described herein, in a milled form and at least one cosmetic emollient as well as methods of making the gel compositions.” EX1001, 4:1-5.

62. The '057 patent explains that “[t]hrough a milling and dilution process, the polyurethane rubber composition is converted into an elastomeric gel that provides a smooth, non-tacky, non-oily, moisturizing skin-feel with enhanced

playtime on the skin.” EX1001, 5:4-7. The '057 patent states that this gel is “an elegant addition to the cosmetic formulator’s toolbox for creating stable cosmetic formulas with improved compatibility toward more polar cosmetic emollients, actives, and additives that are commonly incorporated into the oil phase of oil-based cosmetics.” EX1001, 5:7-12.

B. The '057 Patent Claims

63. Claim 1 of the '057 patent recites:

1. A cross-linked elastomer comprising a reaction product of a polyester and a multi-functional crosslinker, wherein the polyester is an esterified dilinoleic acid or a branched C₃₆ dicarboxylic acid/diol copolymer.

EX1001, 24:2-5.

64. Dependent claims 2-17 of the '057 patent recite:

2. The cross-linked elastomer of claim 1, wherein the multi-functional crosslinker is polyisocyanate.
3. The cross-linked elastomer of claim 1, wherein the diol is propanediol or butanediol.
4. The cross-linked elastomer of claim 1, where in the polyester is greater than 60% by weight of the total weight of the cross-linked elastomer.

5. The cross-linked elastomer of claim 1, where in the polyester is greater than 75% by weight of the total weight of the cross-linked elastomer.
6. The cross-linked elastomer of claim 1, wherein the cross-linked elastomer is silicone-free.
7. The cross-linked elastomer of claim 1, wherein the branched C₃₆dicarboxylic acid/diol copolymer is dilinoleic acid/propanediol copolymer or dilinoleic acid/butanediol copolymer.
8. A cosmetic and personal care composition comprising the cross-linked elastomer of claim 1 and a carrier fluid.
9. The cosmetic and personal care composition of claim 8, further comprising a water phase and an oil phase.
10. The cosmetic and personal care composition of claim 8, wherein the composition further comprises an active selected from the group consisting of selected from vitamins, sunscreens, plant extracts, fragrances and mixtures thereof.
11. The cosmetic and personal care composition of claim 8, further comprising fragrances, colorants, preservatives, or mixtures thereof.
12. The cosmetic and personal care composition of claim 8, wherein the composition is a foundation, a lotion, a cream, a shampoo, a serum, or a lip care formulation.
13. A gel composition comprising the cross-linked elastomer of claim 1 dispersed in a carrier fluid.

14. The gel composition of claim 13, the cross-linked elastomer is in micronized form.

15. The gel composition of claim 14, wherein the cross-linked elastomer in micronized form has a particle size from 1 to 100 microns.

16. The gel composition of claim 15, wherein the particle size is less than 60 microns.

17. The gel composition of claim 13, wherein the gel has a viscosity ranging from 15,000 cP to 1,000,000 cP.

EX1001, 24:6-48.

C. The '057 Patent Prosecution History

65. I understand from counsel that original claim 1 of the '105 application read:

A method of preparing a non-aqueous gel composition, comprising:

a) micronizing a cross-linked polyurethane elastomer rubber composition, comprising a cross-linked polyurethane elastomer rubber and a urethanation catalyst in the presence of a cosmetic emollient wherein the cosmetic emollient forms a solvent matrix substantially surrounding the cross-linked polyurethane elastomer rubber; and optionally,

b) combining the mixture resulting from step a) with a secondary solvent whereby a non-aqueous gel composition is formed.

EX1002, 36.

66. I understand that a Response to the Restriction Requirement was filed on February 19, 2025, in which new claims were added, including claim 28, which recites that the cross-linked elastomer is a reaction product of a polyester and a multi-functional crosslinker. EX1002, 927. New dependent claims 29-35 were added, which recited for the first time a “multi-functional crosslinker” (claim 28) and “esterified dilinoleic acid” (claim 31). EX1002, 927.

67. I understand that on April 10, 2025, the Examiner issued a Non-Final Office Action. The Examiner rejected claims 28-29, 34-35, and 46 as being anticipated by U.S. Patent No. 3,192,185 (“Achterhof et al.”). EX1002, 1021-1022. According to the Examiner, Achterhof et al. discloses polyurethane elastomers, including material prepared from a polyester and a polyisocyanate, and is cross-linked. EX1002, 1022.

68. I understand that in the Response to the Non-Final Office Action filed on April 18, 2025, Grant Industries amended claim 28 to recite: “A cross-linked elastomer comprising a reaction product of a polyester and a multi-functional crosslinker, wherein the polyester is an esterified dilinoleic acid or a branched C₃₆ dicarboxylic acid/diol copolymer.” EX1002, 1032. Grant Industries argued that this amendment overcame the rejection because it incorporates the subject matter of claims 31 and 32, which were not rejected. EX1002, 1036-37.

69. I understand that the Examiner issued a Notice of Allowance on May

14, 2025, stating that claims 28-29,33-35,46,50-51 and 54-62 were allowed because “[t]he specific species elected (the polyurethane prepared from DAPD polyol and PDT) is not suggested by the prior art. Also, cross-linked elastomers prepared from multifunctional crosslinkers and esterified dilinoleic acid are free of the prior art.” EX1002, 1097-1098.

X. CLAIM CONSTRUCTION

70. I address the construction of terms in claims 1-7 and 13-17 of the ’057 patent below. In particular, I address the scope of the terms “multi-functional crosslinker” and “esterified dilinoleic acid” because, as used in the claims, both terms are extraordinarily broad as compared to the disclosure in the specifications of the priority applications. I do not address the scope of any other claim terms. I understand that indefiniteness arguments are not permitted in an IPR, and I therefore also do not offer any opinion as to whether the scope of the claim terms is defined with reasonable certainty. I saw nothing in the ’057 patent that indicates that any other terms in claims 1-7 and 13-17 should be given any particular meaning other than their plain meaning.

XI. GROUND 1: THE ’924 PUBLICATION ANTICIPATES CLAIMS 1-7 AND 13-17.

71. The ’057 patent issued on June 24, 2025, from the ’105 application, filed on December 14, 2022. The ’057 patent claims priority to the ’831 application, filed on August 13, 2020, and the ’831 application claims priority to

two provisional applications: (1) the '015 provisional, filed on February 13, 2020; and (2) the '968 provisional, filed on August 30, 2019.

72. As explained below, claims 1-17 of the '057 patent are not entitled to claim priority to any of the '831 application, the '015 provisional, and the '968 provisional. Therefore, claims 1-17 are entitled to a filing date no earlier than December 14, 2022. Consequently, the '924 publication (the published application of the '831 parent application) qualifies as prior art. And, as explained below, the '924 publication discloses each and every element of claims 1-7 and 13-17 of the '057 patent arranged as claimed and in a manner enabling to a POSA.

A. Claims 1-17 of the '057 patent are not entitled to a priority date earlier than December 14, 2022

73. It is my understanding from counsel that for a patent to gain the benefit of the filing date of an earlier application (also known as claiming priority to an earlier application), the earlier application must enable and provide adequate written description of the later-claimed subject matter in the patent. I further understand from counsel that priority is assessed on a claim-by-claim basis. In other words, the subject matter of each patent claim must be compared to the disclosure of the earlier application to determine whether the claimed subject matter is adequately described and enabled by the earlier application, such that the patent claim is entitled to rely on the filing date of the earlier application.

74. The '057 patent claims recite two vast genera: “multi-functional

crosslinker” and “esterified dilinoleic acid.” I explain below why each of these genera is extremely large. I have also reviewed each of the ’831 application, the ’015 provisional, and the ’968 provisional, and the documents that were incorporated by reference into the ’831 application, the ’015 provisional, and the ’968 provisional, and considered whether the disclosures in those documents support the full scope of the “multi-functional crosslinker” and “esterified dilinoleic acid” genera. I explain next why my conclusion is that none of the ’831 application, the ’015 provisional, and the ’968 provisional provide enough disclosure to support the full breadth of “multi-functional crosslinker” or of “esterified dilinoleic acid” in the ’057 patent claims.

1. The “esterified dilinoleic acid” genus is not supported by the ’015 provisional, the ’968 provisional, nor the ’831 application.

75. Claim 1 recites that “the polyester is an *esterified dilinoleic acid*.” EX1001, claim 1. The term “esterified dilinoleic acid” appears nowhere in any of the priority specifications and was first introduced in claim 31 in the same February 19, 2025 Response to Restriction Requirement filed in the ’105 application that introduced the term “multi-functional crosslinker.” EX1002, 1032.

76. As I discuss below, the term “esterified dilinoleic acid” is incredibly broad. Yet, in contrast to the breadth of that term, the priority specifications disclose only dilinoleic acid and a list of polyols, as well as two specific, closely

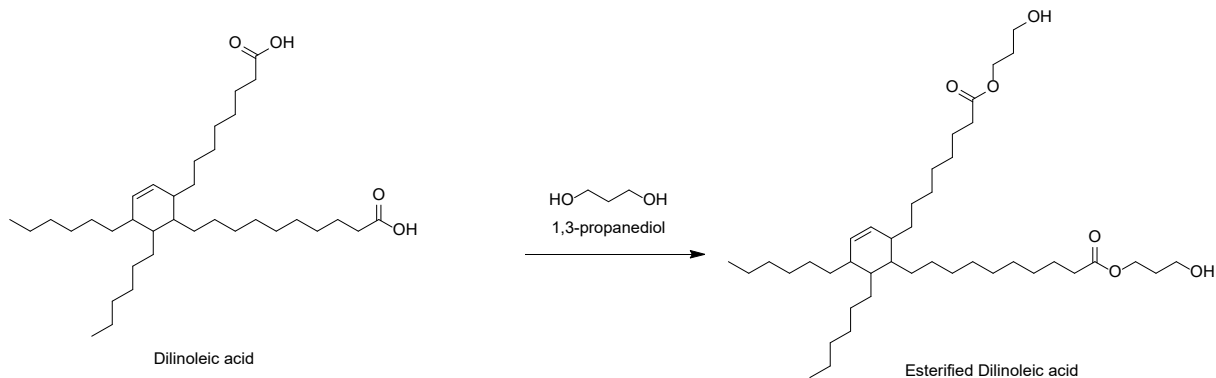
related dilinoleic acid/diol-based polyester species: dilinoleic acid/propanediol copolymer (“DAPD”) and dilinoleic acid/butanediol copolymer (“DABD”). In other words, to the extent the priority specifications provide disclosure that is in any way related to “esterified dilinoleic acid,” that disclosure relates only to esterified dilinoleic acid made by reacting a dilinoleic acid with an alcohol, which is but one species of the multitude of species encompassed by the term “esterified dilinoleic acid.”

a. The term “esterified dilinoleic acid” is extremely broad.

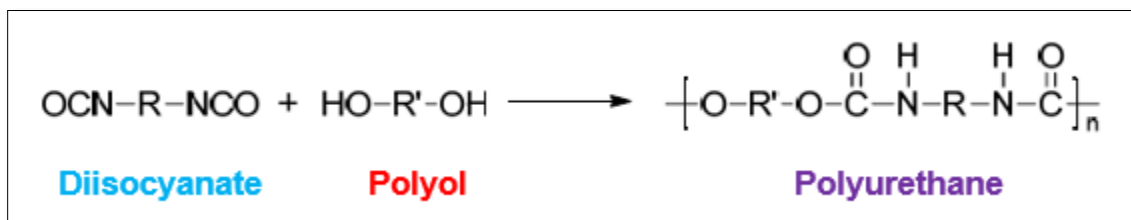
77. The term “esterified dilinoleic acid” recited in claim 1 encompasses a broad genus. As discussed in turn below, the term “esterified dilinoleic acid” imposes no limitation on the (i) alcohol used to esterify the dilinoleic acid, (ii) functional groups incorporated during esterification; (iii) degree of esterification and the resulting molecular weight, or (iv) the branching architecture. Because these parameters are independent of one another, every possible selection for one variable can be combined with every possible selection for each remaining variable, exponentially expanding the range of structural variability. As a result, each factors operates independently and multiplicatively to expand the scope of the term “esterified dilinoleic acid.”

i. The term “esterified dilinoleic acid” does not specify the type of alcohol used to esterify the dilinoleic acid.

78. The term “esterified dilinoleic acid” does not specify how the dilinoleic acid is esterified. An esterified dilinoleic acid can be produced by reacting dilinoleic acid with an alcohol (*see, e.g.*, EX1015, 252), as diagramed below.

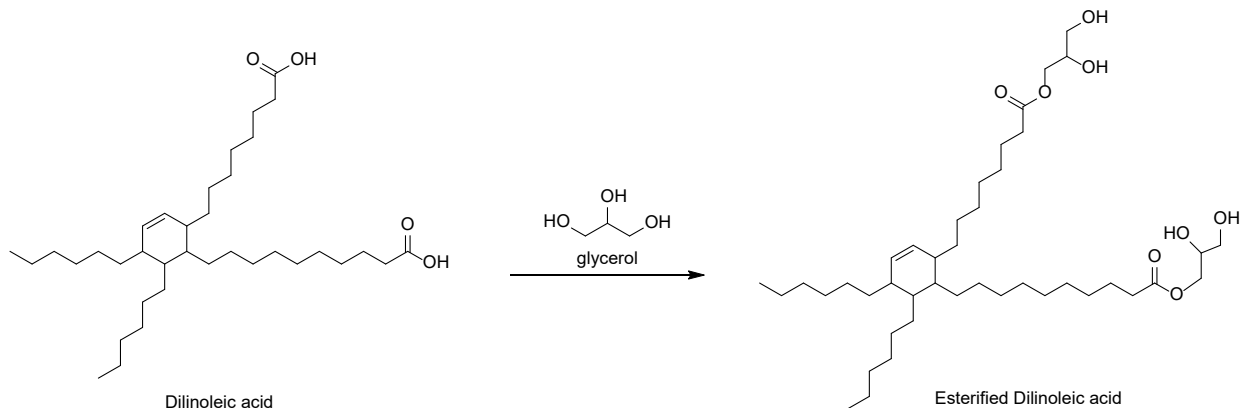


If the alcohol is a diol (such as propanediol), as shown above, and the alcohol is provided in excess in the reaction, then the esterified dilinoleic acid will contain a terminal hydroxyl (OH) group. This -OH group can then react with a “multi-functional crosslinker,” such as polyisocyanate, to form a linear polyurethane, as depicted below. *See, e.g.*, EX1032, 114455 (“[I]socyanates are incorporated into PU synthesis via a hydroxyl-group-containing compound due to their high reactivity . . .”).



EX1015, 2 (annotated).

79. If the alcohol is a triol, such as glycerol, and the alcohol is provided in excess in the reaction, then the esterified dilinoleic acid will contain multiple -OH groups, as shown below.



This will affect reactivity with the “multi-functional crosslinker” (e.g., polyisocyanate) because multiple functional groups are present on the esterified dilinoleic acid that can interact with the crosslinker. *See, e.g.*, EX1032, 114455. This will, in turn, increase cross-link density. *See* Section VII.B.

80. However, claim 1 does not limit the alcohol used to esterify dilinoleic acid to a diol or triol. Instead, any number of alcohols can be utilized, including primary alcohols or even secondary or tertiary alcohols. *See, e.g.*, EX1046, 781 (characterizing alcohols as primary, secondary, or tertiary).⁴ The type of alcohol

⁴ A primary (1°) alcohol (RCH₂OH) has the OH group on a carbon atom attached to one other carbon atom; a secondary (2°) alcohol (R₂CHOH) has the OH group on a carbon atom attached to two other carbon atoms; and a tertiary (3°)

used can influence the formation and properties of the polyester. For example, polyesters terminated with secondary hydroxyl groups are usually less reactive compared to polyesters containing primary hydroxyl groups. *See, e.g.*, EX1032, 114456, 114462.

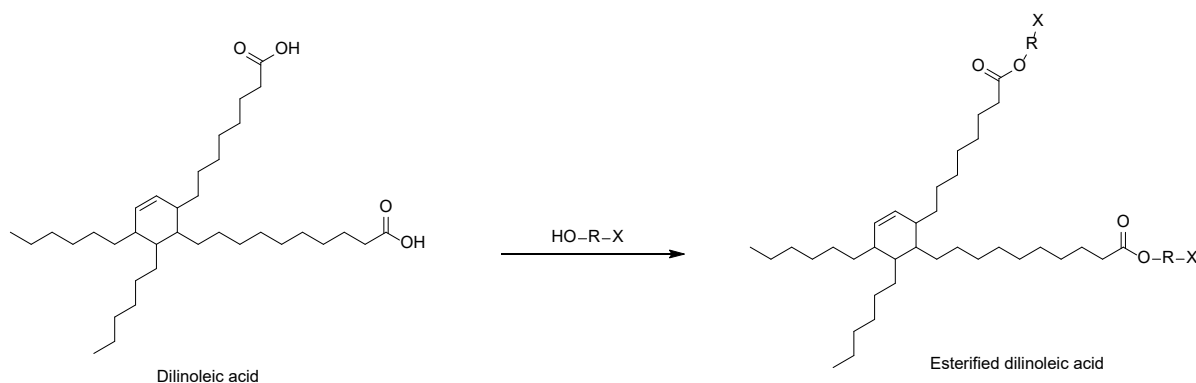
81. Accordingly, the term “esterified dilinoleic acid” encompasses a large number of chemically distinct polyesters formed from dilinoleic acid and a wide range of alcohols.

ii. The term “esterified dilinoleic acid” does not specify the resulting end-group functionality.

82. The term “esterified dilinoleic acid” does not specify the identity of the chemical reactive groups (i.e., functional groups) present on the “esterified dilinoleic acid” that would react with the “multi-functional crosslinker.”

83. If the alcohol used to esterify dilinoleic acid contains functional groups in addition to the hydroxyl group, these functional groups could be present in the esterified dilinoleic acid, as shown in the reaction scheme below, where X represents a functional group other than hydroxyl.

alcohol (R_3COH) has the OH group on a carbon atom attached to three other carbon atoms. EX1046, 781.



Examples of additional functional groups include an amine (NH_2), amide (CON), epoxide (∇), acid (COOH), anhydride ($(\text{RC}(\text{O}))_2\text{O}$), or thiol (SH). *See, e.g.*, EX1047, 3-5 (depicting various functional groups, including amines, ketones, acids, and thiols); *see also* EX1046, 706-707, 791 (depicting carbonyl and amide functional groups).

84. Because the “esterified dilinoleic acid” may be hydroxyl-terminated or mixed-terminated with multiple functional groups, it can react with many “multi-functional crosslinkers.” *See, e.g.*, EX1033, 78 (“If the polymer has free functional groups, OH or COOH , another reagent (aziridines, blocked isocyanates, carbodiimides, waterborne polyisocyanates and melamine formaldehydes) can react with these groups to create additional crosslinking.”).

85. Accordingly, the term “esterified dilinoleic acid” encompasses an extremely large number of chemically distinct species that differ in type and number of functional groups, which materially affect reactivity and performance.

iii. The term “esterified dilinoleic acid” does not place a limit on the degree of esterification present and the resulting molecular weight.

86. The degree of esterification, and the resulting molecular weight, is also a significant source of variability for the “esterified dilinoleic acid.” Dilinoleic acid contains carboxylic acid functional groups that may be partially esterified (leaving residual acid groups), substantially esterified (leaving minimal acid groups), or effectively fully esterified (leaving no meaningful residual acid groups), depending on stoichiometry and reaction completion. *See, e.g.*, EX1048, 3940 (explaining that the amount of unreacted alcohol groups can be predicted by the degree of esterification).

87. Those outcomes are not minor variants: the degree of esterification materially changes the properties of the ester. Ester functional groups “are polar but have no hydrogen atom attached directly to an oxygen atom . . . [and] are therefore incapable of engaging in intermolecular hydrogen bonding with one another and thus have considerably lower boiling points than their isomeric carboxylic acids counterparts.” EX1046, 827.

88. The degree of esterification also impacts the molecular weight of the polyester. This is because the polyester could be a short-chain linear or cyclic oligomer consisting of repeating units of acids and esters. *See, e.g.*, EX1049, 197-198. Alternatively, the polyester can be a linear high-molecular-weight polyester

chain consisting of more repeating units of esters than acids. *See, e.g.*, EX1049, 197.

89. High-molecular-weight polyesters generally form softer blocks when incorporated into polyurethanes. EX1045, 448. Low molecular weight polyesters form more rigid polyurethanes. EX1032, 114461. Increasing rigidity leads to “higher compressive strength, modulus, thermal stability and dimensional stability polyurethanes.” EX1045, 448; *see also* EX1032, 1144661. If the molecular weight of the polyester is excessively low, the resulting polymer becomes more friable. EX1045, 448. To avoid this, the polyester requires the addition of more isocyanate to increase the molecular weight and produce a more rigid polyurethane. EX1045, 448.

90. Thus, a POSA would understand that “esterified dilinoleic acid” therefore encompasses everything from low-molecular-weight esterified oligomers to higher-molecular-weight polyesters—each with materially different rheology, swelling behavior, and mechanical properties.

91. Accordingly, the term “esterified dilinoleic acid” encompasses multiple, chemically distinct species that differ in molecular weight.

iv. The term “esterified dilinoleic acid” does not place a limit on the amount of branching present.

92. The branching architecture of the “esterified dilinoleic acid” broadens

the genus of “esterified dilinoleic acid” even further because polyesters can be linear or branched. EX1037, 2293 (Definition 1.30) (defining a polymer chain as “comprising a linear or branched sequence”). The extent of branching, whether lightly or highly branched, of the “esterified dilinoleic acid” depends on a number of factors, including the functionality of the polymer chain and monomer units (EX1050, Figure 1), as well as the presence of a tricarboxylic acid impurity in the dilinoleic acid starting material. The presence of a tricarboxylic acid impurity promotes additional branching, whereas in its absence, the resulting “esterified dilinoleic acid” polyester may be predominantly linear, notwithstanding the alkyl branching inherent to the dimer acid. *See, e.g.*, EX1070, ¶¶[0027]-[0029].

93. The transition from linear to branched structures of the “esterified dilinoleic acid” is not a trivial formulation choice as it changes the properties of the resulting polymer. For instance, the topology of the polymer will change as branched polymers can be star-shaped, hyperbranched, or long-chain branched. EX1038, Table 2. Viscosity is also affected, as branched polymers tend to be less viscous than their linear counterparts. EX1051, 1277-1278. Other properties that are affected include crystallization and melting behaviors, glass transition, thermal and hydrolytic degradations, phase characteristics, lower critical solution temperature phase transition, and encapsulation capability. EX1051, 1285.

94. Claim 1’s “esterified dilinoleic acid” limitation does not limit the

architecture to a linear form, nor does it exclude branching. Thus, claim 1 sweeps in a wide array of “esterified dilinoleic acid” architectures that a POSA would recognize as numerous chemically distinct species within the genus.

95. Accordingly, the term “esterified dilinoleic acid” encompasses a large number of chemically distinct species that differ in branching architectures.

* * *

96. Taken together, these independently operating variables combine multiplicatively to expand the already broad genus encompassed by the term “esterified dilinoleic acid,” which is disclosed nowhere in the ’057 patent except in claim 1. EX1001, 24:4.

b. The priority specifications disclose, at most, a species-level subset of the massive genus of “esterified dilinoleic acid.”

97. As discussed in turn below, the priority specifications do not describe the full genus of “esterified dilinoleic acid.”

i. The ’831 application does not describe the full scope of “esterified dilinoleic acid.”

98. The ’057 patent claims priority to the ’831 application. The ’831 application was filed on August 13, 2020.

99. The only two specific, closely related diol-based polyester species disclosed in the ’831 application are dilinoleic acid/propanediol copolymer

(“DAPD”) and dilinoleic acid/butanediol copolymer (“DABD”).⁵ EX1052, 10-11, 18-21.

100. DAPD is listed as an example polymer/prepolymer, including as the “preferred prepolymer.” EX1052, 10-11. DAPD is the prepolymer used throughout the examples, including Examples 1-8, 10, and 12-22. EX1052, 18-21. The only disclosure of DABD is in Example 9 of the ’831 application. EX1052, 21.

101. Thus, the only disclosed species of polyester disclosed in the ’831 application are DAPD and DABD. The ’831 application does not describe any other type of polyester, wherein the polyester is an “esterified dilinoleic acid” or a branched C₃₆ dicarboxylic acid/diol copolymer.

102. As such, it is my opinion that the ’831 application does not provide sufficient written description of the claimed genus of “esterified dilinoleic acid.”

ii. The ’015 provisional does not describe the full scope of the “esterified dilinoleic acid.”

103. The ’057 patent also claims priority to the ’015 provisional. The ’015 provisional was filed on February 13, 2020.

104. Similar to the ’831 application, the ’015 provisional discloses DAPD

⁵ The difference between propanediol and butanediol lies in one carbon atom: propanediol contains 3 carbon atoms while butanediol contains 4 carbon atoms. EX1046, 601.

in a list as an example polymer/prepolymer and as the preferred prepolymer.

EX1053, 8-9. DAPD is also the prepolymer used in Examples 1-8, 10, and 12-22.

EX1053, 16:19-30. DABD is used only in Example 9. EX1053, 19-20.

105. Thus, the only disclosed species of polyester in the '015 provisional are DAPD and DABD. The '015 provisional does not describe any other type of polyester, wherein the polyester is an “esterified dilinoleic acid” or a branched C₃₆ dicarboxylic acid/diol copolymer.

106. As such, it is my opinion that the '015 provisional does not provide sufficient written description of the claimed genus of “esterified dilinoleic acid.”

iii. The '968 provisional does not describe the full scope of the “esterified dilinoleic acid” genus.

107. The '057 patent also claims priority to the '968 provisional. The '968 provisional was filed on August 30, 2019.

108. The '968 provisional discloses only DAPD in its list of polymers and as the preferred prepolymer. EX1054, 8-9. DAPD is the only prepolymer used in Examples 1-13 of the '968 provisional. EX1054, 14:36-25. DABD is not disclosed in the '968 provisional.

109. Thus, the only polyester disclosed in the '968 provisional is DAPD. The '968 provisional does not describe any other type of polyester, wherein the polyester is an “esterified dilinoleic acid” or a branched C₃₆ dicarboxylic acid/diol copolymer.

110. As such, it is my opinion that the '968 provisional does not provide sufficient written description of the claimed genus of “esterified dilinoleic acid.”

iv. The polyols disclosed in the priority specifications do not describe the full scope of the “esterified dilinoleic acid.”

111. Although the '831 application, '015 provisional, and '968 provisional include lists of polyols which can be used to esterify the dilinoleic acid (EX1052, 11-12; EX1053, 10; EX1054, 10), those disclosures do not support the full scope of the expansive genus of “esterified dilinoleic acid” claimed in the '057 patent because the term “esterified dilinoleic acid” is so broad as discussed above. *See* Section XI.A.1.a. As discussed above, the “esterified dilinoleic acid” can have different end-groups, degrees of esterification, molecular weights, and branching. *See* Sections XI.A.1.a.ii.-iv. Thus, merely identifying potential polyol starting materials, without disclosing resulting esterified dilinoleic acid polyesters spanning the genus's structural variability, is insufficient to support the claimed scope of “esterified dilinoleic acid.”

v. Nothing incorporated by reference in the priority specifications adds disclosure that might support the full scope.

112. Nothing incorporated by reference in the '831 application, '015 provisional, and '968 provisional provides support for the broad scope of “esterified dilinoleic acid.”

113. The '831 application incorporates by reference only the '968 provisional, the '015 provisional, and U.S. Patent No. 8,222,363 ("the '363 patent"). EX1052, 1:4-6, 33:5-7. As discussed above, the '968 provisional discloses only DAPD and DABD. *See* Section XI.A.1.b.iii. And, the '015 provisional disclosed only DAPD. *See* Section XI.A.1.b.ii.

114. The '968 provisional and '015 provisional also incorporate only the '363 patent by reference. EX1054, 23:11-13, EX1053, 29:11-14.

115. The '363 patent is directed to silicone elastomers (EX1055, Abstract) and does not disclose the term "esterified dilinoleic acid" at all. In fact, the only disclosure of a fatty acid in the '363 patent is in relation to carrier fluids, and not their use in the synthesis of polyurethane polymers: "Additional organic carrier fluids suitable as a stand alone [*sic*] compound or as an ingredient to the carrier fluid include fats, oils, fatty acids, and fatty alcohols." EX1055, 8:17-19. As such, the '363 patent does not add any disclosure to the priority documents that would help to support the full genus of the term "esterified dilinoleic acid."

116. In summary, the '831 application, the '968 provisional, and the '015 provisional do not provide any additional disclosure vis-à-vis "esterified dilinoleic acid" that would help with written description support for the large genus of "esterified dilinoleic acids" recited in claim 1. Each of these priority filings discloses at most two species of "esterified dilinoleic acid"—DAPD and DABD—

and does not disclose any other types esterified dilinoleic acids encompassed by the term.

2. The “multi-functional crosslinker” genus is not supported by the ’015 provisional, the ’968 provisional, nor the ’831 application.

117. Claim 1 recites “a reaction product of a polyester and a multi-functional crosslinker.” EX1001, 24:2-5. Similar to the “esterified dilinoleic acid” term, the first time the term “multi-functional crosslinker” was introduced was during the prosecution history of the ’105 application, when new claim 28 was added in a Response to Restriction Requirement filed on February 19, 2025. EX1002, 1032. The term “multi-functional crosslinker” appears nowhere in any of the priority specifications (the ’831 application, the ’015 provisional, and the ’968 provisional). At best, the only disclosure of a “multi-functional crosslinker” anywhere in the ’057 patent and the priority specifications is “a multifunctional, e.g. a tri-functional, polyurethane crosslinker.” EX1001, 3:31-32; *see also* EX1052, 4:3-5; EX1053, 3:30-31, EX1054, 3:29-30. And, as I explain below, the term “multi-functional crosslinker” is much, much broader than a “multi-functional polyurethane crosslinker.”

118. In contrast to the breadth of the term “multi-functional crosslinker,” each of the priority specifications disclose only one type of multi-functional crosslinker: polyisocyanates. Disclosing this single species of multi-functional

crosslinker does not support the full scope of that term, which encompasses numerous species.

a. The term “multi-functional crosslinker,” when considered by itself, encompasses an immense genus of chemically distinct crosslinkers.

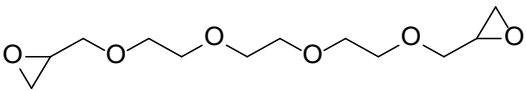
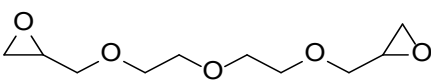
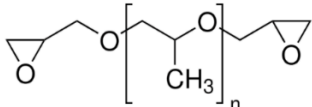
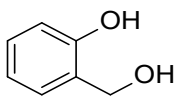
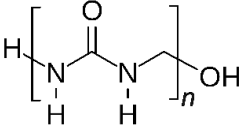
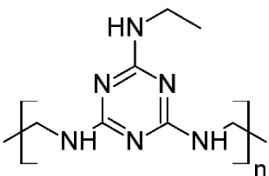
119. The term “multi-functional crosslinker” by itself is extraordinarily broad, encompassing an immense genus of chemically distinct crosslinkers. This is because crosslinking refers to chemically joining polymer chains to increase network connectivity and, in many cases, produces a three-dimensional network. EX1039, 218; *see also* Section VII.B. Crosslinkers are often added to polymers for structural modification and to offer mechanical support that will enhance the material properties of the resulting polymer. EX1032, 114462 (Table 2). A multi-functional chemical compound that can react with more than two functional groups in the polymer can serve as a crosslinker. *See, e.g.*, EX1033, 78. Crosslinking can occur when (i) the crosslinker has two or more reactive functional groups and the polymer has more than two reactive functional groups or (ii) the crosslinker has more than two reactive functional groups and the polymer has two or more reactive functional groups. *See, e.g.*, EX1064, 103-105 (describing that crosslinking can occur in polymerizations involving “reactants with functionalities greater than two”).

120. There were many classes of crosslinkers that were known in the art

before 2019, including epoxy-based crosslinkers (EX1056, 37), phenol-based crosslinkers (EX1057, 1), urea-based crosslinkers (EX1058, 233), melamine-based crosslinkers (EX1059, Abstract), aziridine crosslinkers (EX1061, 704-705), polyisocyanate crosslinkers (EX1032, 114454), multi-functional amine crosslinkers (EX1062, 37267), and multi-functional acid crosslinkers (EX1062, 37267).

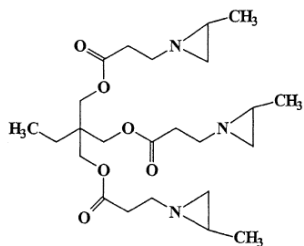
121. Each of these classes of multi-functional crosslinkers comprises distinct crosslinking species. For example, epoxy-based crosslinkers include diglycidyl ether of triethylene glycol (DGETEG), poly(propylene glycol)diglycidyl ether (PPGDGE), and diglycidyl ether of diethylene glycol (DGEG) (EX1056, 37); phenol-based crosslinkers include phenol-formaldehyde resins such as hydroxymethyl phenol (EX1057, 1); urea-based crosslinkers include urea-formaldehyde resins (EX1058, 233); melamine-based crosslinkers include melamine-formaldehyde resins (EX1059, 2631); aziridine crosslinkers include trimethylolpropane tris-(1-(2-methyl)aziridino)propionate (TTMAP), trimethylolpropane tris-3-(1-aziridinopropionate) (TTAP), and pentaerythritol tris-3-(1-aziridinopropionate) (PTAP) (EX1060, Abstract); polyisocyanate linkers include diisocyanates such as methylene diphenyl isocyanate (MDI), 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethyl-cyclohexane (IPDI), and hexamethylene diisocyanate trimer (HDI) (EX1032, 114464, 114470). The variations in these

structures are depicted in the table below:

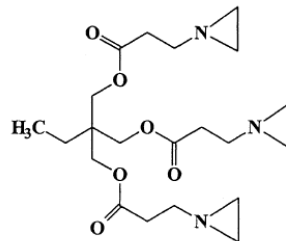
Examples of Multi-Functional Crosslinkers	
Epoxy-based	
	
Triethylene glycol diglycidyl ether	Diethylene glycol diglycidyl ether
	
Poly(propylene glycol) diglycidyl ether	
Phenol-based	
	
Hydroxymethyl phenol	
Urea-based	
	
Urea formaldehyde resin	
Melamine-based	
	
Melamine formaldehyde resin	

Examples of Multi-Functional Crosslinkers

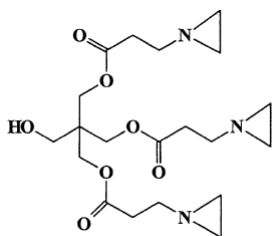
Aziridine



Trimethylolpropane tris-(1-(2-methyl)aziridino)propionate

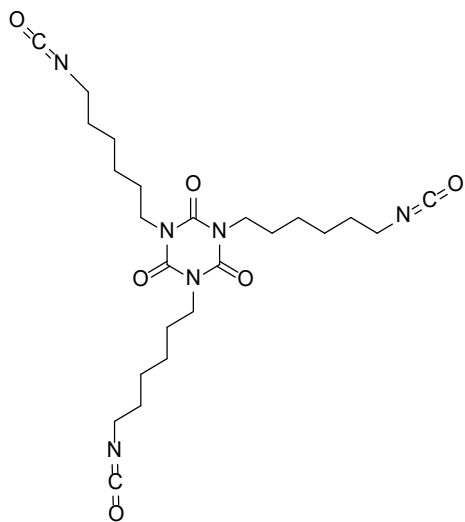


Trimethylolpropane tris-3-(1-aziridinopropionate)

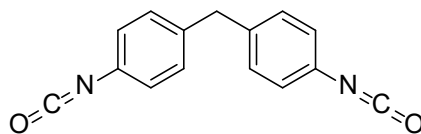


Pentaerythritol tris-3-(1-aziridinopropionate)

Polyisocyanate



Hexamethylene diisocyanate trimer



Methylene diphenyl diisocyanate

122. Any of these multi-functional crosslinkers could be suitable for

reacting with the polyester, as required by claim 1.

123. Additionally, any of these multi-functional crosslinkers could be suitable for controlling the cross-link density, and in turn, the material properties of the resulting elastomer. “Varying crosslink density . . . allows one to control, among other things, the modulus, softening behavior, clarity and chemical resistance of a material.” EX1033, 79; *see also* EX1034, 2 (“Mechanical properties [of polymers] including hardness and tensile strength are adjusted with the polyol, crosslinker and chain extender.”); EX1013, 209 (“Modulus, hardness and swelling behavior of cured elastomeric particles are all influenced by crosslink density”). For instance, a lower cross-link density can increase the flexibility of the polymer. *See* EX1032, 114458.

124. An “increase of the cross-link density in vegetable oil-based [polyurethanes] can be achieved either by changing the monomer ratio or by increasing the functionality of the comonomers.” EX1015, 31; *see also* EX1013, 209 (cross-link density “can be controlled to a reasonable extent by *choice* of the starting . . . polymer and the *crosslinker*” (emphasis added)). In other words, a POSA may select different crosslinking densities to achieve different material properties, confirming that there is no single or narrow class of suitable crosslinkers, but rather a wide range of chemically distinct crosslinkers available to choose from depending on the desired performance characteristics. *See* EX1033,

78; *see also* EX1034, 2; EX1013, 209.

125. Thus, any number of “multi-functional crosslinkers” could be capable of reacting with a fully formed polyester (i.e., an already synthesized polyester such as an “esterified dilinoleic acid” or a “branched C₃₆ dicarboxylic acid/diol polymer”), as required by claim 1 through a variety of functional groups and reaction mechanisms. This contributes to the immense breadth of the “multi-functional crosslinker” genus.

b. The term “multi-functional crosslinker,” when considered in context with the polyester it interacts with, encompasses an immense genus of chemically distinct crosslinkers.

126. Claim 1 requires the multi-functional crosslinker to interact with a polyester. This requirement does not narrow the scope of multi-functional crosslinkers contemplated by claim 1. To the contrary, because “esterified dilinoleic acid” itself represents a chemically broad and unconstrained class of polyesters (as explained above in Section XI.A.1), the nature of the claimed reaction necessarily depends on the particular structure and functionality of the esterified dilinoleic acid species selected. As a result, rather than limiting the scope of permissible crosslinkers, the claimed interaction further enlarges the already expansive universe of “multi-functional crosslinkers” encompassed by the claim.

127. Indeed, the “esterified dilinoleic acid” of claim 1 does not specify the alcohol used to esterify the dilinoleic acid nor does it specify any particular end-

group functionality or other features of the polyester. *See* Sections XI.A.1.a.i.-ii.

As discussed above, the type of alcohol used to esterify the dilinoleic acid affects its reactivity. *See* Section XI.A.1.a.i. Furthermore, if the alcohol used to esterify dilinoleic acid contains functional groups in addition to the hydroxyl group, these functional groups could be present in the esterified dilinoleic acid as well. *See* Section XI.A.1.a.ii.

128. As a result, the claim encompasses an “esterified dilinoleic acid” genus bearing a wide variety of potential functional groups, such as hydroxyl, carboxylic acid, or amine groups, depending on how the polyester is synthesized. Each such variant, in turn, implicates a different universe of chemically compatible “multi-functional crosslinkers,” including crosslinkers reactive toward any of those functionalities and operating through fundamentally different chemistries and mechanisms of action.

129. Thus, the already expansive and undefined genus of “multi-functional crosslinkers” is further enlarged by the undefined chemical variability of the claimed “esterified dilinoleic acid.”

- c. The priority specifications disclose, at most, a single class of multi-functional crosslinker (polyisocyanate) within the broad “multi-functional crosslinker” genus.**

130. As discussed in turn below, the priority specifications do not describe the full genus of “multi-functional crosslinker.”

i. The '831 application discloses only polyisocyanates, which does not support the full scope of the “multi-functional crosslinkers”

131. The '057 patent claims priority to the '831 application. The '831 application was filed on August 13, 2020.⁶

132. The '831 application's one and only reference to a “crosslinker” is as follows: “a multifunctional, e.g. a tri-functional, *polyurethane* crosslinker.” EX1052, 4:3-6. The only example of a polyurethane crosslinker disclosed in the '831 application is a polyisocyanate:

- “In another aspect of the invention, there are provided processes for preparing the *cross-linked polyurethane elastomer* rubber compositions described herein. The processes include reacting a *polyisocyanate* with a prepolymer having at least two free hydroxyl groups in the presence of a urethanation catalyst and a cosmetic emollient under conditions sufficient to form a cross-linked polyurethane rubber.” EX1052, 4:27-31 (emphasis added);
- “The *cross-linked polyurethane elastomer* rubber compositions of the

⁶ Notably, U.S. Patent No. 11,534,389, which issued from the '831 application, limits its claims to “a cross-linked *polyurethane* elastomer rubber.” EX1065, 26:6-21 (emphasis added).

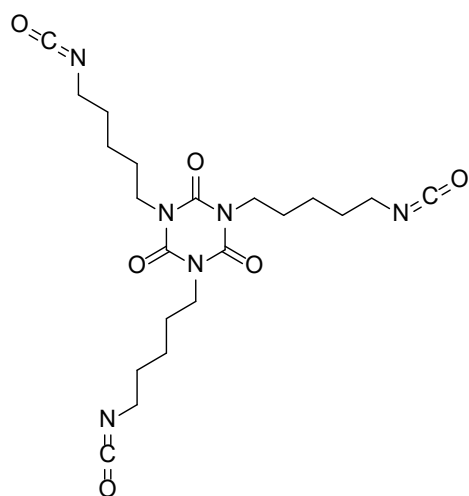
invention preferably are those in which the prepolymer, the *polyisocyanate*, and the cosmetic emollient are bio-based and biodegradable.” EX1052, 6:1-3 (emphasis added);

- “[T]he ratios of bio-based hydroxyl functionality of the bio-based prepolymer to the NCO functionality of the *polyisocyanate* can be between 2: 1 to 1:2, and preferably 1:1.” EX1052, 8:12-13 (emphasis added).

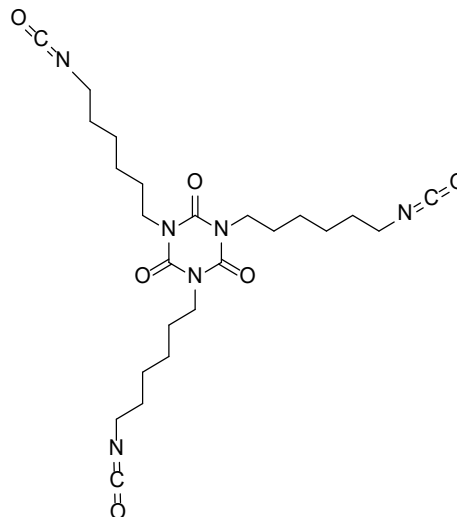
133. The ’831 application also discloses a laundry list of specific polyisocyanates, referred to as “functionalized isocyanates,” including, e.g., 1,3-phenylene diisocyanate, 1,5-diisocyanato-2-methylpentane, and 1,6-hexamethylene diisocyanate. EX1052, 13:8-14. However, no lists of other non-isocyanate crosslinkers are provided.

134. The only compound used as a crosslinker in any of the *twenty-two* examples in the ’831 application is polyisocyanate: “As outlined in the description of the invention, the formation of a polyurethane rubber involves the cross-linking of a bio-sourced pre-polymer containing at least two hydroxyl groups with a *polyisocyanate* in the presence of a catalyst and sufficient amounts of bio-based cosmetic emollients.” EX1052, 18:8-11 (emphasis added). Specifically, the polyisocyanate used in Examples 1-12 and 14-22 is pentylene diisocyanate trimer (“PDT”). EX1052, 18:11-22:3, 23:6-34:25. Only one example, Example 13, discloses the use of a polyisocyanate other than PDT: hexamethylene diisocyanate

trimer (“HDT”). These two polyisocyanates with highly similar structures that only vary by the presence of one carbon atom in each chain, as depicted below.



PDT



HDT

135. Accordingly, the '831 application discloses only a single class of multi-functional crosslinker—namely, polyisocyanates. The '831 application does not disclose any other types or classes of multi-functional crosslinkers, including non-isocyanate crosslinkers, nor does it describe crosslinking chemistries outside the context of polyurethane formation.

136. As such, it is my opinion that the '831 application does not provide sufficient written description of the claimed genus of “multi-functional crosslinkers.”

ii. The '015 provisional also discloses only polyisocyanates

137. The '057 patent also claims priority to the '015 provisional. The '015

provisional was filed on February 13, 2020.

138. Just like in the '831 application, the '015 provisional discloses a “crosslinker” exclusively in the polyurethane context: “a multifunctional, e.g. a tri-functional, polyurethane crosslinker.” EX1053, 3:30-31. The '015 provisional discloses only polyisocyanates as an example of a polyurethane crosslinker by disclosing reacting polyols/polyester prepolymers with polyisocyanates in the presence of urethanation catalysts to form “cross-linked polyurethane” elastomer rubbers. EX1053, 4:20-24, 5:26-28.

139. The '015 provisional also provides a list of functionalized isocyanates/polyisocyanates. EX1053, 7:18-19; 12–13. However, the '015 provisional does not provide a list of any other non-isocyanate crosslinkers.

140. The twenty-two examples of the '015 provisional focus on only two polyisocyanates: PDT (Examples 1-12 and 14-22) and HDT (Example 13). EX1053, 16:10-31:5.

141. Thus, the only polyurethane crosslinker class disclosed in the '015 provisional is polyisocyanates. The '015 provisional does not disclose any non-isocyanate crosslinker classes, nor does it disclose any non-polyurethane crosslinkers.

142. As such, it is my opinion that the '015 provisional does not provide sufficient written description of the claimed genus of “multi-functional

crosslinkers.”

iii. The '968 provisional likewise discloses only polyisocyanates

143. The '057 patent also claims priority to the '968 provisional. The '968 provisional was filed on August 30, 2019.

144. The '968 provisional discloses crosslinking exclusively in the polyurethane context: “a multifunctional, e.g. a tri-functional, polyurethane crosslinker.” EX1054, 3:29-30. The '968 provisional discloses only polyisocyanates as reacting polyols/polyester prepolymers with polyisocyanates in the presence of urethanation catalysts to form “cross-linked polyurethane” elastomer rubbers. EX1054, 4:20-24; 5:24-26; 7:16-17. The '968 provisional discloses only polyisocyanate in its specification and also provides a list of functionalized isocyanates/polyisocyanates and urethanation catalysts. EX1054, 12–13.

145. Unlike the other priority applications, the '968 provisional discloses only thirteen examples. The only polyisocyanate used in these examples is PDT. EX1054, 14:28-25:5.

146. Thus, the only class of polyurethane crosslinker disclosed in the '968 provisional is polyisocyanates. The '968 provisional does not disclose any non-isocyanate crosslinker classes, nor does it disclose any non-polyurethane crosslinkers.

147. As such, it is my opinion that the '968 provisional does not provide sufficient written description support of the claimed genus of “multi-functional crosslinkers.”

iv. Nothing incorporated by reference in the priority specifications adds more disclosure that might support the full scope.

148. I have reviewed the documents incorporated by reference into the priority documents to ascertain their crosslinker disclosure, and none of those documents provide support for the full scope of the “multi-functional crosslinker.”

149. The '831 application incorporates by reference only the '968 provisional, the '015 provisional, and the '363 patent. EX1052, 1:4-6, 33:5-7. The '968 provisional and '015 provisional also both incorporate the '363 patent by reference. EX1054, 23:11-13; EX1053, 29:11-13.

150. As discussed above, the '968 provisional discloses only polyurethane crosslinkers, specifically polyisocyanates, and more specifically, PDT and HDT. Section XI.A.2.b.iii. The '015 provisional contains similar disclosures, with the exception that it does not disclose HDT. Section XI.A.2.b.ii.

151. The '363 patent is directed to silicone elastomers (EX1055, Abstract), not polyurethane elastomers, and does not disclose the term “multi-functional crosslinker” at all. At most, the '363 patent discloses crosslinking silicone elastomers by “incorporating trifunctional and/or tetrafunctional silanes” (EX1055,

13:49-52). Given that each of the '831 application, '015 provisional, and '968 provisional are directed to an elastomer that is not silicone-based, a skilled artisan would understand that a silane crosslinker would not be suitable for use as a “multi-functional crosslinker” in the context of the '057 patent claims EX1052, 5:8-15; EX1053, 5:1-8, EX1054, 5:1-6. Even assuming that the “trifunctional and/or tetrafunctional silanes” described in the '363 patent qualify as multi-functional crosslinkers, that disclosure—whether considered alone or together with the disclosures of the priority applications—still fails to provide written description support for the full scope of the claimed “multi-functional crosslinker.” At most, the '363 patent identifies a single additional class of multi-functional crosslinkers, while the claims encompass multiple distinct classes of multi-functional crosslinkers that remain unsupported, as discussed above. As such, the '363 patent does not add any disclosure to the priority documents that would help to support the full genus of the term “multi-functional crosslinker.”

152. In summary, the '831 application, the '968 provisional, and the '015 provisional do not provide written description support for the vast genus of “multi-functional crosslinker” recited in claim 1. Each of these priority applications discloses only a single class of crosslinkers—polyisocyanates—that react with the disclosed polyester pre-polymers to form polyurethane elastomers. This disclosure aligns with the '057 patent specification's characterization of a “multifunctional,

e.g. a tri-functional, polyurethane crosslinker” and reflects an invention directed specifically to polyurethane elastomer chemistry. EX1001, 3:29-35. The priority applications do not disclose any other classes of multi-functional crosslinkers capable of reacting with a pre-polymer, despite the claim’s broad language encompassing such crosslinkers. I understand that, as a result, the ’057 patent is not entitled to a priority date earlier than its filing date of December 14, 2022.

* * *

153. Because the ’015 provisional, the ’968 provisional, and the ’831 application do not provide written description support for claim 1’s broad genus limitations—(i) “esterified dilinoleic acid” and (ii) “multi-functional crosslinker”—claim 1 is not entitled to a priority date earlier than December 14, 2022, the filing date of the ’105 application.

3. None of dependent claims 2-17 sufficiently narrow the “multi-functional crosslinker” and “esterified dilinoleic acid” genera

154. As discussed in turn below, none of dependent claims 2-17 sufficiently narrow the “multi-functional crosslinker” and “esterified dilinoleic acid” genera. Therefore, no claim of the ’057 patent is entitled to an earlier priority date than December 14, 2022.

a. Claim 2

155. Claim 2 depends from claim 1 and narrows the “multi-functional

crosslinker” to a polyisocyanate. EX1001, 24:6-7. However, it does not limit the separately recited genus of “esterified dilinoleic acid.” EX1001, 24:2-5. As discussed above, the priority applications do not support the “esterified dilinoleic acid” genus as claimed. Therefore, claim 2 is not entitled to a filing date earlier than December 14, 2022.

b. Claims 3-6

156. Claims 3-6 each depends from claim 1 but does not limit either of the “multi-functional crosslinker” or “esterified dilinoleic acid” terms. EX1001, 24:8-17. Therefore, none of claims 3-6 are entitled to a filing date earlier than December 14, 2022.

c. Claim 7

157. Claim 7 depends from claim 1 but does not expressly limit either of the “multi-functional crosslinker” or the “esterified dilinoleic acid” terms. EX1001, 24:18-21. Instead, claim 7 narrows the “branched C₃₆ dicarboxylic acid/diol copolymer” to dilinoleic acid/propanediol and dilinoleic acid/butanediol copolymers. EX1001, 24:18-21. To the extent reciting dilinoleic acid/propanediol and dilinoleic acid/butanediol is considered to also narrow the term “esterified dilinoleic acid” (despite the claim referring to the “branched C₃₆ dicarboxylic acid/diol copolymer”), claim 7 does not narrow the “multi-functional crosslinker.” EX1001, 24:18-21. Therefore, claim 7 is not entitled to a filing date earlier than

December 14, 2022.

d. Claims 8-17

158. Claims 8-17 depend directly or indirectly from claim 1 but do not limit either of the “multi-functional crosslinker” or the “esterified dilinoleic acid” terms. EX1001, 24:22-47. Therefore, none of claims 8-17 are entitled to a filing date earlier than December 14, 2022.

B. The '924 publication anticipates claims 1-7 and 13-17.

159. Because the claims of the '057 patent are entitled to a priority date no earlier than December 14, 2022, I understand that the '924 publication qualifies as prior art. As explained below, the '924 publication discloses each and every element of claims 1-7 and 13-17 of the '057 patent arranged as claimed and in a manner enabling to a POSA, thereby anticipating claims 1-7 and 13-17 of the '057 patent.

1. Claim 1: “A cross-linked elastomer comprising a reaction product of a polyester and a multi-functional crosslinker, wherein the polyester is an esterified dilinoleic acid or a branched C₃₆ dicarboxylic acid/diol copolymer”

160. The '924 publication provides “processes for preparing the cross-linked polyurethane *elastomer* rubber compositions described herein.” EX1007, ¶[0016]. The '924 publication discloses “*reacting a polyisocyanate with a prepolymer* having at least two free hydroxyl groups in the presence of a urethanation catalyst and a cosmetic emollient under conditions sufficient *to form a*

cross-linked polyurethane rubber.” EX1007, ¶[0016] (emphasis added). An example of a prepolymer provided in the ’924 publication is a “polyester.” EX1007, ¶[0021]. Thus, the ’924 publication expressly discloses an embodiment that is “a cross-linked elastomer comprising a reaction product of a polyester and a multi-functional crosslinker,” as recited in claim 1.

161. The ’924 publication goes on to state: “A preferred prepolymer is dilinoleic acid/propanediol copolymer.” EX1007, ¶[0083]. Dilinoleic acid/propanediol copolymer is a branched C₃₆ dicarboxylic acid/diol copolymer because dilinoleic acid is a branched “36-carbon dicarboxylic acid formed by the catalytic dimerization of linoleic acid” and propanediol is a diol, as the name suggests. *See* EX1066, 20 (Table 1); *see also* EX1035, 2; EX1007, ¶¶[0084], [0087]. Thus, the ’924 publication expressly discloses a “branched C₃₆ dicarboxylic acid/diol copolymer,” as recited in claim 1.

162. The ’924 publication also explains that the “polyurethane elastomeric rubber composition . . . comprises a bio-based polyol *cross-linked with a bio-based isocyanate.*” EX1007, ¶[0020] (emphasis added). The ’924 publication provides a list of “functionalized isocyanates” used in the synthesis of polyurethane elastomers. EX1007, ¶¶[0176]-[0221]. Thus, the ’924 publication expressly discloses a “multi-functional crosslinker.”

163. The ’924 publication discloses “Examples” that form “a bio-based and

biodegradable cross-linked polyurethane elastomer rubber and a bio-based and biodegradable cross-linked polyurethane elastomer gel.” EX1007, ¶[0297]. The ’924 publication states that the polyurethane elastomer rubber is formed from “the crosslinking of a bio-sourced pre-polymer containing at least two hydroxyl groups with a polyisocyanate.” EX1007, ¶[0298]. Each of Examples 1-5 disclose a polyurethane elastomer that is a reaction product of PDT (a multi-functional polyurethane crosslinker) and DAPD (a branched C₃₆ dicarboxylic acid/diol copolymer”). EX1007, ¶¶[0299]-[0303]. Each of these Examples is a polyurethane elastomer that has all of the limitations of claim 1 and anticipates claim 1.

164. **Example 1** discloses reacting DAPD with PDT in the presence of a urethanation catalyst, specifically, a bismuth catalyst. Example 1 provides a list of ingredients, the amount of ingredients, mixing times, the reaction temperature, and gelling times needed to make the resulting polyurethane elastomer. EX1007, ¶¶[0298]-[0299].

165. **Example 2** discloses reacting DAPD with PDT in amounts greater than in Example 1 to form the high-density cross-linked elastomer. The reaction is carried out in the presence of a urethanation catalyst, specifically a bismuth catalyst (bismuth neodecanoate). EX1007, ¶[0300].

166. **Example 3** discloses reacting DAPD with PDT in amounts greater than in Example 1 to form the low-density cross-linked elastomer. The reaction is

carried out in the presence of a urethanation catalyst, specifically a bismuth catalyst (bismuth neodecanoate). EX1007, ¶[0301].

167. **Example 4** discloses reacting DAPD with PDT in the presence of a urethanation catalyst, specifically, a bismuth catalyst. It includes a list of ingredients, the amount of ingredients, mixing times, the reaction temperature, and gelling times needed to make the resulting polyurethane elastomer. EX1007, ¶[0302].

168. **Example 5** discloses reacting DAPD with PDT in the presence of a urethanation catalyst, specifically, a bismuth catalyst. It also provides a list of ingredients, the amount of ingredients, mixing times, the reaction temperature, and gelling times needed to make the resulting polyurethane elastomer. EX1007, ¶[0303].

2. Claim 2: “The cross-linked elastomer of claim 1, wherein the multi-functional crosslinker is polyisocyanate.”

169. The '924 publication discloses each and every element of claim 2. In particular, the '924 publication expressly discloses “reacting a polyisocyanate with a [polyester] prepolymer” to form a “cross-linked polyurethane elastomer.” EX1007, ¶¶[0016], [0299]. As discussed above, examples 1-5 each specifically discloses the use of PDT, also referred to in the '924 publication as “1,5-pentamethylene diisocyanate trimer,” in elastomer synthesis. EX1007, ¶¶[0299]-[0303], [0176], [0190]. PDT is expressly disclosed in the '924 publication as being

both a polyisocyanate (EX1007, Table 2) and functionalized (EX1007, ¶[0176]).

Isocyanates, in turn, are described as being crosslinkers used in elastomer synthesis. EX1007, ¶[0020]. Thus, the '924 publication discloses a polyurethane elastomer that has all of the limitations of claim 2 and anticipates claim 2.

3. Claim 3: “The cross-linked elastomer of claim 1, wherein the diol is propanediol or butanediol.”

170. The '924 publication discloses each and every element of claim 3. In particular, the '924 publication expressly identifies “dilinoic acid/*propanediol* copolymer” as a preferred polyester prepolymer. EX1007, ¶¶[0083], [0299]. And Examples 1-5 each specifically discloses the use of DAPD (“copolymer of C₁₈-unsaturated fatty acid dimers and 1,3-propanediol”) in the elastomer synthesis. EX1007, ¶¶[0299]-[0303]. A C₁₈-unsaturated fatty acid dimer is a branched C₃₆ dicarboxylic acid. *See, e.g.*, EX1066, Table 1 (describing linoleic acid as “unsaturated” and dilinoic acid as a “36-carbon dicarboxylic acid”). Thus, the '924 publication expressly discloses C₁₈-unsaturated fatty acid dimers as the branched C₃₆ dicarboxylic acid and propanediol as the diol of a branched C₃₆ dicarboxylic acid/diol copolymer. Thus, the '924 publication expressly discloses propanediol as the diol of a branched C₃₆ dicarboxylic acid/diol copolymer. Thus, the '924 publication discloses a polyurethane elastomer that has all of the limitations of claim 3 and anticipates claim 3.

4. Claim 4: “The cross-linked elastomer of claim 1, where in the polyester is greater than 60% by weight of the total weight of the cross-linked elastomer.”

171. The '924 publication discloses each and every element of claim 4. In particular, in Example 1, the '924 publication discloses a cross-linked elastomer formulation obtained from 11.25 grams of the polyester/polyol component (DAPD polyol) and 3.15 grams of the polyisocyanate crosslinker (PDT). EX1007, ¶[0299]. The “cross-linked elastomer” is formed from the polyester/polyol and the polyisocyanate crosslinker. Thus, the polyester at 11.25 grams comprises approximately 78% by weight of the elastomer-forming reactants ($11.25 \text{ g} \div (11.25 \text{ g} + 3.15 \text{ g}) = 78\%$). Because 78% by weight is greater than 60% by weight, the '924 publication discloses an embodiment that has all of the limitations of claim 4. EX1007, ¶¶[0298]-[0299].

172. Notably, the '924 publication teaches that the other compounds added to the reaction mixture (i.e., emollients such as glycerol triheptanoate) merely aid in processing the elastomer into a gel and are not factored into the molecular weight of the elastomer. EX1007, ¶¶[0034], [0093].

173. Thus, the '924 publication discloses a polyurethane elastomer that has all of the limitations of claim 4 and anticipates claim 4.

5. Claim 5: “The cross-linked elastomer of claim 1, where in the polyester is greater than 75% by weight of the total weight of the cross-linked elastomer.”

174. The '924 publication discloses each and every element of claim 5. As discussed above for claim 4, the '924 publication discloses in Example 1 a cross-linked elastomer where the polyester comprises approximately 78% by weight of the elastomer-forming reactants. EX1007, ¶¶[0298]-[0299]. Because 78% by weight is greater than 75% by weight, the '924 publication discloses a polyurethane elastomer that has all of the limitations of claim 5 and anticipates claim 5.

6. Claim 6: “The cross-linked elastomer of claim 1, wherein the cross-linked elastomer is silicone-free.”

175. The '924 publication discloses each and every element of claim 6. In particular, the '924 publication discloses that “there is a demand for alternatives to silicone elastomers, since silicones, in part, come from non-renewable feedstocks of petroleum origin.” EX1007, ¶[0006]. The '924 publication discloses the goal of its invention “is to create a high performing dispersed elastomer based primarily on feedstocks of renewable bio-sourced origins.” EX1007, ¶[0006]. Indeed, the '924 publication discloses that its invention is “a silicone alternative elastomeric gel of at least 85 or even >98% bio-based material.” EX1007, ¶[0018].

176. In line with the purpose of creating a silicone-free elastomer (EX1007, ¶[0006]), none of the elastomers formed in Examples 1-5 includes a

silicone. EX1007, ¶¶[0299]-[0303]. The only use of silicone in the Examples is in Example 20, in which “[a] commercial silicone elastomer blend from Grant Industries was used as a reference” to determine whether “the polyurethane elastomer gel of this invention [is compatible with] common personal care ingredients and emollients.” EX1007, ¶[0319]. Thus, the ’924 publication discloses a polyurethane elastomer that has all of the limitations of claim 5 and anticipates claim 5.

7. Claim 7: “The cross-linked elastomer of claim 1, wherein the branched C₃₆ dicarboxylic acid/diol copolymer is dilinoleic acid/propanediol copolymer or dilinoleic acid/butanediol copolymer.”

177. The ’924 publication discloses each and every element of claim 7. As discussed above, the ’924 publication discloses dilinoleic acid/propanediol copolymer as a preferred prepolymer and DAPD is the prepolymer used in each of Examples 1-5. EX1007, ¶¶[0046], [0058], [0083], [0299]-[0303]. And, as discussed above, DAPD is a branched C₃₆ dicarboxylic acid/diol copolymer. *See* Section XI.B.1. Thus, ’924 publication discloses a polyurethane elastomer that has all of the limitations of claim 7 and anticipates claim 7.

8. Claim 13: “A gel composition comprising the cross-linked elastomer of claim 1 dispersed in a carrier fluid.”

178. The ’924 publication discloses each and every element of claim 13. In particular, the ’924 publication discloses “a millable elastomeric rubber . . . can be

converted into a cosmetically elegant and stable gel.” EX1007, ¶[0031]. For example, the ’924 publication discloses the process:

Further aspects of the invention include gel compositions which contain a mixture of a cross-linked polyurethane elastomer rubber composition as described herein, in a milled form and at least one cosmetic emollient as well as methods of making the gel compositions. The said gel composition is a rubber dispersion, refined via one or more milling and diluting steps whereby each step yields a targeted equilibrium particle size range leading to a final product in the 1 to 100 micron range, preferable 1 to 60 microns. Still further aspects of the invention include cosmetics, emulsions, lotions, creams, etc., and products which contain the inventive compositions and gels.

EX1007, ¶[0017]. The term “carrier fluid” is used interchangeably with the term “cosmetic emollient” throughout the ’924 publication. For instance, the ’924 publication discloses “polar carrier fluids like MCTs [medium chain triglycerides].” EX1007, ¶[0009]. The ’924 publication also discloses “[p]referable emollients include plant origin medium chain triglycerides (MCT) such as glyceryl trihexanoate, glyceryl triheptanoate, and glyceryl trioctanoate, or mixtures thereof.” EX1007, ¶[0293].

179. The ’924 publication discloses that the cross-linked polyurethane elastomer rubber turns into a “smooth gel upon processing with an emollient.” EX1007, ¶[0031]. The ’924 publication discloses that the carrier fluid functions to

disperse the elastomer (i.e., turn it into a gel). EX1007, ¶¶[0032], [0025]. And, the '924 publication discloses that the polymer-to-carrier-fluid ratio is important because insufficient carrier fluid results in an elastomer that cannot be properly dispersed when milled. EX1007, ¶[0032].

180. As discussed above, Example 6 of the '924 publication is a process for preparing an elastomer gel containing a volatile cosmetic emollient. EX1007, ¶[0304]. Example 6 discloses a process by which the Example 1 rubber is mixed with glyceryl triheptanoate “to form a soft, concentrated pre-elastomer by high shear mixing which is then dispersed through a high shear mill” and then diluted with “C9-C12 alkanes” to form a product that is described as being an elastomer gel. EX1007, ¶[0304]. The glyceryl triheptanoate and “C9-C12 alkanes” are disclosed in the '924 publication as being emollients (i.e., carrier fluids). *See, e.g.*, EX1007, ¶[0294] (“emollients such as medium chain triglycerides, C9-C12 alkanes, and esters derived from short-chain fatty acids and alcohols such as caprylate/caprate”).

181. In addition, Example 7 of the '924 publication is a process for preparing an elastomer gel containing a non-volatile cosmetic emollient. EX1007, ¶[0304]. The elastomer gel in Example 7 was prepared by mixing the polyurethane rubber of Example 1 with glyceryl triheptanoate and then diluting that mixture with additional glyceryl triheptanoate. EX1007, ¶[0304]. The glyceryl

triheptanoate is a carrier fluid. *See, e.g.*, EX1007, ¶[0294]. Thus, the '924 publication discloses an embodiment that has all of the limitations of claim 13 and anticipates claim 13.

9. Claim 14: “The gel composition of claim 13, the cross-linked elastomer is in micronized form.”

182. The '924 publication discloses each and every element of claim 14. The '924 publication discloses that the “gel compositions can include a mixture of the cross-linked polyurethane elastomer compositions described herein, preferably in micronized form.” EX1007, ¶[0295].

183. To obtain a cross-linked elastomer in micronized form, the “gel composition is a rubber dispersion, refined via one or more milling and diluting steps whereby each step yields a targeted equilibrium particle size range leading to a final product in the 1 to 100 micron range, preferable 1 to 60 microns.” EX1007, ¶[0017].

184. The working examples of the '924 publication disclose successfully milling the cross-linked elastomer into a micronized form. For example, the elastomer gel prepared in Example 6 is disclosed as being “dispersed through a high shear mill to render the polyurethane particles to less than about 60 microns.” EX1007, ¶[0304]. Similarly, Example 7 discloses that the elastomer gel undergoes “high shear mixing to reduce the polyurethane particles to less than about 60 microns.” EX1007, ¶[0305]. Thus, the '924 publication discloses an embodiment

that has all of the limitations of claim 14 and anticipates claim 14.

10. Claim 15: “The gel composition of claim 14, wherein the cross-linked elastomer in micronized form has a particle size from 1 to 100 microns.”

185. The '924 publication discloses each and every element of claim 15. As discussed above for claim 14, the '924 publication expressly states that the gel composition is refined to a “final product in the 1 to 100 micron” range, and “preferably to a range of from about 1 to about 60 microns.” EX1007, ¶¶[0017], [0025]. Thus, the '924 publication discloses an embodiment that has all of the limitations of claim 15 and anticipates claim 15.

11. Claim 16: “The gel composition of claim 15, wherein the particle size is less than 60 microns.”

186. The '924 publication discloses each and every element of claim 16. As discussed above for claim 14, the '924 publication teaches that the gel compositions are preferably refined to “1 to 60 microns,” and further describes milling to reduce the particle size to “less than about 60 microns.” EX1007, ¶¶[0017], [0025].

187. The '924 publication further provides working examples of forming gels with polyurethane (i.e., the cross-linked elastomer) particle sizes of “less than about 60 microns” via dispersion through a high shear mill. EX1007, ¶¶[0304]-[0305], Example 6, Example 7. Thus, the '924 publication discloses an embodiment that has all of the limitations of claim 16 and anticipates claim 16.

12. Claim 17: “The gel composition of claim 13, wherein the gel has a viscosity ranging from 15,000 cP to 1,000,000 cP.”

188. The '924 publication discloses each and every element of claim 17.

The '924 publication expressly discloses that the gel composition “can have a viscosity ranging from about 15,000 to about 1,000,000 cP.” EX1007, ¶[0035].

189. The gels formed in Examples 6 and 7 of the '924 publication also have viscosities within the claimed range. The gel of Example 6 is reported as having a viscosity of 102,440 cP. EX1007, ¶[0304]. The gel of Example 7 is reported as having a viscosity of 416,667 cP. EX1007, ¶[0305]. Thus, the '924 publication discloses an embodiment that has all of the limitations of claim 17 and anticipates claim 17.

13. The '924 publication is an enabling disclosure of a species of claims 1-7 and 13-17 of the '057 patent.

190. The '924 publication provides an enabling disclosure of an embodiment of claims 1-7 and 13-17 of the '057 patent because a POSA reading the '924 publication would not have to engage in undue experimentation to make a cross-linked polyurethane elastomer, and gel compositions containing the cross-linked polyurethane elastomer and a carrier fluid.

191. **Nature of the invention, state of the prior art, and relative skill of those in the art:** Claims 1-7 and 13-17 are directed to cross-linked polyurethane elastomers and compositions comprising those cross-linked polyurethane

elastomers. Polyurethane elastomers were well-known in the art prior to 2019. *See* Section VII. A POSA is explained above in Section V and would have been highly skilled. These factors weigh in favor of enablement.

192. **Predictability of the art:** There is a significant amount of information available in the art regarding the preparation of cross-linked polyurethane elastomers by reacting polyesters with crosslinkers. *See* Section X1.A.2.a; *see also* EX1032, 114455; EX1008, ¶¶[0011], [0106]-[0117]; EX1020, ¶¶[0166]-[0178]; EX1019, 1:15-20. Thus, in view of the formulation-driven considerations disclosed in the '924 publication, this factor weighs in favor of enablement.

193. **Amount of direction provided and number of working examples:** The '924 publication provides Examples 1 to 5 each of which disclose a cross-linked polyurethane rubber elastomer made by reacting DAPD (a polyester and branched C₃₆ dicarboxylic acid/diol copolymer) with PDT (a multi-functional crosslinker). EX1007, ¶¶[0297]-[0303]. Example 9 describes the use of DABD as the polyester and branched C₃₆ dicarboxylic acid/diol copolymer. EX1007, ¶[0308]. Example 13 also describes the use of HDT as the multi-functional crosslinker. EX1007, ¶[0308]. All of these examples specify the reactants, relative proportions, catalysts, reaction conditions, and resulting polyurethane elastomeric products. Moreover, Examples 6-8 describe the preparation of a gel composition

comprising those cross-linked polyurethane elastomer. EX1007, ¶¶[0304]-[0307].

These examples show that the cross-linked polyurethane elastomers disclosed in the '924 publication can be converted into stable gels, dispersed in carrier fluids, micronized to controlled particle sizes.

194. Thus, this factor weighs in favor of enablement.

195. **Quantity of experimentation needed:** The amount of experimentation needed to enable an embodiment of claims 1-7 and 13-17 is not undue because cross-linked polyurethane elastomers were already known in the art, as discussed above. Claims 1-7 and 13-17 require nothing more than synthesizing those cross-linked elastomers using techniques that were well within the ordinary skill of polymer and materials scientists at the time. Furthermore, Examples 1-8 of the '924 publication provide all of the reaction conditions necessary to make an embodiment of claims 1-7 and 13-17. Accordingly, this factor weighs in favor of enablement.

196. Thus, the '924 publication provides sufficient detail to enable a POSA to produce a cross-linked polyurethane elastomer encompassed by claims 1-7 and 13-17 and gel compositions comprising those elastomers, without undue experimentation.

XII. GROUND 2: SCHÜWER-573 ANTICIPATES CLAIMS 1-7

197. As discussed above, claims 1-17 are entitled to a filing date of, at best,

December 14, 2022. However, even if the claims of the '057 patent were entitled to a filing date of August 30, 2019, which they are not, claims 1-7 are still anticipated by Schüwer-573. Schüwer-573 was published on April 1, 2015 (EX1008) and qualifies as prior art. As explained below, Schüwer-573 discloses each and every element of claims 1-7 of the '057 patent arranged as claimed and in a manner enabling to a POSA, thereby anticipating claims 1-7 of the '057 patent.

A. Claim 1: “A cross-linked elastomer comprising a reaction product of a polyester and a multi-functional crosslinker, wherein the polyester is an esterified dilinoleic acid or a branched C₃₆ dicarboxylic acid/diol copolymer”

198. Schüwer-573 discloses each and every element of claim 1. Schüwer-573 anticipates claim 1 because it expressly discloses a cross-linked elastomer comprising a reaction product of a polyester (polycondensate) and a diol, with a multi-functional crosslinker.

199. Specifically, Schüwer-573 describes the preparation of a polycondensate by polycondensation of a dimer fatty acid, such as a dimer of linoleic acid, and a diol, such as 1,4-butanediol. EX1008, ¶¶[0032]-[0037], [0042], [0122], [0125]. Dimers of linoleic acid include dilinoleic acid (EX1035, 2), which is available under the trade name PRIPOL 1009 or PRIPOL 1006 (EX1008, ¶[0037]). The polyester is a branched C₃₆ dicarboxylic acid/diol copolymer because dilinoleic acid is a branched “36-carbon dicarboxylic acid formed by the catalytic dimerization of linoleic acid” and butanediol is a diol, as the name

suggests. *See* EX1066, 20 (Table 1); *see also* EX1035, 2. Thus, Schüwer-573 expressly discloses a “branched C₃₆ dicarboxylic acid/diol copolymer,” as recited in claim 1.

200. Schüwer-573 further discloses that this polycondensate is then cross-linked with a multi-functional crosslinker. In particular, Schüwer-573 discloses: “[c]rosslinking of the above polycondensate (A) is accomplished by reacting the polycondensate with one or more cross-linking agents.” EX1008, ¶[0070].

Schüwer-573 further goes on to disclose that “[a] typical example of a commercially available polyisocyanate crosslinking agent is produced by Bayer (Germany), under the trade mark DESMODUR or Japan Polyurethane under the Trade mark CORONATE.” EX1008, ¶[0074]. DESMODUR N3600 (the polyisocyanate used in Preparative Example 5 of Schüwer-573) is polyfunctional (i.e., multi-functional). EX1067, 12.

201. The working examples of Schüwer-573 describe how this crosslinking occurs. Preparative Example 5 discloses the reaction of a polycondensate (i.e., a polyester) with DESMODUR N3600 (i.e., a polyisocyanate that acts as the multi-functional crosslinking agent). EX1008, ¶[0126]. Polysorb ID 37, a plasticizer (EX1068, 1), is also added to the reaction mixture. EX1008, ¶[0126]. Plasticizers are added, not to aid in the formation of a polymer, but to influence their properties by “improv[ing] flexibility, plasticity, processability, and elongation of polymers.”

EX1069, 1. Thus, the reaction of the polycondensate with the polyisocyanate in Preparative Example 5 yields a cross-linked elastomer, as required by claim 1.

Thus, Schüwer-573 discloses an embodiment that has all of the limitations of claim 1 and anticipates claim 1.

B. Claim 2: “The cross-linked elastomer of claim 1, wherein the multi-functional crosslinker is polyisocyanate.”

202. Schüwer-573 discloses each and every element of claim 2. In particular, Schüwer-573 expressly discloses the use of multi-functional crosslinkers, such as polyisocyanate. *See, e.g.*, EX1008, ¶[0073]. As discussed above, DESMODUR N3600 is listed in Schüwer-573 as an example of a polyisocyanate and is described in Preparative Example 5 as the agent used to cross-link a polycondensate to form a cross-linked elastomer. EX1008, ¶¶[0074], [0126]. And, DESMODUR N3600 is multi-functional. EX1008, ¶[0126]; EX1067, 12. Thus, Schüwer-573 discloses an embodiment that has all of the limitations of claim 2 and anticipates claim 2.

C. Claim 3: “The cross-linked elastomer of claim 1, wherein the diol is propanediol or butanediol.”

203. Schüwer-573 discloses each and every element of claim 3. Schüwer-573 identifies 1,4-butanediol as a preferred diol used to form the polycondensate. EX1008, ¶[0046] (“1,4-butanediol is commercially available from BioAmber for example (USA). In a preferred embodiment in combination with any of the above

or below embodiments, 1,4-butanediol is present in a concentration of 5 wt% to 40 wt%, more preferably 10 wt% to 20 wt%, relative to the polycondensate.”).

204. Schüwer-573 also provides examples using 1,4-butanediol in the synthesis of a cross-linked elastomer. Preparative Example 4 details reacting PRIPOL 1009 (dilinoleic acid) with 1,4-butanediol to form a polycondensate (i.e., a polyester). EX1008, ¶[0125]. This polyester is then cross-linked with a polyisocyanate, as described in Preparative Example 5, resulting in a cross-linked elastomer that falls squarely within the scope of claim 3. EX1008, ¶[0126]. Thus, Schüwer-573 discloses an embodiment that has all of the limitations of claim 3 and anticipates claim 3.

D. Claim 4: “The cross-linked elastomer of claim 1, where in the polyester is greater than 60% by weight of the total weight of the cross-linked elastomer.”

205. Schüwer-573 discloses each and every element of claim 4. Specifically, Preparative Example 5 discloses a cross-linked elastomer formulation containing 10 g of polycondensate (a polyester) and 0.4 g of DESMODUR N3600 (a “commercially available aliphatic polyisocyanate crosslinking agent”). EX1008, ¶¶[0074], [0126]. The cross-linked elastomer is formed from the polycondensate and the polyisocyanate crosslinker.

206. Schüwer-573 discloses preparing a cross-linked elastomer using an oil additive (e.g., a Polysorb ID 37 plasticizer). EX1008, ¶¶[0088], [0095]. However,

Schüwer-573 does not disclose that the Polysorb ID 37 plasticizer is an elastomer-forming reactant. Indeed, as discussed in Section XII.A, plasticizers do not aid in the formation of the polymer, but rather influence its properties. Accordingly, the oil additive is not included when determining the amount of polyester relative to the weight of the cross-linked elastomer. Thus, the polyester at 10 g comprises approximately 96% by weight of the elastomer-forming reactants ($10 \text{ g} \div (10 \text{ g} + 0.4 \text{ g}) = 96\%$). EX1008, ¶[0126]. 96% by weight is greater than the 60% by weight threshold required by claim 4.

207. Schüwer-573 further discloses that the crosslinker is used in much smaller amounts compared to the polycondensate during the curing process. EX1008, ¶[0126]. The amounts of DESMODUR used in Preparative Example 5 are: 2.5 weight% (with regard to polycondensate), 4.5 weight% (with regard to polycondensate), 4.0 weight% (with regard to polycondensate), and 3.5 weight% (with regard to polycondensate). EX1008, ¶[0126]. In other words, the polycondensate is the primary elastomer-forming component. Thus, Schüwer-573 discloses an embodiment that has all of the limitations of claim 4 and anticipates claim 4.

E. Claim 5: “The cross-linked elastomer of claim 1, where in the polyester is greater than 75% by weight of the total weight of the cross-linked elastomer.”

208. Schüwer-573 discloses each and every element of claim 5. As

discussed above for claim 4, Schüwer-573 discloses in Preparative Example 5 a polyester that is present at approximately 96% by weight of the elastomer-forming reactants. EX1008, ¶[0126]. Because 96% by weight is greater than 75% by weight, Schüwer-573 discloses an embodiment that has all of the limitations of claim 5 and anticipates claim 5.

F. Claim 6: “The cross-linked elastomer of claim 1, wherein the cross-linked elastomer is silicone-free.”

209. Schüwer-573 discloses each and every element of claim 6. In particular, Schüwer-573 discloses: “[t]he cost associated with silicone based product together with the more complex chemical process required for the synthesis of silicon based medical tape are the main drawback of those materials.” EX1008, ¶[0009]. Indeed, Schüwer-573 discloses that its formulations rely on “organic based polymers” that are used in adhesive formulations “that possess[] equivalent or enhanced properties as compared to already known adhesives (silicon or acrylic based) but at advantageous production and raw material costs.” EX1008, ¶¶ [0009], [0010].

210. And none of the elastomers in Preparative Examples 1-5 include silicone. EX1008, ¶¶[0122]-[0127]. A silicone adhesive is only used in Comparative Example 3 to compare the adhesive properties (peel force, surface tension, cell removal area) of the silicone-free elastomers of the invention with silicone elastomers. EX1008, ¶[0127], Table 3, Table 4. Thus, Schüwer-573

discloses an embodiment that has all of the limitations of claim 6 and anticipates claim 6.

G. Claim 7: “The cross-linked elastomer of claim 1, wherein the branched C₃₆ dicarboxylic acid/diol copolymer is dilinoleic acid/propanediol copolymer or dilinoleic acid/butanediol copolymer.”

211. Schüwer-573 discloses each and every element of claim 7. As discussed above, Schüwer-573 discloses a dilinoleic acid/butanediol copolymer formed from the polycondensation of dilinoleic acid (EX1008, ¶[0037]) and 1,4-butanediol (EX1008, ¶[0042]), which is then cross-linked with a polyisocyanate to form a cross-linked elastomer. EX1008, ¶¶[0032]-[0037], [0042], [0122], [0125]-[0126]. And, as discussed above, dilinoleic acid/butanediol is a branched C₃₆ dicarboxylic acid/diol copolymer. *See* Section XII.A. Thus, Schüwer-573 discloses an embodiment that has all of the limitations of claim 7 and anticipates claim 7.

H. Schüwer-573 is an enabling disclosure of claims 1-7 of the ’057 patent.

212. Schüwer-573 provides an enabling disclosure of claims 1-7 of the ’057 patent because a POSA reading Schüwer-573 would not have to engage in undue experimentation to obtain the cross-linked elastomer of the claimed invention.

213. **Nature of the invention, state of the prior art, and relative skill of those in the art:** Claims 1-7 are directed to cross-linked polyurethane elastomers,

which were well-known in the art prior to 2019. *See* Section VII. A POSA is explained above in Section V and would have been highly skilled. These factors weigh in favor of enablement.

214. **Predictability of the art:** There is a significant amount of information available in the art regarding the preparation of cross-linked elastomers by reacting polyesters with crosslinkers. *See* Section X1.A.2.a; *see also* EX1032, 114455; EX1008, ¶¶[0011], [0106]-[0117]; EX1020, ¶¶[0166]-[0178]; EX1019, 1:15-20. That copious amount of information improves predictability here. This factor weighs in favor of enablement.

215. **Amount of direction provided and number of working examples:** Schüwer-573 teaches the synthesis of esterified dilinoleic acid/diol polycondensates (i.e., polyesters) using commercially available dimer fatty acids (e.g., dilinoleic acid sold under the PRIPOL trade names) and defined diols (including 1,4-butanediol), followed by cross-linking with aliphatic polyisocyanates such as DESMODUR N3600. EX1008, ¶¶[0037], [0042], [0074], [0125]–[0126]. Each of Examples 1 to 5 disclose the reactants, relative proportions, catalysts, reaction conditions necessary to form the polyesters and the cross-linked polyurethane elastomeric products. These examples cover variations in molecular weight and cross-linking conditions, confirming that the disclosed elastomer species can be reliably synthesized across a range of formulations.

EX1008, ¶¶[0122]–[0127]. Thus, this factor weighs in favor of enablement.

216. **Quantity of experimentation needed:** The amount of experimentation needed to enable an embodiment of claims 1-7 is not undue because, as discussed above, the cross-linked elastomers recited in claims 1-7 were already known in the art. Claims 1-7 require nothing more than synthesizing those cross-linked elastomers using techniques that were well within the ordinary skill of polymer and materials scientists at the time. *See, e.g.*, EX1046, 831 (referring to polycondensation reactions as “commercially important”); *see also* EX1032, 114455. Furthermore, Examples 1 to 5 of Schüwer-573 provide all of the reaction conditions necessary to make an embodiment of claims 1-7. Accordingly, this factor weighs in favor of enablement.

217. Thus, Schüwer-573 provides sufficient detail to enable a POSA to produce a cross-linked polyurethane elastomer encompassed by claims 1-7 of the '057 patent without undue experimentation.

XIII. CONCLUSION

In signing this declaration, I recognize that the declaration will be filed as evidence in an *inter partes* review before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required, I will appear for cross-examination within the United States during the time allotted.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.



Brent Sumerlin, Ph.D.

Date: September 17, 2026