

**UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

Anagen LLC, Petitioner, v. Veradermics, Incorporated, Patent Owner

Case No. To Be Assigned

U.S. Patent No. 12,491,184

**PETITION FOR POST-GRANT REVIEW OF CLAIMS 1–20 OF U.S.**  
**PATENT NO. 12,491,184 UNDER 35 U.S.C. §§ 321–329 AND 37 C.F.R. §**  
**42.200 ET SEQ.**

**TABLE OF CONTENTS**

|                                                                                    |    |
|------------------------------------------------------------------------------------|----|
| I. INTRODUCTION.....                                                               | 6  |
| II. MANDATORY NOTICES (37 C.F.R. § 42.8).....                                      | 10 |
| III. GROUNDS FOR STANDING AND PGR ELIGIBILITY.....                                 | 30 |
| III.A. Grounds for Standing (37 C.F.R. § 42.204(a)).....                           | 30 |
| III.B. PGR Eligibility and Timeliness (35 U.S.C. § 321(c); AIA § 6(f)(2) (A))..... | 30 |
| III.C. Discretionary Considerations.....                                           | 31 |
| IV. IDENTIFICATION OF THE CHALLENGE (37 C.F.R. § 42.204).....                      | 31 |
| IV.A. Challenged Claims and Relief Requested.....                                  | 31 |
| IV.B. Grounds of Unpatentability.....                                              | 32 |
| IV.C. Exhibit List.....                                                            | 37 |
| V. SUMMARY OF THE '184 PATENT.....                                                 | 37 |
| V.A. Claims.....                                                                   | 37 |
| V.B. Specification.....                                                            | 38 |
| V.C. Prosecution History.....                                                      | 41 |
| VI. PERSON OF ORDINARY SKILL IN THE ART (POSITA).....                              | 43 |
| VII. CLAIM CONSTRUCTION.....                                                       | 45 |

|                                                                                                                                                                                                                                                                                                                                                                |    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| VII.A. "about 4.5 mg of minoxidil" (Claim 1; carried into all dependent claims).....                                                                                                                                                                                                                                                                           | 46 |
| VII.B. "no cardiac effects" (Claims 19–20).....                                                                                                                                                                                                                                                                                                                | 47 |
| VII.C. "modified release pharmaceutical formulation" (Claim 1).....                                                                                                                                                                                                                                                                                            | 48 |
| VII.D. Release-kinetics terms (Claims 12–16).....                                                                                                                                                                                                                                                                                                              | 48 |
| VII.E. Claim 1's "wherein ... provides" clauses are limiting.....                                                                                                                                                                                                                                                                                              | 50 |
| VIII. STATE OF THE ART AS OF OCTOBER 25, 2022.....                                                                                                                                                                                                                                                                                                             | 51 |
| VIII.A. Clinical use of low-dose oral minoxidil for hair loss.....                                                                                                                                                                                                                                                                                             | 52 |
| VIII.B. Immediate-release and sublingual minoxidil pharmacokinetics.....                                                                                                                                                                                                                                                                                       | 52 |
| VIII.C. Minoxidil-specific formulation disclosures.....                                                                                                                                                                                                                                                                                                        | 53 |
| VIII.D. Conventional modified-release formulation technology.....                                                                                                                                                                                                                                                                                              | 54 |
| VIII.E. Cardiovascular pharmacology and reported safety observations.....                                                                                                                                                                                                                                                                                      | 54 |
| IX. THE CHALLENGED CLAIMS ARE UNPATENTABLE.....                                                                                                                                                                                                                                                                                                                | 55 |
| IX.A. GROUND 1 — § 112(a) written description: the specification does not reasonably convey possession of the claimed method of administering an about-4.5-mg modified-release minoxidil formulation that provides both recited C <sub>max</sub> and T <sub>max</sub> ranges; certain dependent claims add further unsupported result-defined limitations..... | 55 |
| IX.A.1. Governing law.....                                                                                                                                                                                                                                                                                                                                     | 55 |
| IX.A.2. Claim 1 is not a dose claim; it claims a result-defined formulation.....                                                                                                                                                                                                                                                                               | 57 |
| IX.A.3. The specification states the envelope but identifies no embodiment that provides it.....                                                                                                                                                                                                                                                               | 60 |
| IX.A.4. The worked examples do not bridge formulation structure to the claimed in-vivo result.....                                                                                                                                                                                                                                                             | 62 |
| IX.A.5. The original claims and the priority documents do not supply the missing possession.....                                                                                                                                                                                                                                                               | 64 |
| IX.A.6. The dependent claims do not cure and in several instances deepen the defect.....                                                                                                                                                                                                                                                                       | 67 |
| IX.A.7. In the alternative, Claims 1–11, 17, and 18 are not enabled across their scope.....                                                                                                                                                                                                                                                                    | 68 |
| IX.A.8. Conclusion on Ground 1.....                                                                                                                                                                                                                                                                                                                            | 71 |
| IX.B. GROUND 2 — Claims 19 and 20 are indefinite under § 112(b): "no cardiac effects" fails to inform a POSITA with reasonable certainty whether the limitation is met, because the patent ties no measurement                                                                                                                                                 |    |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| method, detection threshold, magnitude criterion, or assessment period to that term.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 72 |
| IX.B.1. Governing law.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 72 |
| IX.B.2. The patent's definition makes Claim 19 depend on an unspecified observation and causation protocol.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 73 |
| IX.B.3. The intrinsic record supplies no objective test.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 74 |
| IX.B.4. The known pharmacology makes the missing protocol consequential.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 76 |
| IX.B.5. "No clinically significant cardiac effects" is not the claim, and Patent Owner's narrowing construction fails § 112(a).....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 78 |
| IX.B.6. Claim 20 does not cure the defect.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 79 |
| IX.B.7. Ground 2 conclusion.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 79 |
| IX.C. GROUND 3A — Claims 12–16 are indefinite under § 112(b): the patent supplies no dissolution conditions, kinetic model, fitting interval, goodness-of-fit threshold, or classification rule by which a POSITA could determine with reasonable certainty whether a formulation exhibits zero-order, pseudo-zero-order, first-order, pseudo-first-order, or second-order release. GROUND 3B (alternative) — Claims 12 and 16 lack enablement under § 112(a): the patent does not enable an about-4.5-mg modified-release minoxidil formulation exhibiting zero-order or second-order release without undue experimentation..... | 80 |
| IX.C.1. Governing law.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 80 |
| IX.C.2. The claimed kinetic classifications.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 81 |
| IX.C.3. Ground 3A — the patent's own prototype data demonstrate method dependence.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 81 |
| IX.C.4. Ground 3A — the reaction-kinetics definitions add ambiguity rather than an operational boundary.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 83 |
| IX.C.5. Ground 3B — Claims 12 and 16 are not enabled at "about 4.5 mg".....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 84 |
| IX.C.6. Ground 3 conclusion.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 88 |
| IX.D. GROUND 4 — Claims 1, 3–7, 9, 11, 13–15, 18 are obvious under § 103 over Sinclair-535 in view of Reynolds 2002.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 88 |
| IX.D.0. Governing principles, prior-art status, and the reasonable expectation of success shared by Grounds 4–6.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 89 |
| IX.D.1. The references' complementary teachings.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 94 |

|                                                                                                                                                                                                                                                                                                |     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| IX.D.2. A POSITA had reason to combine Sinclair's oral-minoxidil method with Reynolds's matrix platform.....                                                                                                                                                                                   | 95  |
| IX.D.3. Reasonable expectation of meeting Claim 1's two limitations; anticipated rebuttals.....                                                                                                                                                                                                | 96  |
| IX.D.4. Claim 1 mapping.....                                                                                                                                                                                                                                                                   | 97  |
| IX.D.5. Dependent claims.....                                                                                                                                                                                                                                                                  | 97  |
| IX.D.6. Ground 4 conclusion.....                                                                                                                                                                                                                                                               | 98  |
| IX.E. GROUND 5A — Claims 1, 5–7, 9, 11, 18, 19, and 20 are obvious under § 103 over Vañó-Galván 2021 in view of Sinclair-535, Fleishaker 1989, the Loniten label, and Reynolds 2002; GROUND 5B — Claims 8 and 10 are obvious over the Ground 5A combination further in view of Beach 2021..... | 99  |
| IX.E.1. The references have defined, claim-specific roles.....                                                                                                                                                                                                                                 | 100 |
| IX.E.2. Reason to combine.....                                                                                                                                                                                                                                                                 | 101 |
| IX.E.3. Claim 1 mapping.....                                                                                                                                                                                                                                                                   | 102 |
| IX.E.4. Dependent claims; Claims 19–20 under Patent Owner's narrowing construction.....                                                                                                                                                                                                        | 102 |
| IX.E.5. Grounds 5A/5B conclusion.....                                                                                                                                                                                                                                                          | 104 |
| IX.F. GROUND 6 — Claims 1–7, 9, 11, 13–15, 17, and 18 are obvious under § 103 over Sinclair-535 in view of Cardinal and Fleishaker 1989.....                                                                                                                                                   | 104 |
| IX.F.1. Cardinal is a matrix-platform reference that names minoxidil and not a worked minoxidil formulation.....                                                                                                                                                                               | 105 |
| IX.F.2. Reason to combine.....                                                                                                                                                                                                                                                                 | 105 |
| IX.F.3. Claim 1 mapping.....                                                                                                                                                                                                                                                                   | 107 |
| IX.F.4. Dependent claims.....                                                                                                                                                                                                                                                                  | 107 |
| IX.F.5. Ground 6 conclusion.....                                                                                                                                                                                                                                                               | 109 |
| X. SECONDARY CONSIDERATIONS DO NOT OUTWEIGH THE EVIDENCE OF OBVIOUSNESS.....                                                                                                                                                                                                                   | 109 |
| X.A. No presumed or direct nexus.....                                                                                                                                                                                                                                                          | 110 |
| X.B. No long-felt unmet need shown to have been satisfied by the claimed invention.....                                                                                                                                                                                                        | 111 |
| X.C. No unexpected result attributable to the claimed combination.....                                                                                                                                                                                                                         | 111 |
| X.D. No commercial success.....                                                                                                                                                                                                                                                                | 113 |
| X.E. No skepticism or failure of others.....                                                                                                                                                                                                                                                   | 113 |

|                                                                                                                                    |     |
|------------------------------------------------------------------------------------------------------------------------------------|-----|
| X.F. No copying, independent praise, or licensing.....                                                                             | 113 |
| XI. CONCLUSION.....                                                                                                                | 114 |
| CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24.....                                                                              | 115 |
| CLAIM LISTING APPENDIX — CLAIMS 1–20 OF U.S. PATENT NO.<br>12,491,184 (37 C.F.R. § 42.24(a)(1); excluded from the word count)..... | 116 |
| PETITIONER'S EXHIBIT LIST (37 C.F.R. § 42.63(e)).....                                                                              | 119 |
| CERTIFICATE OF SERVICE.....                                                                                                        | 123 |

## I. INTRODUCTION

U.S. Patent No. 12,491,184 ("the '184 patent") issued December 9, 2025, from Application No. 19/094,716, and is assigned to Veradermics, Incorporated. The '184 patent is a continuation of Application No. 18/437,724, which issued as U.S. Patent No. 12,268,688 ("the '688 patent").

The '688's four independent method claims each recite a blood level of about 1–20 ng/mL, a C<sub>max</sub> of about 0.25–20 ng/mL, and a T<sub>max</sub> of about 30–360 minutes, at doses of about 3.5–20 mg (Claims 1 and 24), about 9 mg (Claim 18), and about 4.5 mg (Claim 14). (Ex. 1002, cols. 100–102.) The '184 patent presents a different claim set. Its sole independent claim, Claim 1, recites a method of treating hair loss by orally administering to a human subject a modified-release formulation comprising about 4.5 mg of minoxidil that provides both a C<sub>max</sub> of about 0.25–20 ng/mL and a T<sub>max</sub> of about 30–360 minutes. Claims 2–20 depend directly or indirectly from Claim 1. Among other limitations, Claim 2 adds a blood level maintained for at least about eight hours, Claims 12–16 recite five alternative orders of release kinetics, Claim 17 requires an enteric coating, Claim 19 requires "no cardiac effects," and Claim 20 identifies specified cardiac effects.

This Petition challenges all 20 claims under 35 U.S.C. § 112 (Grounds 1, 2, 3A, and 3B) and Claims 1–11, 13–15, and 17–20 under 35 U.S.C. § 103 (Grounds

4, 5A, 5B, and 6), as identified in § IV.B. The Petition is timely: it is filed within nine months of the '184 patent's issue. 35 U.S.C. § 321(c).

The § 112 challenges do not rest on any categorical proposition that clinical testing or actual reduction to practice is required. They rest on what this specification discloses, and does not disclose, about the claimed invention.

First, the specification does not reasonably convey possession of the method recited in Claim 1, and therefore of any claim. Claim 1 requires administration of an about-4.5-mg modified-release formulation that provides both recited in-vivo results. Yet the specification identifies no about-4.5-mg modified-release formulation as providing either recited in-vivo result, reports no measured human PK result for any modified-release formulation at any dose, and provides no formulation-to-PK relationship from which a POSITA would recognize that any disclosed formulation possesses those properties. Claim 2's eight-hour maintenance rests on the same absent disclosure. Outside the claims, about 4.5 mg appears only inside dose enumerations — in the widest, one of more than forty values spanning about 0.125–100 mg — and no embodiment pairs it with either claimed window or any result. What the specification does contain, in-vitro dissolution data for prototypes at other doses and reference curves labeled "Estimated from PBPK Slides", is not measured in-vivo pharmacokinetic data for any modified-release formulation.

The specification itself states that "[n]o PK studies in humans have been previously conducted with MR oral formulations of minoxidil" and that the relevance of the findings from "other products containing minoxidil" to modified-release oral formulations "is not known, but it is the only supportive information currently available." (Ex. 1001, cols. 65–66.) On this record the recited Cmax and Tmax ranges are stated targets, not demonstrated properties of an invention the specification reasonably conveys the inventors possessed. See § IX.A. The same deficiencies support the claim-specific enablement alternative set out there.

Second, Claim 1, and with it every claim the § 103 grounds reach, is also obvious. Grounds 4–6 apply distinct prior-art pathways combining established low-dose oral-minoxidil treatment, measured human minoxidil pharmacokinetics, and known modified-release formulation technology; the reasonable expectation common to them is shown from the documents at § IX.D.0. The same Examiner has since applied the Ground 4 architecture, an oral-minoxidil reference in view of Reynolds, to reject every claim of the '184's sibling application (Ex. 1029; § V.C).

Third, Claims 19 and 20 are indefinite. The specification defines "cardiac effect" as "any effect on the heart or the vascular system as a result of the administration of a pharmaceutical formulation." (Ex. 1001, col. 5, ll. 34–40.) Neither the claims nor the specification ties a measurement method, detection threshold, observation period, or clinical standard to that definition, and accepted

methods classify the same patient differently; Claims 19 and 20 therefore fail to inform a POSITA with reasonable certainty whether the limitation is met. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014); § IX.B.

Fourth, Claims 12–16 are indefinite, and Claims 12 and 16 alternatively lack enablement. The claims require zero-order, pseudo-zero-order, first-order, pseudo-first-order, or second-order release. The specification supplies verbal and rate-law definitions but identifies no governing dissolution conditions, sampling interval, fitting procedure, goodness-of-fit metric, acceptance threshold, or rule for choosing among competing classifications. The patent's own examples demonstrate the problem: the same 10-mg prototype is characterized as pseudo-zero-order under a single-stage dissolution method and as showing "more of a first-order" profile under a two-stage method. The claims do not tell a POSITA which classification controls. Nor does the specification disclose any about-4.5-mg minoxidil formulation exhibiting zero-order release (Claim 12) or second-order release (Claim 16), or claim-specific guidance for obtaining those results without undue experimentation. See § IX.C.

The information presented demonstrates that it is more likely than not that every challenged claim is unpatentable. 35 U.S.C. § 324(a).

## **II. MANDATORY NOTICES (37 C.F.R. § 42.8)**

### **A. Real Parties-in-Interest (37 C.F.R. § 42.8(b)(1))**

Petitioner Anagen LLC identifies the following real parties-in-interest: Anagen LLC; Hair Inc.; HairDAO Payments LLC; and HairDAO Association. Anagen LLC is wholly owned by Hair Inc.; Hair Inc. and HairDAO Payments LLC are wholly owned by HairDAO Association. Following a reasonable investigation concerning the funding, direction, control, and intended beneficiaries of this proceeding, Petitioner is aware of no other real party-in-interest.

### **B. Related Matters (37 C.F.R. § 42.8(b)(2))**

The '184 patent claims priority through PCT/US2023/035920 and U.S. Provisional Application Nos. 63/419,155 and 63/433,203. Petitioner identifies the following administrative matters that may affect, or be affected by, a decision in this proceeding:

| Matter                                           | Relationship to the '184 patent                           | Status (per USPTO Patent Center)        |
|--------------------------------------------------|-----------------------------------------------------------|-----------------------------------------|
| U.S. Patent No. 12,268,688 (App. No. 18/437,724) | Parent; the '184 is a continuation (Ex. 1001, field (63)) | Issued April 8, 2025                    |
| U.S. App. No. 19/094,703 (Pub. No.               | Continuation of App. No. 18/437,724 (a sibling of the     | Pending (non-final Office Action mailed |

| Matter                                              | Relationship to the '184 patent                                                                                       | Status (per USPTO Patent Center) |
|-----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|----------------------------------|
| US 2025/0221993)                                    | '184; US 2025/0221993, Cross-Reference to Related Applications)                                                       | March 16, 2026; Ex. 1029)        |
| U.S. App. No. 19/065,184 (Pub. No. US 2025/0319082) | Divisional of App. No. 18/437,724 (a sibling of the '184; US 2025/0319082, Cross-Reference to Related Applications)   | Pending                          |
| U.S. App. No. 19/065,201 (Pub. No. US 2025/0319083) | Continuation of App. No. 18/437,724 (a sibling of the '184; US 2025/0319083, Cross-Reference to Related Applications) | Pending                          |
| U.S. App. No. 19/215,242 (Pub. No. US 2025/0367194) | Continuation of App. No. 19/094,716 (the '184)                                                                        | Pending                          |
| U.S. App. No.                                       | Continuation of App. No.                                                                                              | Pending                          |

| Matter                                                 | Relationship to the '184 patent                   | Status (per USPTO Patent Center) |
|--------------------------------------------------------|---------------------------------------------------|----------------------------------|
| 19/230,054 (Pub. No. US 2025/0367197)                  | 19/094,716 (the '184)                             |                                  |
| U.S. App. No.<br>19/230,047 (Pub. No. US 2025/0367196) | Continuation of App. No.<br>19/094,716 (the '184) | Pending                          |
| U.S. App. No.<br>19/253,708 (Pub. No. US 2025/0319087) | Continuation of App. No.<br>19/094,716 (the '184) | Pending                          |
| U.S. App. No.<br>19/253,703 (Pub. No. US 2025/0319086) | Continuation of App. No.<br>19/094,716 (the '184) | Pending                          |
| U.S. App. No.<br>19/255,878 (Pub. No. US 2025/0332168) | Continuation of App. No.<br>19/094,716 (the '184) | Pending                          |
| U.S. App. No.<br>19/258,817 (Pub. No. US 2025/0325546) | Continuation of App. No.<br>19/094,716 (the '184) | Pending                          |

| Matter                                                    | Relationship to the '184 patent                   | Status (per USPTO Patent Center) |
|-----------------------------------------------------------|---------------------------------------------------|----------------------------------|
| U.S. App. No.<br>19/260,035 (Pub. No.<br>US 2025/0332169) | Continuation of App. No.<br>19/094,716 (the '184) | Pending                          |
| U.S. App. No.<br>19/267,464 (Pub. No.<br>US 2025/0339431) | Continuation of App. No.<br>19/094,716 (the '184) | Pending                          |
| U.S. App. No.<br>19/267,447 (Pub. No.<br>US 2025/0339430) | Continuation of App. No.<br>19/094,716 (the '184) | Pending                          |
| U.S. App. No.<br>19/308,124 (Pub. No.<br>US 2026/0034129) | Continuation of App. No.<br>19/094,716 (the '184) | Pending                          |
| U.S. App. No.<br>19/315,454 (Pub. No.<br>US 2025/0381186) | Continuation of App. No.<br>19/094,716 (the '184) | Pending (issue fee paid)         |
| U.S. App. No.<br>19/328,077 (Pub. No.                     | Continuation of App. No.<br>19/094,716 (the '184) | Pending                          |

| Matter                                                    | Relationship to the '184 patent                      | Status (per USPTO Patent Center) |
|-----------------------------------------------------------|------------------------------------------------------|----------------------------------|
| US 2026/0014150)                                          |                                                      |                                  |
| U.S. App. No.<br>19/329,494 (Pub. No.<br>US 2026/0014152) | Continuation of App. No.<br>19/094,716 (the '184)    | Pending                          |
| U.S. App. No.<br>19/402,798 (Pub. No.<br>US 2026/0083737) | Continuation of App. No.<br>19/328,077 (same family) | Pending                          |
| U.S. App. No.<br>19/404,931 (Pub. No.<br>US 2026/0083738) | Continuation of App. No.<br>19/328,077 (same family) | Pending                          |
| U.S. App. No.<br>19/412,564 (Pub. No.<br>US 2026/0102398) | Continuation of App. No.<br>19/315,454 (same family) | Pending                          |
| U.S. App. No.<br>19/415,540 (Pub. No.<br>US 2026/0097035) | Continuation of App. No.<br>19/267,464 (same family) | Pending                          |
| U.S. App. No.                                             | Continuation of App. No.                             | Pending                          |

| Matter                                                 | Relationship to the '184 patent                      | Status (per USPTO Patent Center) |
|--------------------------------------------------------|------------------------------------------------------|----------------------------------|
| 19/423,775 (Pub. No. US 2026/0108516)                  | 19/267,447 (same family)                             |                                  |
| U.S. App. No.<br>19/424,838 (Pub. No. US 2026/0124207) | Continuation of App. No.<br>19/258,817 (same family) | Pending                          |
| U.S. App. No.<br>19/427,815 (Pub. No. US 2026/0108519) | Continuation of App. No.<br>19/255,878 (same family) | Pending                          |
| U.S. App. No.<br>19/215,216 (Pub. No. US 2025/0375448) | Continuation of App. No.<br>19/094,703 (same family) | Pending                          |
| U.S. App. No.<br>19/230,007 (Pub. No. US 2025/0367195) | Continuation of App. No.<br>19/094,703 (same family) | Pending                          |
| U.S. App. No.<br>19/230,051 (Pub. No. US 2025/0360131) | Continuation of App. No.<br>19/094,703 (same family) | Pending                          |

| Matter                                                    | Relationship to the '184 patent                      | Status (per USPTO Patent Center)     |
|-----------------------------------------------------------|------------------------------------------------------|--------------------------------------|
| U.S. App. No.<br>19/235,535 (Pub. No.<br>US 2025/0302835) | Continuation of App. No.<br>19/094,703 (same family) | Pending                              |
| U.S. App. No.<br>19/236,933 (Pub. No.<br>US 2025/0302836) | Continuation of App. No.<br>19/094,703 (same family) | Pending                              |
| U.S. App. No.<br>19/241,304 (Pub. No.<br>US 2025/0367198) | Continuation of App. No.<br>19/094,703 (same family) | Pending                              |
| U.S. App. No.<br>19/242,858 (Pub. No.<br>US 2025/0367199) | Continuation of App. No.<br>19/094,703 (same family) | Pending                              |
| U.S. App. No.<br>19/245,208 (Pub. No.<br>US 2025/0312346) | Continuation of App. No.<br>19/094,703 (same family) | Pending                              |
| U.S. App. No.<br>19/250,029 (Pub. No.                     | Continuation of App. No.<br>19/094,703 (same family) | Pending (notice of allowance mailed) |

| Matter                                                    | Relationship to the '184 patent                      | Status (per USPTO Patent Center)     |
|-----------------------------------------------------------|------------------------------------------------------|--------------------------------------|
| US 2025/0319085)                                          |                                                      |                                      |
| U.S. App. No.<br>19/303,300 (Pub. No.<br>US 2025/0367200) | Continuation of App. No.<br>19/094,703 (same family) | Pending                              |
| U.S. App. No.<br>19/315,441 (Pub. No.<br>US 2025/0387394) | Continuation of App. No.<br>19/094,703 (same family) | Pending (notice of allowance mailed) |
| U.S. App. No.<br>19/324,046 (Pub. No.<br>US 2026/0007670) | Continuation of App. No.<br>19/094,703 (same family) | Pending                              |
| U.S. App. No.<br>19/329,476 (Pub. No.<br>US 2026/0014151) | Continuation of App. No.<br>19/094,703 (same family) | Pending                              |
| U.S. App. No.<br>19/397,854 (Pub. No.<br>US 2026/0124206) | Continuation of App. No.<br>19/329,476 (same family) | Pending                              |
| U.S. App. No.                                             | Continuation of App. No.                             | Pending                              |

| Matter                                                 | Relationship to the '184 patent                      | Status (per USPTO Patent Center)     |
|--------------------------------------------------------|------------------------------------------------------|--------------------------------------|
| 19/409,546 (Pub. No. US 2026/0091034)                  | 19/324,046 (same family)                             |                                      |
| U.S. App. No.<br>19/414,251 (Pub. No. US 2026/0091035) | Continuation of App. No.<br>19/303,300 (same family) | Pending                              |
| U.S. App. No.<br>19/420,555 (Pub. No. US 2026/0102399) | Continuation of App. No.<br>19/315,441 (same family) | Pending                              |
| U.S. App. No.<br>19/424,083 (Pub. No. US 2026/0108517) | Continuation of App. No.<br>19/250,029 (same family) | Pending                              |
| U.S. App. No.<br>19/424,087 (Pub. No. US 2026/0108518) | Continuation of App. No.<br>19/245,208 (same family) | Pending (notice of allowance mailed) |
| U.S. App. No.<br>19/425,963 (Pub. No. US 2026/0124208) | Continuation of App. No.<br>19/242,858 (same family) | Pending                              |

| Matter                                                    | Relationship to the '184 patent                      | Status (per USPTO Patent Center)     |
|-----------------------------------------------------------|------------------------------------------------------|--------------------------------------|
| U.S. App. No.<br>19/428,043 (Pub. No.<br>US 2026/0108520) | Continuation of App. No.<br>19/241,304 (same family) | Pending (notice of allowance mailed) |
| U.S. App. No.<br>19/432,541 (Pub. No.<br>US 2026/0115193) | Continuation of App. No.<br>19/230,051 (same family) | Pending                              |
| U.S. App. No.<br>19/402,812 (Pub. No.<br>US 2026/0137683) | Continuation of App. No.<br>19/329,476 (same family) | Pending                              |
| U.S. App. No.<br>19/441,484 (Pub. No.<br>US 2026/0130909) | Continuation of App. No.<br>19/235,535 (same family) | Pending                              |
| U.S. App. No.<br>19/442,899 (Pub. No.<br>US 2026/0130911) | Continuation of App. No.<br>19/215,242 (same family) | Pending                              |
| U.S. App. No.<br>19/442,911 (Pub. No.                     | Continuation of App. No.<br>19/230,047 (same family) | Pending                              |

| Matter                                                    | Relationship to the '184 patent                      | Status (per USPTO Patent Center) |
|-----------------------------------------------------------|------------------------------------------------------|----------------------------------|
| US 2026/0130912)                                          |                                                      |                                  |
| U.S. App. No.<br>19/442,979 (Pub. No.<br>US 2026/0130913) | Continuation of App. No.<br>19/230,051 (same family) | Pending                          |
| U.S. App. No.<br>19/443,936 (Pub. No.<br>US 2026/0130914) | Continuation of App. No.<br>19/328,077 (same family) | Pending                          |
| U.S. App. No.<br>19/445,410 (Pub. No.<br>US 2026/0130915) | Continuation of App. No.<br>19/308,124 (same family) | Pending                          |
| U.S. App. No.<br>19/445,445 (Pub. No.<br>US 2026/0130916) | Continuation of App. No.<br>19/215,216 (same family) | Pending                          |
| U.S. App. No.<br>19/234,212<br>(unpublished)              | Continuation of App. No.<br>19/094,703 (same family) | Pending                          |
| U.S. App. No.                                             | Continuation of App. No.                             | Pending (notice of               |

| Matter                                               | Relationship to the '184 patent                          | Status (per USPTO Patent Center) |
|------------------------------------------------------|----------------------------------------------------------|----------------------------------|
| 19/412,714<br><br>(unpublished)                      | 19/315,441 (same family)                                 | allowance mailed)                |
| U.S. App. No.<br><br>19/413,834<br><br>(unpublished) | Continuation of App. No.<br><br>19/308,124 (same family) | Pending                          |
| U.S. App. No.<br><br>19/422,011<br><br>(unpublished) | Continuation of App. No.<br><br>19/260,035 (same family) | Pending                          |
| U.S. App. No.<br><br>19/427,955<br><br>(unpublished) | Continuation of App. No.<br><br>19/253,708 (same family) | Pending                          |
| U.S. App. No.<br><br>19/430,022<br><br>(unpublished) | Continuation of App. No.<br><br>19/236,933 (same family) | Pending                          |
| U.S. App. No.<br><br>19/430,093<br><br>(unpublished) | Continuation of App. No.<br><br>19/253,703 (same family) | Pending                          |

| Matter                                       | Relationship to the '184 patent                      | Status (per USPTO Patent Center) |
|----------------------------------------------|------------------------------------------------------|----------------------------------|
| U.S. App. No.<br>19/436,869<br>(unpublished) | Continuation of App. No.<br>19/230,054 (same family) | Pending                          |
| U.S. App. No.<br>19/442,974<br>(unpublished) | Continuation of App. No.<br>19/234,212 (same family) | Pending                          |
| U.S. App. No.<br>19/443,542<br>(unpublished) | Continuation of App. No.<br>19/230,007 (same family) | Pending                          |
| U.S. App. No.<br>19/444,686<br>(unpublished) | Continuation of App. No.<br>19/315,454 (same family) | Pending                          |
| U.S. App. No.<br>19/447,910<br>(unpublished) | Continuation of App. No.<br>19/267,464 (same family) | Pending                          |
| U.S. App. No.<br>19/449,371                  | Continuation of App. No.<br>19/329,476 (same family) | Pending                          |

| Matter                                       | Relationship to the '184 patent                      | Status (per USPTO Patent Center) |
|----------------------------------------------|------------------------------------------------------|----------------------------------|
| (unpublished)                                |                                                      |                                  |
| U.S. App. No.<br>19/461,532<br>(unpublished) | Continuation of App. No.<br>19/324,046 (same family) | Pending                          |
| U.S. App. No.<br>19/462,854<br>(unpublished) | Continuation of App. No.<br>19/260,035 (same family) | Pending                          |
| U.S. App. No.<br>19/533,028<br>(unpublished) | Continuation of App. No.<br>19/315,441 (same family) | Pending                          |
| U.S. App. No.<br>19/538,689<br>(unpublished) | Continuation of App. No.<br>19/255,878 (same family) | Pending                          |
| U.S. App. No.<br>19/538,745<br>(unpublished) | Continuation of App. No.<br>19/303,300 (same family) | Pending                          |
| U.S. App. No.                                | Continuation of App. No.                             | Pending                          |

| Matter                                               | Relationship to the '184 patent                          | Status (per USPTO Patent Center) |
|------------------------------------------------------|----------------------------------------------------------|----------------------------------|
| 19/539,689<br><br>(unpublished)                      | 19/253,708 (same family)                                 |                                  |
| U.S. App. No.<br><br>19/540,478<br><br>(unpublished) | Continuation of App. No.<br><br>19/250,029 (same family) | Pending                          |
| U.S. App. No.<br><br>19/540,549<br><br>(unpublished) | Continuation of App. No.<br><br>19/253,703 (same family) | Pending                          |
| U.S. App. No.<br><br>19/542,655<br><br>(unpublished) | Continuation of App. No.<br><br>19/245,208 (same family) | Pending                          |
| U.S. App. No.<br><br>19/543,842<br><br>(unpublished) | Continuation of App. No.<br><br>19/230,054 (same family) | Pending                          |
| U.S. App. No.<br><br>19/544,903<br><br>(unpublished) | Continuation of App. No.<br><br>19/230,047 (same family) | Pending                          |

| Matter                                       | Relationship to the '184 patent                      | Status (per USPTO Patent Center) |
|----------------------------------------------|------------------------------------------------------|----------------------------------|
| U.S. App. No.<br>19/545,000<br>(unpublished) | Continuation of App. No.<br>19/242,858 (same family) | Pending                          |
| U.S. App. No.<br>19/546,257<br>(unpublished) | Continuation of App. No.<br>19/241,304 (same family) | Pending                          |
| U.S. App. No.<br>19/546,272<br>(unpublished) | Continuation of App. No.<br>19/215,242 (same family) | Pending                          |
| U.S. App. No.<br>19/546,276<br>(unpublished) | Continuation of App. No.<br>19/236,933 (same family) | Pending                          |
| U.S. App. No.<br>19/546,283<br>(unpublished) | Continuation of App. No.<br>19/328,077 (same family) | Pending                          |
| U.S. App. No.<br>19/561,075                  | Continuation of App. No.<br>19/235,535 (same family) | Pending                          |

| Matter                                       | Relationship to the '184 patent                      | Status (per USPTO Patent Center) |
|----------------------------------------------|------------------------------------------------------|----------------------------------|
| (unpublished)                                |                                                      |                                  |
| U.S. App. No.<br>19/561,225<br>(unpublished) | Continuation of App. No.<br>19/315,454 (same family) | Pending                          |
| U.S. App. No.<br>19/561,256<br>(unpublished) | Continuation of App. No.<br>19/234,212 (same family) | Pending                          |
| U.S. App. No.<br>19/561,291<br>(unpublished) | Continuation of App. No.<br>19/308,124 (same family) | Pending                          |
| U.S. App. No.<br>19/566,469<br>(unpublished) | Continuation of App. No.<br>19/230,051 (same family) | Pending                          |
| U.S. App. No.<br>19/566,606<br>(unpublished) | Continuation of App. No.<br>19/267,464 (same family) | Pending                          |
| U.S. App. No.                                | Continuation of App. No.                             | Pending (notice of               |

| Matter                                               | Relationship to the '184 patent                          | Status (per USPTO Patent Center) |
|------------------------------------------------------|----------------------------------------------------------|----------------------------------|
| 19/568,540<br><br>(unpublished)                      | 19/230,007 (same family)                                 | allowance mailed)                |
| U.S. App. No.<br><br>19/569,918<br><br>(unpublished) | Continuation of App. No.<br><br>19/267,447 (same family) | Pending                          |
| U.S. App. No.<br><br>19/569,963<br><br>(unpublished) | Continuation of App. No.<br><br>19/260,035 (same family) | Pending                          |
| U.S. App. No.<br><br>19/570,012<br><br>(unpublished) | Continuation of App. No.<br><br>19/215,216 (same family) | Pending                          |
| U.S. App. No.<br><br>19/572,667<br><br>(unpublished) | Continuation of App. No.<br><br>19/329,476 (same family) | Pending                          |
| U.S. App. No.<br><br>19/572,691<br><br>(unpublished) | Continuation of App. No.<br><br>19/255,878 (same family) | Pending                          |

| Matter                                           | Relationship to the '184 patent                      | Status (per USPTO Patent Center) |
|--------------------------------------------------|------------------------------------------------------|----------------------------------|
| U.S. App. No.<br>19/683,682<br><br>(unpublished) | Continuation of App. No.<br>19/324,046 (same family) | Pending                          |

The rows above reflect the family's complete continuity listing as confirmed against USPTO Patent Center records on August 31, 2026. Petitioner is aware, as of the filing date, of no United States district-court, International Trade Commission, Patent Trial and Appeal Board, reexamination, reissue, or other United States judicial or administrative proceeding involving the '184 patent or any related patent or application other than the prosecution matters identified above. Petitioner will update this notice within 21 days of any change. 37 C.F.R. § 42.8(a)(3).

**C. Lead and Back-up Counsel (37 C.F.R. § 42.8(b)(3))**

Lead counsel: Steven R. Fairchild, USPTO Reg. No. 70,800, Fairchild Law LLC, 170 Parkside Avenue, 3F, Brooklyn, NY 11226; [steve@fairchildlegal.com](mailto:steve@fairchildlegal.com); (703) 994-0193; Facsimile: none.

Back-up counsel: Nathaniel Paul Potter, USPTO Reg. No. 79,616, Nathaniel P. Potter, Attorney at Law, LLC, P.O. Box 142, Butler, KY 41006; npotterip@gmail.com; (859) 466-2066; Facsimile: none.

**D. Service Information (37 C.F.R. § 42.8(b)(4))**

Petitioner consents to electronic service at steve@fairchildlegal.com and npotterip@gmail.com. Postal and hand-delivery address: Fairchild Law LLC, 170 Parkside Avenue, 3F, Brooklyn, NY 11226 (USPTO Customer No. 150652). Telephone: (703) 994-0193. Facsimile: none.

**E. Power of Attorney (37 C.F.R. § 42.10(b))**

A power of attorney appointing the counsel identified above is filed concurrently with this Petition.

**F. Payment of Fees (37 C.F.R. § 42.15(b))**

The post-grant review request and post-institution fees under 37 C.F.R. § 42.15(b)(1)–(2), totaling \$59,375, are paid upon filing; no excess-claim fee is due under § 42.15(b)(3)–(4). The Office is authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 60-7927.

### **III. GROUNDS FOR STANDING AND PGR ELIGIBILITY**

#### **III.A. Grounds for Standing (37 C.F.R. § 42.204(a))**

Petitioner certifies that the '184 patent is available for post-grant review and that Petitioner is not barred or estopped from requesting post-grant review of the challenged claims on the grounds identified in this Petition. Petitioner does not own the '184 patent. Before the filing of this Petition, neither Petitioner nor any real party-in-interest identified in § II.A filed a civil action challenging the validity of any claim of the '184 patent. 35 U.S.C. § 325(a)(1); 37 C.F.R. § 42.201(a). Neither Petitioner, any real party-in-interest, nor any privy of Petitioner is estopped from challenging the claims on these grounds. 35 U.S.C. § 325(e)(1); 37 C.F.R. § 42.201(b).

#### **III.B. PGR Eligibility and Timeliness (35 U.S.C. § 321(c); AIA § 6(f)(2)(A))**

The '184 patent issued December 9, 2025. A petition for post-grant review may be filed no later than nine months after the grant of the patent. 35 U.S.C. § 321(c); 37 C.F.R. § 42.202(a). This Petition is filed no later than September 9, 2026, and is timely.

The '184 patent is subject to the first-inventor-to-file provisions of the America Invents Act. Post-grant review is available for patents described in AIA § 3(n)(1), i.e., patents that contain, or contained at any time, a claim having an

effective filing date on or after March 16, 2013. AIA § 6(f)(2)(A), Pub. L. No. 112-29, 125 Stat. 284, 311 (2011); 35 U.S.C. § 100(i). The earliest application from which the '184 patent claims benefit is U.S. Provisional Application No. 63/419,155, filed October 25, 2022; it further claims benefit of U.S. Provisional Application No. 63/433,203 (filed December 16, 2022) and PCT/US2023/035920 (filed October 25, 2023). Because the entire priority chain post-dates March 16, 2013, the '184 patent is eligible for post-grant review.

### **III.C. Discretionary Considerations**

Under the Office's interim process (Process Memoranda of March 26, 2025 and October 17, 2025), discretionary considerations are briefed separately and decided by the Director; if Patent Owner requests discretionary denial, Petitioner will respond fully in its opposition brief. The prosecution and PCT history relevant to the merits is set out in § V.C.

## **IV. IDENTIFICATION OF THE CHALLENGE (37 C.F.R. § 42.204)**

### **IV.A. Challenged Claims and Relief Requested**

Petitioner challenges all 20 issued claims of the '184 patent, Claims 1–20, and requests institution of post-grant review and a final written decision determining that each challenged claim is unpatentable. 37 C.F.R. §§ 42.22(a)(1), 42.204(b)(1).

## IV.B. Grounds of Unpatentability

| Ground | Statutory basis                                                                                                                                                         | References / basis                                                                                                                                                                                                                                                                                                                                                                                                                                    | Claims                                    |
|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| 1      | 35 U.S.C. § 112(a),<br><br>lack of written<br><br>description (Claims 1–20); separately and in the alternative, lack of enablement (Claims 1–11, 17, and 18) (§ IX.A.7) | The '184 patent (Ex. 1001) and the Omidian Declaration (Ex. 1015). The specification does not reasonably convey possession of the claimed about-4.5-mg modified-release method providing both recited ranges. In the alternative, the specification does not enable that result without undue experimentation; Dr. Omidian is relied on for the development program left to the skilled artisan (Ex. 1015 ¶¶ 27–30), and the enablement conclusion is | WD: 1–20;<br><br>enablement: 1–11, 17, 18 |

| Ground | Statutory basis                                                                                                                                                                                                                                                      | References / basis                                                                                                                                                                                                                                                                                                                                                                              | Claims |
|--------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
|        |                                                                                                                                                                                                                                                                      | Petitioner's. § IX.A.                                                                                                                                                                                                                                                                                                                                                                           |        |
| 2      | 35 U.S.C. § 112(b),<br><br>indefiniteness;<br><br>separately and in the<br><br>alternative, § 112(a),<br><br>lack of written<br><br>description and<br><br>enablement under<br><br>Patent Owner's<br><br>anticipated narrowing<br><br>construction (§<br><br>IX.B.5) | The '184 patent (Ex. 1001),<br><br>including the definition of<br><br>"cardiac effect" at col. 5, ll.<br><br>34–40; the published clinical<br><br>pharmacology of minoxidil<br><br>(Exs. 1005, 1006, 1007,<br><br>1018). "No cardiac effects"<br><br>is tied to no method,<br><br>threshold, or period<br><br>distinguishing no effect from<br><br>an undetected or trivial one.<br><br>§ IX.B. | 19, 20 |
| 3A     | 35 U.S.C. § 112(b),<br><br>indefiniteness                                                                                                                                                                                                                            | The '184 patent (Ex. 1001)<br><br>and the Omidian Declaration<br><br>(Ex. 1015). Claims 12–16<br><br>recite release-kinetic orders<br><br>with no governing<br><br>dissolution method or                                                                                                                                                                                                        | 12–16  |

| Ground | Statutory basis                                            | References / basis                                                                                                                                                                                                                            | Claims                   |
|--------|------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|        |                                                            | classification rule; the patent's own 10 mg prototype receives different classifications under different methods (cols. 97–98). § IX.C.                                                                                                       |                          |
| 3B     | 35 U.S.C. § 112(a),<br>lack of enablement<br>(alternative) | The '184 patent (Ex. 1001) and the Omidian Declaration (Ex. 1015). No formulation-specific example or design guidance enables zero-order (Claim 12) or second-order (Claim 16) release at about 4.5 mg without undue experimentation. § IX.C. | 12, 16                   |
| 4      | 35 U.S.C. § 103                                            | Sinclair-535 (Ex. 1003) in view of Reynolds 2002 (Ex. 1004). § IX.D.                                                                                                                                                                          | 1, 3–7, 9, 11, 13–15, 18 |
| 5A     | 35 U.S.C. § 103                                            | Vañó-Galván 2021 (Ex.                                                                                                                                                                                                                         | 1, 5–7, 9, 11,           |

| Ground | Statutory basis | References / basis                                                                                                                                                                                                  | Claims                    |
|--------|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
|        |                 | 1005) in view of<br><br>Sinclair-535 (Ex. 1003),<br><br>Fleishaker 1989 (Ex. 1006),<br><br>the Loniten label (Ex. 1007),<br><br>and Reynolds 2002 (Ex. 1004), each reference's role identified in § IX.E.1. § IX.E. | 18, 19, 20                |
| 5B     | 35 U.S.C. § 103 | The Ground 5A combination further in view of Beach 2021 (Ex. 1019). § IX.E.                                                                                                                                         | 8, 10                     |
| 6      | 35 U.S.C. § 103 | Sinclair-535 (Ex. 1003) in view of Cardinal (Ex. 1012) and Fleishaker 1989 (Ex. 1006). § IX.F.                                                                                                                      | 1–7, 9, 11, 13–15, 17, 18 |

Within each § 103 ground, Petitioner relies on the particular combination and rationale identified in the corresponding merits section; the grounds are distinct paths. Ground 4 is the two-reference path: an oral-minoxidil reference in

view of Reynolds's tunable HPMC matrix, the same architecture the Office applied to the '184's sibling application, where it combined Sinha with Reynolds (Ex. 1029; § V.C). Grounds 5A and 5B add the clinical-use, human immediate-release pharmacokinetic, and label evidence, and are the only § 103 route to Claims 8, 10, 19, and 20. Ground 6 rests on references that each name minoxidil. The reasonable-expectation showing common to Grounds 4–6 is set out at § IX.D.0. The prosecution-history facts bearing on the Office's prior consideration of this art are set out at § V.C; the sibling application's Sinha-and-Reynolds rejection is offered only as nonbinding corroboration of the materiality of Reynolds's teachings. The '184's own prosecution contains no rejection applying Sinclair-535 or Reynolds.

Post-grant review may be instituted where the information presented shows that it is more likely than not that at least one challenged claim is unpatentable. 35 U.S.C. § 324(a); 37 C.F.R. § 42.208(c). If instituted, review proceeds on all challenged claims and all grounds. 37 C.F.R. § 42.208(a). Each ground independently meets that standard for the claims it reaches; Grounds 1–3 additionally raise § 112 challenges available in post-grant review. 35 U.S.C. § 321(b).

#### **IV.C. Exhibit List**

Pursuant to 37 C.F.R. § 42.63(e), the Appendix of Exhibits following the certificates identifies each exhibit by number with a brief description, and the exhibits accompany this Petition. The Appendix is excluded from the word count. 37 C.F.R. § 42.24(a)(1).

#### **V. SUMMARY OF THE '184 PATENT**

##### **V.A. Claims**

The '184 patent issued with 20 claims: independent Claim 1; Claims 2–19, each depending directly from Claim 1; and Claim 20, depending from Claim 19. Every challenged claim therefore incorporates Claim 1's "about 4.5 mg" limitation.

Claim 1 recites a method of treating hair loss by orally administering a modified-release pharmaceutical formulation comprising about 4.5 mg of minoxidil, or a molar-equivalent amount of a pharmaceutically acceptable salt thereof, wherein the formulation "provides" a C<sub>max</sub> of about 0.25–20 ng/mL and a T<sub>max</sub> of about 30–360 minutes. All 20 claims are reproduced verbatim in the Claim Listing appendix, which is excluded from the word count. 37 C.F.R. § 42.24(a)(1).

## V.B. Specification

The '184 patent is a continuation of the application that issued as the '688 patent and carries forward that disclosure. The following features are material to this Petition.

1. No 4.5 mg modified-release formulation made, tested, or exemplified in the specification. Table 8 (Example 6) discloses four prototype compositions, A–D, containing 2 mg or 10 mg of minoxidil in a 150 mg tablet, using HPMC K4M or HPMC K200M as the release modifier. Tables 9–10 and FIGS. 6–7 (Example 7) report in-vitro dissolution for 2.5 mg and 10 mg batches. No 4.5 mg formulation is made, tested, or exemplified, and no experiment or result is reported at that dose; outside the claims, the value appears only inside dose enumerations — among more than forty values spanning about 0.125–100 mg (col. 13, l. 58 to col. 14, l. 3), and among twenty values spanning about 0.625–10 mg in an embodiment chain that reaches the HPMC K4M/K200M release modifier (cols. 51–52; col. 56, ll. 46–53). The surrounding embodiments recite the claim's remaining elements only separately: a T<sub>max</sub> of about 30–360 minutes in embodiments of its own (col. 57), a C<sub>max</sub> of about 2.5–20 ng/mL — a subrange of the claimed concentrations — under the same HPMC branch (col. 57), and the claimed about 0.25–20 ng/mL C<sub>max</sub> in standalone embodiments reciting no dose and

no Tmax (e.g., cols. 51, 58). No embodiment expressly links about 4.5 mg to either claimed window: after the dose list, the general description recites a steady-state blood level, the claimed Cmax, and the claimed Tmax in separate "In some embodiments" sentences for a generic daily dose (col. 14, ll. 35–58), identifying no formulation shown to provide them.

2. No measured in-vivo pharmacokinetic result for any modified-release prototype. Example 5 describes a proposed Phase 1 crossover study of modified-release prototypes and reports no result. The specification states that "[n]o PK studies in humans have been previously conducted with MR oral formulations of minoxidil" and that the relevance of the findings from "other products containing minoxidil" to modified-release oral formulations "is not known, but it is the only supportive information currently available." (Ex. 1001, cols. 65–66; quoted in full at § IX.A.3.) The only tabulated human pharmacokinetic measurements are the immediate-release data in Table 3 (col. 67), which reproduce the 2.5, 5, and 10 mg values reported in Fleishaker 1989 (compare Ex. 1006, Table I), not data from any prototype of Patent Owner, and not at 4.5 mg.
3. The case reports do not supply the missing evidence. Examples 1–2 report subjective hair-growth and blood-pressure observations with divided immediate-release dosing; 1.25 mg four times daily (Example 1), and 2.5 mg

twice daily, then 0.625 mg four times daily (Example 2). Neither identifies a disclosed modified-release formulation, a 4.5 mg dose, or any C<sub>max</sub>, T<sub>max</sub>, or composition. Example 2 records a consistent systolic decrease of approximately 10 mmHg at 2.5 mg immediate release. Example 1 records that the patient "did not observe any change in heart rate, systolic blood pressure, or diastolic blood pressure >10% from baseline" and reports no "cardiac effects", an observational criterion that the specification's definition of "cardiac effect" (feature 5) does not adopt. Examples 3–4 report decisions not to treat two patients with arrhythmias. None of Examples 1–5 reports efficacy or pharmacokinetic results from any tested modified-release prototype.

4. "About" is expressly defined, with a prior-art carve-out. The definition appears at col. 4, l. 49 to col. 5, l. 10 and is quoted and addressed at § VII.A.
5. "Cardiac effect" is defined categorically. The specification defines "cardiac effect" as "any effect on the heart or the vascular system as a result of the administration of a pharmaceutical formulation" (col. 5, ll. 34–40), identifies a hemodynamic change in blood pressure as one such effect, and lists tachycardia, hypotension, premature ventricular contractions, and other tachyarrhythmias as examples. The definition and its relationship to Claims 19–20 are addressed at §§ VII.B and IX.B.

6. The modified-release experimental disclosure is compositions and in-vitro dissolution at other doses. Example 6 gives the Table 8 compositions at 2 mg and 10 mg; Example 7 reports one-stage and two-stage dissolution at 2.5 mg and 10 mg; FIGS. 2–7 are in-vitro dissolution; FIG. 1 is the proposed study design. No modified-release prototype is reported as administered to any human.
7. The kinetic characterization depends on the dissolution method. The specification states that the 10 mg one-stage dissolution data "exhibits pseudo zero order kinetics (Table 9 and FIG. 6)" and that "a 2-stage dissolution results in more of a first-order release profile with a large burst due to the acid-stage (Table 10 and FIG. 7)." (Ex. 1001, cols. 97–98.) FIGS. 6–7 also carry reference curves labeled "Pseudo Zero Order (Estimated from PBPK Slides)" and "Pseudo First Order (Estimated from PBPK Slides)", estimated reference curves, not measurements. The specification discloses no procedure or criterion for deciding whether a formulation satisfies any of the five kinetic-order limitations of Claims 12–16. See § IX.C.

### **V.C. Prosecution History**

Application No. 19/094,716 was filed March 28, 2025 as a continuation of Application No. 18/437,724, which issued as the '688 patent, and was examined by Examiner Raymond J. Henley III, Art Unit 1629. The only Office Action was a

Non-Final Office Action mailed April 28, 2025, rejecting the pending claims solely for nonstatutory double patenting over the '688 patent (Ex. 1035 at 48–52); Applicant responded and filed a terminal disclaimer. Three Notices of Allowability followed: the original mailed June 18, 2025; a Corrected Notice mailed August 8, 2025, after the June 27, 2025 information disclosure statement; and a Corrected Notice mailed October 21, 2025, after the September 15 and 18, 2025 information disclosure statements. In each, Box 6 ("Examiner's Statement of Reasons for Allowance") was left unchecked, and no statement of reasons for allowance was provided. (Ex. 1035 at 81–89; see § VII.E.)

The Examiner's PTO-892 identified only the '688 patent (Ex. 1035 at 53). At the PCT stage, the International Searching Authority's written opinion found every examined claim (97 claims) to lack inventive step under PCT Article 33(3) over combinations including Follica/Barman (Ex. 1039), Williams (Ex. 1008), Sinclair-535 (Samson) (Ex. 1003), Biovail (Ex. 1009), and Cardinal (Ex. 1012) (Ex. 1023, Box V and at 31–33). The opinion is nonbinding; Petitioner cites it only as the record of what the Office, acting as ISA, found in the international phase. Sinclair-535 was listed on information disclosure statements (Ex. 1035 at 14, 24, 37) and initialed as considered (*id.* at 14, 24), as were Reynolds, Cardinal, Fleishaker, Vañó-Galván, and Panchaprateep (Ex. 1001 at 1–3); the prosecution history contains no rejection or written discussion applying it to any claim. Sinha

(Ex. 1034) was likewise listed (Ex. 1035 at 65, 70) and initialed (*id.* at 70) and was not applied or discussed. Sinha (Ex. 1034) is prior art under 35 U.S.C. § 102(a)(2) as of the September 27, 2022 international filing date of PCT/US2022/044912 (published as WO 2023/055740); the certified provisional (Ex. 1043) could only move that date earlier under § 102(d)(2). Sinha was not published before October 25, 2022; Petitioner does not cite it for what a POSITA then knew or as motivation for any combination. In a later, non-final Office Action in sibling Application No. 19/094,703, the same Examiner applied Sinha in view of Reynolds to reject every then-pending claim (Ex. 1029); Petitioner relies on it only as the Office's own later reading of the architecture asserted in Ground 4. The '184 prosecution history contains no rejection under 35 U.S.C. § 112 and no written discussion of the written-description, enablement, or indefiniteness issues presented in Grounds 1–3.

## **VI. PERSON OF ORDINARY SKILL IN THE ART (POSITA)**

Petitioner applies the earliest asserted priority date, October 25, 2022; the level of ordinary skill would not have differed materially at any later effective filing date. A POSITA as of that date was a pharmaceutical scientist with an advanced degree, including a Ph.D. in pharmaceutics, polymer science, or chemical engineering, and two to three years of working experience with oral modified-release dosage forms, including hydrophilic matrices such as HPMC, lipid and hydrophobic matrices, reservoir systems, osmotic systems, and

multiparticulate systems, and familiarity with the pharmacokinetic principles used in formulation development, including C<sub>max</sub>, T<sub>max</sub>, and AUC; or, absent an advanced degree, a bachelor's or master's degree with at least five years of experience developing oral modified-release platforms. (Ex. 1015 ¶ 15.)

Petitioner's expert, Dr. Hossein Omidian, who also publishes as Hamid Omidian and is a Professor of Pharmaceutical Sciences, testifies to the level of skill in the art and to the formulation science on which the challenged claims turn. His declaration is Ex. 1015 and his curriculum vitae is Ex. 1049. He opines on oral modified-release formulation science and the biopharmaceutic principles by which release from a dosage form affects systemic drug input: the design and behavior of hydrophilic-matrix and other modified-release architectures, dissolution methodology and the assessment of release kinetics, the formulation variables available to a POSITA, and what the '184 specification does and does not teach a formulator. (Ex. 1015 ¶¶ 16, 27–37, 47–53.) He does not offer opinions on therapeutic dose selection, patient management, clinical interpretation, or independently modeled clinical pharmacokinetic endpoints. (Ex. 1015 ¶ 16.)

Petitioner does not rely on him to establish Claim 1's numerical C<sub>max</sub> and T<sub>max</sub> limitations or Claim 2's eight-hour limitation. Where pharmacokinetic values bear on the analysis, the Petition relies on the values as reported in the exhibits of record and on the '184 patent's own statements, identified where cited, and no

pharmacokinetic modeling or extrapolation is required; the reasons a POSITA would have treated dose and release rate as result-effective variables, and the reasonable expectation that follows, are set out with record support at § IX.D.0. Petitioner does not rely on a dermatology expert; the hair-loss indications recited in Claims 5–11 are established by the cited clinical literature itself (Ex. 1003 ¶ [0030]; Ex. 1005; Ex. 1019).

## VII. CLAIM CONSTRUCTION

Under 37 C.F.R. § 42.200(b), the Board applies the claim-construction standard used in a civil action under 35 U.S.C. § 282(b). Claim terms receive their ordinary meaning to a POSITA in light of the intrinsic record. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005) (en banc). A patentee acts as its own lexicographer where it "clearly set[s] forth a definition" and "clearly express[es] an intent" to redefine the term. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365–66 (Fed. Cir. 2012); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Only terms necessary to resolve the controversy require express construction. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Petitioner construes Claim 1's C<sub>max</sub> and T<sub>max</sub> "wherein ... provides" clauses as limiting for the reasons explained in § VII.E.

**VII.A. "about 4.5 mg of minoxidil" (Claim 1; carried into all dependent claims)**

The patentee is its own lexicographer for "about." The specification at col. 4, l. 49 to col. 5, l. 10 provides:

"Typically, the term 'about' as used herein means greater or lesser than the value or range of values stated by 1/10 of the stated values, e.g., +10%. The term 'about' also refers to variations that would be recognized by one skilled in the art as being equivalent so long as such variations do not encompass known values practiced by the prior art."

For purposes of this Petition, the express numerical component of that definition yields 4.05–4.95 mg. The additional reference to POSITA-recognized equivalents and the prior-art exclusion need not be given complete metes and bounds: Petitioner does not assert that "about 4.5 mg" is indefinite and does not rely on a construction extending the term beyond its expressly stated  $\pm 10\%$  component. Petitioner does not contend that 5 mg falls within that range. The same component applies to each other "about" value in Claim 1, so that the recited C<sub>max</sub> window reads about 0.225–22 ng/mL and the T<sub>max</sub> window about 27–396 minutes, and C<sub>max</sub> and T<sub>max</sub> are single-dose values as the specification defines them (Ex. 1001, cols. 6–7) and as Table 3 reports them. Grounds 4–6 explain why

selecting about 4.5 mg would have been obvious in view of the prior art's disclosed doses and dose ranges.

#### **VII.B. "no cardiac effects" (Claims 19–20)**

The specification at col. 5, ll. 34–40 defines "cardiac effect" as "any effect on the heart or the vascular system as a result of the administration of a pharmaceutical formulation," adds that "[a] cardiac effect can be a hemodynamic change in blood pressure," and states that "[a] cardiac effect can be selected from tachycardia, hypotension, premature ventricular contractions, and other tachyarrhythmias." Under that express definition, "no cardiac effects" requires the absence of any effect on the heart or vascular system resulting from administration of the formulation. The identified effects are nonexclusive examples; they do not narrow the definition's reference to "any effect."

The definition identifies no measurement method, observation period, detection threshold, magnitude, duration, or other objective criterion for determining whether an "effect" exists. Petitioner does not propose supplying those missing parameters through claim construction. Ground 2 explains why their absence prevents Claims 19 and 20 from informing a POSITA, with reasonable certainty, where "no cardiac effects" ends and a physiologically present but unobserved, transient, or clinically insignificant effect begins.

A construction limited to "clinically significant" effects would contradict the specification's express reference to "any effect." If Patent Owner nevertheless proposes such a construction, the specification supplies no objective standard for clinical significance, as Ground 2 addresses; Ground 5 separately addresses obviousness under that narrowing construction, resting on the design objective Sinclair states (§ IX.E.4).

#### **VII.C. "modified release pharmaceutical formulation" (Claim 1)**

The patentee is its own lexicographer for this term. The specification at col. 6, ll. 16–25 defines "modified release" as "pharmaceutical compositions that do not otherwise release the entirety of the active ingredient immediately," which "may release the active ingredient at a sustained or controlled rate over an extended period of time, or may release the active ingredient after a lag time after administration," and states that "[m]odified release includes extended release, sustained release, controlled release, and delayed release." (Ex. 1001, col. 6, ll. 16–25.) Petitioner applies that express definition; its application to the prior art is addressed in Grounds 4–6.

#### **VII.D. Release-kinetics terms (Claims 12–16)**

The specification defines each kinetic order at cols. 5–8:

- Zero order release (Claim 12; col. 8, ll. 41–45): "rate of drug release ... constant and independent of the concentration of the reactants. ...  $\text{rate} = k$ , with  $k$  having the units of  $\text{M/sec}$ ."
- Pseudo zero order release (Claim 13; col. 7, ll. 8–13): "appears to follow zero order kinetics, but is actually a result of a first order reaction with a large excess of one of the reactants."
- First order release (Claim 14; col. 5, ll. 63–67): " $\text{rate} = k[A]$  (or  $B$  instead of  $A$ ), with  $k$  having the units of  $\text{sec}^{-1}$ ."
- Pseudo first order release (Claim 15; col. 7, ll. 14–20): "a second order or bimolecular reaction that is made to behave like a first-order reaction."
- Second order release (Claim 16; col. 7, ll. 21–28): " $\text{rate} = k[A]^2$  (or substitute  $B$  for  $A$  or  $k$  multiplied by the concentration of  $A$  times the concentration of  $B$ ), with the units of the rate constant  $\text{M}^{-1} \text{sec}^{-1}$ ."

Petitioner applies these express definitions. They describe apparent and underlying reaction orders using chemical-reaction rate laws, but do not identify the dissolution conditions, sampling interval, mathematical transformation, fitting method, goodness-of-fit criterion, or other procedure by which a POSITA would determine whether a dosage form satisfies a particular claimed order. Petitioner does not propose supplying those parameters through construction; their absence is addressed in Ground 3.

## VII.E. Claim 1's "wherein ... provides" clauses are limiting

Claim 1 recites a method "comprising orally administering ... a modified release pharmaceutical formulation comprising about 4.5 mg of minoxidil ...; wherein the modified release pharmaceutical formulation provides: a C<sub>max</sub> of minoxidil that is about 0.25 ng/ml to about 20 ng/ml; and a T<sub>max</sub> of minoxidil that is about 30 to about 360 minutes." The two numerical pharmacokinetic clauses are substantive limitations on the formulation administered in the claimed method.

First, the clauses appear in the body of the claim, use the affirmative verb "provides," and state two separately enumerated numerical requirements. They do not describe the purpose of treating hair loss; they specify which modified-release formulations containing about 4.5 mg fall within the claim, only those that provide both recited results. Reading them as non-limiting would remove express numerical requirements from the body of the claim. *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed. Cir. 2005); *Griffin v. Bertina*, 285 F.3d 1029, 1033–34 (Fed. Cir. 2002).

Second, Claim 1 is otherwise open-ended. It requires a modified-release formulation containing about 4.5 mg of minoxidil but specifies no excipient, release-controlling material, architecture, coating, or release profile, variables that affect systemic drug input. The C<sub>max</sub> and T<sub>max</sub> clauses constrain that otherwise open-ended universe of formulations by requiring specific pharmacokinetic

performance. That is the functional relationship given limiting effect in *Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370, 1374–76 (Fed. Cir. 2019).

Third, the patentee treated the clauses as substantive throughout the family: every independent claim of the '688 patent recites them (Ex. 1002, cols. 100–102), '688 Claim 14 pairs them with "about 4.5 mg," and the '184's original claims recited them as filed. They are performance requirements, not statements of intended use.

Petitioner therefore construes Claim 1 as requiring administration of a modified-release formulation that provides both the recited C<sub>max</sub> and the recited T<sub>max</sub>. Whether a prior-art formulation satisfies those limitations is a merits question for Grounds 4–6. If Patent Owner instead contends that either clause lacks patentable weight, Claim 1 is correspondingly broader, and Grounds 4–6 independently address its remaining limitations.

## **VIII. STATE OF THE ART AS OF OCTOBER 25, 2022**

The following describes the knowledge reflected in the publicly available art before October 25, 2022. The particular combinations asserted against each challenged claim, including the evidence of motivation to combine and reasonable expectation of success, are addressed claim by claim in Grounds 4–6 and at § IX.D.0.

### **VIII.A. Clinical use of low-dose oral minoxidil for hair loss**

Before October 25, 2022, the clinical use of low-dose oral minoxidil for hair loss was documented in clinical practice. Vañó-Galván 2021 reported a retrospective multicenter study of 1,404 patients treated with low-dose oral minoxidil for hair loss at ten centers in six countries, across multiple forms of alopecia, and reported systemic adverse events, lightheadedness, fluid retention, and tachycardia, that were infrequent in that cohort. (Ex. 1005 at 1645, 1647–48, Tables I–II.) Oral administration of minoxidil for alopecia had been proposed decades earlier: Bazzano, WO 83/02558, disclosed oral preparations ("tablets, liquids, capsules") for treating alopecias, an oral dose range of 0.01–10.0 mg/kg, and a worked tablet example (Ex. 1040 at 7, 10–11); the Sinclair/Samson family later disclosed low-dose oral minoxidil across the alopecias, including a range of about 0.1–20 mg for telogen effluvium (Ex. 1041 at 39, claim 17).

### **VIII.B. Immediate-release and sublingual minoxidil pharmacokinetics**

The pharmacokinetics of immediate-release oral minoxidil had been measured at doses on either side of the claimed 4.5 mg. Fleishaker 1989 reported a Latin-square crossover study in 30 healthy subjects receiving single immediate-release oral doses of 2.5, 5, and 10 mg, with C<sub>max</sub> of 16.8 ng/mL at 2.5 mg and 37.2 ng/mL at 5 mg and the corresponding T<sub>max</sub>, AUC, and half-life values (Ex. 1006 at 162; *id.* at 164, Table I). The Loniten® label and earlier publications

describe oral minoxidil absorption, pharmacology, and hemodynamic activity (Exs. 1007, 1017, 1018); none reports modified-release human pharmacokinetics. Bokhari reported a mean peak plasma concentration following the initial 0.45 mg sublingual dose and restated Fleishaker's 2.5 and 5 mg oral peaks (Ex. 1013); Petitioner relies on it only for the data it reports.

### **VIII.C. Minoxidil-specific formulation disclosures**

Sinclair-535 disclosed minoxidil formulations and methods for treating hair loss (Ex. 1003). It described orodispersible embodiments and, in an embodiment paragraph following ¶ [0011]'s introduction of "an orodispersive dose," stated that "the dose of minoxidil results in a minoxidil blood concentration of about 0.25 ng/mL to about 10 ng/mL" (¶ [0013]), a statement relied on only as an objective in that embodiment sequence, not as measured results from a swallowed modified-release product (Ex. 1015 ¶ 40); reported conventional swallowed-oral dosing data; 2.5 mg and 5 mg producing peak serum concentrations of 18.5 and 41 ng/mL at one hour (¶ [0146]); identified 20 ng/mL as "[t]he serum concentration threshold for any hemodynamic response," citing a steady-state intravenous-infusion study (¶ [0145]; see also ¶¶ [0148], [0164]); and described swallowed oral minoxidil in clinical use for androgenetic alopecia (¶ [0150]). It also enumerated dosage forms including a "lipid matrix tablet" (¶ [0017]); Grounds 4–6 identify the modified-release teachings relied upon.

#### **VIII.D. Conventional modified-release formulation technology**

Hydrophilic-matrix tablets employing polymers such as HPMC were well-known and routinely used modified-release platforms before the priority date. Reynolds and Cardinal describe conventional matrix architectures and the variables used to set release rate and duration (Exs. 1004, 1012). Dr. Omidian explains that these were the standard tools of a modified-release formulator and that changing release behavior could directionally lower the peak and delay its timing relative to immediate release (Ex. 1015 ¶¶ 47–53); he is relied on for those tools and their direction only. The numerical showing is at § IX.D.0.

#### **VIII.E. Cardiovascular pharmacology and reported safety observations**

Minoxidil's cardiovascular mechanism was established in the art. The Loniten® label describes minoxidil as an "orally effective direct acting peripheral vasodilator" that lowers blood pressure by "decreasing peripheral vascular resistance," with reflex responses including increased heart rate and cardiac output and salt-and-water retention (Ex. 1007); Lowenthal and Affrime describe "a potent oral vasodilator acting on the arteriolar side of the circulation" (Ex. 1018). Fleishaker reported blood-pressure and pulse effects that "were generally small and of little clinical significance" (Ex. 1006 at 162); Vañó-Galván reported infrequent lightheadedness, fluid retention, and tachycardia in clinical use (Ex. 1005). Ground

2 and Ground 5 address the distinction between the definition's "any effect" and a clinically significant adverse effect.

Petitioner does not contend that every modified-release minoxidil formulation necessarily satisfies the claimed ranges.

## **IX. THE CHALLENGED CLAIMS ARE UNPATENTABLE**

**IX.A. GROUND 1 — § 112(a) written description: the specification does not reasonably convey possession of the claimed method of administering an about-4.5-mg modified-release minoxidil formulation that provides both recited C<sub>max</sub> and T<sub>max</sub> ranges; certain dependent claims add further unsupported result-defined limitations**

### **IX.A.1. Governing law**

Under 35 U.S.C. § 112(a), the specification must "contain a written description of the invention." The test is whether the disclosure "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The inquiry is objective and confined to the four corners of the specification; reciting a desired result does not itself show possession. *Id.* at 1349, 1351.

Where a claim is defined by a functional or performance result, the specification must reasonably convey that the inventor possessed formulations achieving that result, by a representative species, by structural features common to the members that achieve it, or by a disclosed correlation between formulation and result; it may not merely recite the result. *Ariad*, 598 F.3d at 1349–53 (a plan for obtaining the claimed invention does not show possession); *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1344–49 (Fed. Cir. 2013) (a plan to identify variants achieving the claimed function, without "blaze marks" to the claimed species, does not describe it). The Federal Circuit has applied that rule to claims defined by an in-vivo pharmacokinetic result. In *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326–27 (Fed. Cir. 2000), claims to a controlled-release formulation defined by a Cmax/C24 ratio lacked written description even though the specification contained pharmacokinetic data from which qualifying values could be calculated, because no "blaze marks" directed the reader to that ratio as the invention. The same rule governs in post-grant review. *Purdue Pharma L.P. v. Collegium Pharm., Inc.*, 86 F.4th 1338 (Fed. Cir. 2023) (affirming post-grant-review finding of no written description).

Three further rules apply. A dose that appears in the specification only as one value in a list of ranges, with nothing linking it to the claimed effect, is not described merely because it is on the page. *Biogen Int'l GmbH v. Mylan Pharms.*

*Inc.*, 18 F.4th 1333, 1343 (Fed. Cir. 2021), reh'g en banc denied, 28 F.4th 1194 (Fed. Cir. 2022). A recited performance result is not described where the specification supplies nothing from which a POSITA would credit that the described formulation achieves it. *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368, 1380–84 (Fed. Cir. 2019). And a disclosure that merely renders the claimed invention obvious does not describe it. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571–72 (Fed. Cir. 1997).

Enablement is related but distinct. The specification must teach a POSITA to make and use the full scope of the claimed invention without undue experimentation; where a claim covers a class defined by the result it achieves, the class must be enabled, and a research assignment does not suffice. *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610–15 (2023); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

#### **IX.A.2. Claim 1 is not a dose claim; it claims a result-defined formulation**

This challenge does not rest on a categorical rule that clinical testing or actual reduction to practice is required. The absence of measured in-vivo pharmacokinetic data is one component of the total disclosure. The specification also identifies no about-4.5-mg modified-release formulation as providing either claimed range, no example achieving both, and no reasoned relationship by which a POSITA would recognize that any disclosed formulation possesses those

properties; its in-vitro dissolution data at other doses (cols. 97–98) and "Estimated from PBPK Slides" curves (FIGS. 6–7) are not in-vivo data for any modified-release formulation. The recited ranges therefore remain stated targets, not demonstrated properties of an invention the specification shows the inventors possessed.

Claim 1 does not claim "about 4.5 mg of minoxidil" simpliciter. It claims a method of orally administering a "modified release pharmaceutical formulation" comprising about 4.5 mg of minoxidil that "provides" both a C<sub>max</sub> of "about 0.25 ng/ml to about 20 ng/ml" and a T<sub>max</sub> of "about 30 to about 360 minutes." Under § VII.E those are limitations of the administered formulation, so Claim 1 covers the subset of about-4.5-mg modified-release formulations that generate both recited human results. The specification's own definition makes that subset structurally heterogeneous: "modified release" includes extended, sustained, controlled, and delayed release and is confined to no particular matrix, coating, osmotic, reservoir, or multiparticulate architecture (Ex. 1001, col. 6, ll. 16–25; § VII.C). The claim identifies no structural feature separating formulations inside the envelope from those outside it. Dr. Omidian explains that target exposure values do not identify the formulation that produces them; substantially different input profiles can produce the same exposure values, so a formulation scientist starting from the

target alone cannot identify a single correct formulation or even a single correct release curve (Ex. 1015 ¶ 23).

The dependent claims add further results: a blood level of about 1–20 ng/mL "maintained" for at least about eight hours (Claim 2), five release-kinetic classifications (Claims 12–16), and "no cardiac effects" (Claim 19). None repairs the absence of possession of Claim 1's formulation-and-result combination; several deepen it (§ IX.A.6).

Patent Owner may respond that the claimed Cmax and Tmax ranges appear *ipsis verbis* in the specification, and that under *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1308–09 (Fed. Cir. 2015), a property inherent in an adequately described formulation need not itself be described, while under *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190–91 (Fed. Cir. 2014), written description requires neither examples nor an actual reduction to practice. Neither answers the defect here, because the defect is not the absence of clinical testing as such; it is the absence of any disclosure identifying a formulation, or a technically meaningful class of formulations, as possessing the claimed combination of dose and in-vivo pharmacokinetic properties. *Allergan* credited the recited clinical results because the specification described the very formulation claimed, so that the results were properties of a described species; *Alcon* likewise concerned the stability of a described formulation. Here the '184 identifies no 4.5 mg formulation

as providing either claimed window and reports no in-vivo result for any modified-release formulation at any dose (§ IX.A.3); the recited properties do the work of identifying the claimed species. The ranges appear in the specification exactly as they appear in the claims: as targets. *Ariad*, 598 F.3d at 1350.

**IX.A.3. The specification states the envelope but identifies no embodiment that provides it**

The only human pharmacokinetic data in the '184 is prior-art, immediate-release Loniten data reproduced from Fleishaker (Table 3, col. 67; Ex. 1006, Table I) and not a study of any modified-release formulation of Patent Owner. The specification says so five times:

"To date, no clinical safety and efficacy studies have been conducted with MR oral formulations of minoxidil or a pharmaceutically acceptable salt thereof." (Ex. 1001, § 6.4, col. 70.)

"Given the well-established safety and efficacy profile of minoxidil ..., no non-clinical or clinical studies in humans have been conducted with MR oral formulations of minoxidil ... to date." (*Id.*, col. 65, § 5.3.)

"Applicant has not conducted any non-clinical studies with MR oral formulations" of minoxidil. (*Id.*, col. 65, § 5.3.1.)

"No PK studies in humans have been previously conducted with MR oral formulations of minoxidil or a pharmaceutically acceptable salt thereof." (*Id.*, col. 66, § 5.3.2.)

The relevance of the prior immediate-release findings "to MR oral formulations ... remains to be determined" (*id.*, col. 65, § 5.3) and "is not known, but it is the only supportive information currently available" (*id.*, col. 66, § 5.3.2).

The last two concede Ground 1's core proposition on the face of the patent. The '184 thus presents a stronger case than *Faulding*, where the specification at least contained measured pharmacokinetic data from which the claimed ratio could be derived and still failed for want of blaze marks; here, by the patentee's own admission, no modified-release pharmacokinetic study was conducted, so there is neither the data nor the nexus.

The described development work is prospective. In the cols. 63–64 protocol, Regimens C–F are dosed "TBD mg" from pharmacokinetics not yet generated; prototypes "will be selected from" a "design space" of 2–10 mg and 6–18 h never narrowed to 4.5 mg; and a footnote pre-commits that "[n]o dose selected will be expected to result in a geometric mean C<sub>max</sub> >20 ng/ml" or exceed 30 mg. A stated acceptance criterion is not a disclosed embodiment that satisfies it: variables and a plan, but no example, as in *Novozymes*.

The figures confirm the predictive character of the disclosure. The only curves the specification associates with its release objectives are labeled "Estimated from PBPK Slides" (FIGS. 6–7, in-figure curve labels; Ex. 1015 ¶ 32), and four of Table 11's seven solubility values are "theoretically determined" from a European patent (Ex. 1001, col. 99, ll. 21–23). Estimates are not forbidden; the defect is that the patent discloses no model, inputs, validation, or correlation from which a POSITA could identify which about-4.5-mg formulations would produce the claimed results, and the estimate-labeled curves show in-vitro release and not plasma concentration (Ex. 1015 ¶ 24).

#### **IX.A.4. The worked examples do not bridge formulation structure to the claimed in-vivo result**

The specification's only worked compositions (Table 8, col. 97) are HPMC K4M / HPMC K200M matrix tablets at 2 mg and 10 mg; its dissolution data are single-stage profiles for those prototypes (FIGS. 2–5) and one- and two-stage profiles for a separate 030448 batch series at 2.5 mg and 10 mg (Tables 9–10; FIGS. 6–7; cols. 97–98); the specification does not identify which, if any, Table 8 composition corresponds to those batches (Ex. 1015 ¶ 24). None is an about-4.5-mg formulation, and no prototype or batch is reported with any measured plasma concentration, C<sub>max</sub>, or T<sub>max</sub>. Petitioner does not contend that every dose requires its own example or that in-vitro testing can never support an in-vivo

limitation; the narrower point is that this patent provides neither an example having the claimed in-vivo result nor a disclosed relationship by which a POSITA could infer it from the examples. Dr. Omidian explains that the specification discloses no relationship, measured or modeled from measured inputs, connecting any composition or its in-vitro release to the claimed human exposure values (Ex. 1015 ¶ 24). His opinion is not based merely on the absence of human testing or actual reduction to practice; it rests on the absence of a disclosed structure-to-performance correlation supporting the claimed result (Ex. 1015 ¶ 25).

The recited floor confirms the result-defined breadth of the claim. The 0.25 ng/mL lower endpoint matches the endpoint of the blood-concentration range Sinclair states (Ex. 1003 ¶ [0013], "about 0.25 ng/mL to about 10 ng/mL"); in the '184 it appears only as a recited number. The specification's own human exposure data (Table 3, col. 67) bottom out at 16.8 ng/mL, and nothing in the disclosure describes a 4.5 mg formulation producing a peak near 0.25 ng/mL or explains how one would be reached. Dr. Omidian confirms that the specification reports no formulation producing a peak at or near the recited floor and discloses no relationship between formulation variables and that value (Ex. 1015 ¶ 25). The patentee recited a range its disclosure gives the skilled artisan no way to reach.

Patent Owner may also invoke *Nalpropion Pharms., Inc. v. Actavis Labs. FL, Inc.*, 934 F.3d 1344, 1348–50 (Fed. Cir. 2019), which affirmed written

description for a sustained-release dissolution-profile limitation supported by the patentee's own data generated with a different dissolution method. *Nalpropion* credited existing measurements of the claimed formulation taken by a different method; here there is no data to credit. The '184 contains no measured in-vivo pharmacokinetics of any modified-release formulation at any dose, by the patentee's own admissions (§ IX.A.3); flexibility in crediting data cannot supply data that does not exist.

The specification's description of the release architectures Claims 12–16 recite is likewise borrowed: its osmotic-pump and matrix-tablet taxonomy at cols. 16–17 reproduces the corresponding passage of U.S. Pub. No. 2020/0108008, an olaparib sustained-release publication it incorporates by reference (cols. 16–17, 44), with minoxidil substituted for olaparib. A description carried over from a different drug at a different dose, with no minoxidil embodiment or result attached to it, is a list of platforms a POSITA could investigate and not a disclosure that the inventors possessed a 4.5 mg formulation meeting the claimed envelope.

#### **IX.A.5. The original claims and the priority documents do not supply the missing possession**

Claim 1's dose and pharmacokinetic limitations appeared in the claims as originally filed. Original claims form part of the original disclosure, but original claim language does not by itself demonstrate possession of a result-defined genus.

*Ariad*, 598 F.3d at 1349–50. The original claim shows that the applicant claimed the target; neither it nor the remainder of the disclosure identifies a representative formulation achieving it, structural features common to formulations that do, or a formulation-to-pharmacokinetic correlation by which a POSITA could recognize the members of the genus.

Patent Owner may invoke *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, No. 2024-1094, slip op. at 9–12 (Fed. Cir. Apr. 16, 2026) (petition for reh'g en banc filed June 17, 2026), for the proposition that, where a claim uses a well-known genus that is not itself the invention, the specification read in light of background knowledge may disclose a representative number of species. The claimed genus here is not uniform for the claimed purpose: not every modified-release formulation of about 4.5 mg produces both recited results, the specification identifies no member that does, and the patentee itself states that the relevance of immediate-release data to modified-release formulations "is not known" (Ex. 1001, cols. 65–66). Dr. Omidian explains that routine development tools alone do not make a particular bounded C<sub>max</sub>, T<sub>max</sub>, eight-hour, or kinetic-order result predictable without quantitative data for that endpoint (Ex. 1015 ¶ 50). Nor is there tension with Grounds 4–6: obviousness asks whether a POSITA would reasonably have expected at least one embodiment to succeed; written description asks what the inventors disclosed as possessed; enablement asks whether the full scope can

be practiced without undue experimentation; that the tools are routine does not make a result-defined genus enabled across every architecture it embraces (Ex. 1015 ¶¶ 27, 30, 50). Claim 1 is not limited to the HPMC matrices the specification happens to show; it covers every architecture the definition embraces (col. 6; § VII.C), and even for the HPMC species the specification never identifies which of Prototypes A–D, or which point in its 2–10 mg and 6–18 h design space, is described as providing the claimed windows at about 4.5 mg; the cap is a stop rule for a study not yet run (col. 63, n. b) and not a description of a formulation that satisfies it. *Lockwood*, 107 F.3d at 1571–72.

The prior art supplied the expectation on which Grounds 4–6 rely; the specification does not identify the embodiment, and "a description that merely renders the invention obvious does not satisfy the requirement." *Ariad*, 598 F.3d at 1352; *Lockwood*, 107 F.3d at 1571–72.

The provisional applications are corroborative and not the premise of the ground: the complete specification fails whatever date Claim 1 receives, and no earlier document cures the defect. In both provisionals (Summaries, Ex. 1010 ¶¶ [0001]–[0009] and Ex. 1011 ¶¶ [0001]–[0009], state no numerical dose) "about 4.5 mg" appears only inside undifferentiated dose lists, never with both windows (Ex. 1010 ¶¶ [0051], [0097], [00131], [00203], claim 49; Ex. 1011 ¶¶ [0055], [00107], [00147], [00269], claim 99), and the issued specification carries the list forward

(col. 13, l. 58 – col. 14, l. 3). Dr. Omidian confirms that the Summaries and the Ex. 1010 passages do not identify the dose-plus-peak-plus-time combination Claim 1 recites (Ex. 1015 ¶ 26) and that the issued specification presents 4.5 mg as one entry among more than forty enumerated values (¶ 44). Petitioner submits this is *Biogen*: a dose present on the page as one of dozens, linked to neither claimed window. Independently of Dr. Omidian's opinion, the issued specification's sibling embodiments do not supply the combination: the twenty-dose list and the 2.5–20 ng/mL recitation are separate alternative narrowings of the same HPMC embodiment (cols. 56–57), one reciting no window and the other no dose, and even combined they recite no T<sub>max</sub>, span only a subrange of the claimed concentrations, and rest on no measured result for any formulation.

#### **IX.A.6. The dependent claims do not cure and in several instances deepen the defect**

Every challenged claim incorporates Claim 1. Petitioner does not contend that the added limitations of Claims 3–11 and 17 are themselves undescribed; each incorporates Claim 1's undescribed combination and adds nothing that identifies a formulation providing it. Claims 3–4 (excipients), 5–10 (indications), 11 (regrowth), and 18 (dosing frequency) identify no formulation shown to provide Claim 1's envelope. Claim 17 adds an enteric coating. The specification lists candidate enteric polymers and the general acid-resistant mechanism (Ex. 1001,

col. 18) but discloses no about-4.5-mg coated embodiment, no coating tied to any release outcome in vivo, and no resulting exposure data.

Claim 2 adds another in-vivo result: a blood level of about 1–20 ng/mL maintained for at least about eight hours. The patent provides no measured modified-release concentration-time curve at any dose, much less one establishing that duration at about 4.5 mg (§ IX.A.3).

Claims 12–16 add release-order labels, addressed independently in Ground 3. The labels do not identify an embodiment that provides Claim 1's envelope: the only kinetic-order characterizations the specification attaches to measured prototype data are the method-dependent labels on the 10 mg data, "pseudo zero order" under the one-stage method and "more of a first-order release profile" under the two-stage method (cols. 97–98), in-vitro release at a different dose. Claim 19 adds "no cardiac effects," and Claim 20 enumerates effects; both are addressed independently in Ground 2, and the specification reports no cardiovascular assessment of any about-4.5-mg modified-release product.

Claims 1–20 therefore lack written description.

#### **IX.A.7. In the alternative, Claims 1–11, 17, and 18 are not enabled across their scope**

Claim 1 spans every modified-release architecture the specification's definition embraces, matrix, reservoir, osmotic, multiparticulate, enteric (col. 6, ll.

16–25; § VII.C), so long as an about-4.5-mg formulation produces both claimed ranges. The patent provides no working example within that result-defined genus and no validated rule for moving from composition and dissolution to the claimed human result. *Amgen*, 598 U.S. at 610–15. Dr. Omidian describes what is left to the skilled artisan: a choice among nine fundamentally different delivery platforms operating by different mechanisms with different materials and processing (Ex. 1015 ¶ 27); then, within a single matrix platform, experimental determination across interacting variables of polymer, drug loading, filler, tablet geometry, porosity, compression, and processing, where naming a commercial HPMC grade does not by itself teach which material and structure will produce the required performance (Ex. 1015 ¶ 28); then selection of a discriminating dissolution method and testing across fast, intermediate, and slow prototypes to learn how formulation changes move exposure (Ex. 1015 ¶ 29). The general techniques are routine; reaching each claim's particular acceptance criteria from this disclosure is not routine verification (Ex. 1015 ¶ 30). That is the research program the patent's own future-tense protocol outlines (§ IX.A.3). See *Wyeth LLC v. AstraZeneca Pharms. LP*, No. 2024-2325, slip op. at 14–15, 19 (Fed. Cir. July 9, 2026) (method-of-treatment claims reciting a "unit dosage" not enabled by in vitro data and "projected" dose ranges where the specification "disclosed no actual dosages for

any compound within the scope of the claims"; the artisan's knowledge supplements but cannot substitute for that disclosure).

The *Wands* factors confirm undue experimentation for Claim 1. Breadth: every modified-release architecture of about 4.5 mg that meets both ranges. Guidance: none at 4.5 mg (§ IX.A.4). Working examples: none in vivo, at any dose. Predictability: the patentee's own statement that the relevance of its only human data to modified-release formulations "is not known" (col. 66, § 5.3.2). Quantity of experimentation: Dr. Omidian describes the choice among fundamentally different delivery platforms and testing across fast, intermediate, and slow prototypes to identify how formulation changes affect systemic exposure (Ex. 1015 ¶¶ 27–29); Petitioner submits the claim's full scope requires that work for each architecture the definition embraces, with no disclosed formulation-to-exposure relationship to start from, and the specification's own protocol commits to that program without narrowing it (cols. 63–64; § IX.A.3). *Wands*, 858 F.2d at 737.

The dependent claims are addressed separately. Claims 3–11 and 18 supply no formulation-to-exposure information and narrow neither the architectures nor the envelope; each fails with Claim 1. Claim 17 narrows the dosage form to an enteric-coated formulation, but the specification's generic enteric-polymer list (col. 18) identifies no 4.5 mg enteric-coated formulation, no coating connected to the

claimed ranges, and no in-vivo data for any enteric-coated embodiment; the unguided program remains. Claim 2 adds a further in-vivo result, the eight-hour blood level, for which the specification supplies no measurement, model, or formulation-specific guidance at any dose, and is not enabled a fortiori. Claims 12–16 are addressed under Ground 3 and Claims 19–20 under Ground 2; Petitioner does not rely on Claim 1's non-enablement alone to establish the unpatentability of any dependent claim.

#### **IX.A.8. Conclusion on Ground 1**

Under *Ariad*, *Novozymes*, and *Faulding*, the dispositive absence is any disclosed member, common structural feature, or correlation linking the genus to the recited combination at about 4.5 mg — an absence the patentee's own § 5.3 admissions concede. Because no dependent claim supplies the missing description, Petitioner has shown that it is more likely than not that Claims 1–20 are unpatentable under § 112(a) for lack of written description, and requests a final written decision so holding; in the alternative, Claims 1–11, 17, and 18 are unpatentable for lack of enablement for the reasons stated at § IX.A.7.

**IX.B. GROUND 2 — Claims 19 and 20 are indefinite under § 112(b): "no cardiac effects" fails to inform a POSITA with reasonable certainty whether the limitation is met, because the patent ties no measurement method, detection threshold, magnitude criterion, or assessment period to that term**

**IX.B.1. Governing law**

A patent must inform a POSITA, with reasonable certainty, of the scope of the invention. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). Terms of degree and functional limitations are not inherently indefinite, but the intrinsic record must provide objective boundaries or a reasonably certain way to determine whether the limitation is met. *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370–74 (Fed. Cir. 2014); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341–45 (Fed. Cir. 2015). A claim whose scope turns on a measurement is indefinite where the record does not say which of several outcome-determinative methods governs. *Dow Chem. Co. v. Nova Chems. Corp.*, 803 F.3d 620, 630–35 (Fed. Cir. 2015).

*Nevro Corp. v. Boston Scientific Corp.*, 955 F.3d 35, 39–40 (Fed. Cir. 2020), held a "paresthesia-free" limitation not indefinite because the specification gave "detailed guidance and examples" of signal parameters from which a POSITA "would know whether" a system produced that reported sensation. Claim 19 is governed instead by a definition reaching "any effect on the heart or the vascular

system" of a drug whose action is itself vascular, with no measurement by which absence would be established.

### **IX.B.2. The patent's definition makes Claim 19 depend on an unspecified observation and causation protocol**

The specification defines "cardiac effect" as "any effect on the heart or the vascular system as a result of the administration of a pharmaceutical formulation," adds that such an effect "can be a hemodynamic change in blood pressure," and lists tachycardia, hypotension, premature ventricular contractions, and "other tachyarrhythmias" as examples. Ex. 1001, col. 5, ll. 34–40. The definition's first sentence is operative lexicography; the others are illustrative. The absolute form is deliberate: the specification's own embodiments repeatedly recite "substantially no cardiac effects" (e.g., col. 56, ll. 1–3), and Claim 8 of the parent '688 patent claims "substantially no cardiac effects" (Ex. 1002, col. 100); Claim 19 deletes the qualifier, foreclosing a construction that softens "no" to "substantially no." The specification also recites, separately, hair regrowth "with substantially no clinically significant hemodynamic changes in blood pressure" (col. 27; col. 55, ll. 64–67); the patentee knew how to state a clinical-significance qualifier and stated none in Claim 19. Claim 19 recites that oral administration "results in no cardiac effects," with no qualifier such as "clinically significant" or "substantially." Ex. 1001, Claim 19.

The phrase is categorical at the conceptual level, but applying it requires choices neither the claim nor its definition fixes:

- what variable must be measured: blood pressure, heart rate, rhythm, cardiac output, vascular resistance, symptoms, or another endpoint;
- what instrument, precision, and detection threshold governs;
- when and for how long the subject must be observed after dosing;
- whether the comparison is within-subject baseline, placebo, population normal, or another control;
- how ordinary physiologic variability and measurement error are treated; and
- how an observed change is attributed "as a result of" the formulation rather than background variation, activity, anxiety, concomitant medication, or another cause.

Without those rules, the same administered formulation and subject could satisfy or fail the claim depending on the sensitivity of the instrument, timing and frequency of measurement, baseline convention, or attribution rule. That is a boundary problem and not merely an evidentiary disagreement.

### **IX.B.3. The intrinsic record supplies no objective test**

The specification is not short of numbers; it is short of a rule tied to the claim term. Example 5's dose rationale calls a heart-rate increase ">5 bpm" significant (Ex. 1001, col. 69); its protocol for a study reported as not conducted

(*id.*, cols. 66, 70) sets a screening exclusion for orthostatic hypotension (*id.*, col. 77), a baseline "[f]or the purpose of withdrawal criteria" (*id.*, col. 74), a mild-to-severe adverse-event scale (*id.*, col. 84), and vital-sign and ECG schedules (*id.*, cols. 86–87). None decides whether an administered formulation produced a "cardiac effect." Nor does the statement that "[h]emodynamic effects are typically seen above plasma concentrations of 20 ng/mL," from which the same column predicts that cardiovascular effects "are not expected" from modified-release use (*id.*, col. 71): it states frequency and a prediction, but not what counts; the column reports T-wave alterations in approximately 60% of treated patients and commits to ECG monitoring "for cardiovascular effects"; and a Claim 19 that merely restated Claim 1's ceiling would add nothing to it. The ">5 bpm" criterion is the heart-rate rule behind the study's 20 ng/mL exposure cap; blood pressure, the definition's own first example, receives none there (*id.*, col. 69). The specification does not say whether an "effect" means an adverse event, a clinically or statistically significant change, or a change exceeding measurement variability, and supplies no threshold at which a measured hemodynamic response counts as "no cardiac effects" under its own definition. Ex. 1015 ¶ 56.

Nor does Example 1. That case report states that a patient on 1.25 mg four times daily "did not observe any change in heart rate, systolic blood pressure, or diastolic blood pressure >10% from baseline" and noticed no "cardiac effects." Ex.

1001, Example 1. A ten-percent change criterion in one anecdote is not a definition, is not in Claim 19, and is not the categorical "any effect" the specification defines. If anything, it is one more yardstick applied to a term the patent's definition ties to none, which is the reasonable-certainty problem and not its cure. See *Enviro Tech Chem. Servs., Inc. v. Safe Foods Corp.*, No. 2024-2160, slip op. at 6 (Fed. Cir. May 4, 2026) (specification's "conflicting guidance" on a term's boundary defeated reasonable certainty). Example 2 then reports a "consistent decrease of systolic blood pressure by approximately 10 mmHg" at 2.5 mg twice daily. Ex. 1001, Example 2. The specification never says whether that change is a "cardiac effect" or by what rule the question is decided.

#### **IX.B.4. The known pharmacology makes the missing protocol consequential**

The defect is not that Claim 19 is negative or broad; negative limitations are not indefinite for that reason alone. It is that the intrinsic record ties no method, threshold, magnitude, or assessment period to the term, and accepted methods classify the same patient differently.

Two documentary facts turn the gap into a demonstration. The Loniten label reports that changes "in direction and magnitude of the ECG T-waves occur in approximately 60% of patients," with no associated symptoms. Ex. 1007 at 9, § 7(a). Vañó-Galván advises that a baseline electrocardiogram is unnecessary at doses of 5 mg or less, ordering one case by case. Ex. 1005 at 1649. Under the "any

effect" definition, an asymptomatic T-wave change occurring in most treated patients is a "cardiac effect," yet the art's practice at hair-loss doses is not to record an ECG; whether an administration falls inside Claim 19 depends on whether anyone looked. Fleishaker reported time- and treatment-related blood-pressure and pulse findings while characterizing the changes as generally small or clinically insignificant (Ex. 1006 at 162). Vañó-Galván reported a favorable overall safety experience yet tabulated tachycardia, fluid retention, and lightheadedness in subsets of its 1,404 patients. Ex. 1005 at 1648, Table II. A change may thus be detected yet described as minor; the patent never says whether it is an "effect," whether an undetected change counts, or which monitoring conditions govern. A boundary that turns on the happenstance of monitoring is not an objective boundary. A vascular response is a continuous variable read against physiological noise, unlike a discrete sensation a patient reports as present or absent; whether an "effect" exists depends on the instrument, the timing, and the threshold chosen, the specification fixes none of them, and the same administration therefore falls inside Claim 19 under one accepted protocol and outside it under another. *Nautilus*, 572 U.S. at 910; *Dow*, 803 F.3d at 634–35.

**IX.B.5. "No clinically significant cardiac effects" is not the claim, and Patent Owner's narrowing construction fails § 112(a)**

Patent Owner may ask the Board to read "no cardiac effects" as "no clinically significant cardiac effects." The express "any effect" definition forecloses that narrowing. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365–66 (Fed. Cir. 2012). The two alternatives are stated once: under the broad construction Claim 19 fails § 112(b) for the reasons above; under the narrow construction it fails § 112(a), and Ground 5 addresses it over the prior art.

Under the narrow construction, enablement fails because the specification discloses no in-vivo human safety data for any modified-release formulation at any dose and defines "clinical significance" only as "the practical importance of a treatment effect on daily life" (col. 5, ll. 41–43), no metric, threshold, or protocol; a POSITA could not, without undue experimentation, identify and practice embodiments that satisfy the limitation across its scope. The *Wands* factors apply as in Ground 3B. Written description fails on the same record: no working example, pharmacokinetic datum, clinical datum, or defined threshold shows possession of an about-4.5-mg modified-release formulation that avoids clinically significant cardiovascular effects (§ IX.A). *Ariad*, 598 F.3d at 1351. Under the categorical construction the same defects follow from the specification's silence (§§ IX.A.3, IX.B.3); Petitioner offers no clinical opinion on that point.

#### **IX.B.6. Claim 20 does not cure the defect**

Claim 20 recites tachycardia, hypotension, premature ventricular contractions, and other tachyarrhythmias. The most favorable reading for Patent Owner is that Claim 20 requires none of the listed effects. Even then, the patent ties no diagnostic threshold, monitoring method, duration, baseline, or causal-attribution standard to any item. A transient heart-rate change may or may not be called tachycardia depending on threshold and context; hypotension depends on a numerical or clinical convention; and rhythm findings depend on monitoring modality and duration. Claim 20 therefore inherits Claim 19's uncertainty and does not supply the missing boundary; each enumerated effect still needs an assessment window, a per-patient or population convention, and a measurement protocol, and the specification provides none.

#### **IX.B.7. Ground 2 conclusion**

Because the patent supplies no reasonably certain rule for deciding whether administration caused "any effect" on the heart or vascular system, Claims 19 and 20 are indefinite under § 112(b). Claims 19 and 20 are more likely than not unpatentable under § 112.

**IX.C. GROUND 3A — Claims 12–16 are indefinite under § 112(b): the patent supplies no dissolution conditions, kinetic model, fitting interval, goodness-of-fit threshold, or classification rule by which a POSITA could determine with reasonable certainty whether a formulation exhibits zero-order, pseudo-zero-order, first-order, pseudo-first-order, or second-order release. GROUND 3B (alternative) — Claims 12 and 16 lack enablement under § 112(a): the patent does not enable an about-4.5-mg modified-release minoxidil formulation exhibiting zero-order or second-order release without undue experimentation**

#### **IX.C.1. Governing law**

Claims must inform a POSITA, with reasonable certainty, of the scope of the invention, *Nautilus*, 572 U.S. at 910, and a claim whose scope turns on a measurement is indefinite where the intrinsic record does not identify which of several outcome-determinative methods governs. *Dow*, 803 F.3d at 630–35. Under § 112(a), the specification must enable the full scope of each claim without undue experimentation, *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); a claim to a class requires enablement of the class, *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610–15 (2023), and a research assignment does not suffice. *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1160–63 (Fed. Cir. 2019). The ground does not rest on the proposition that overlapping claims are inherently indefinite. Different claims may overlap. The defect is that the patent supplies no reproducible measurement

and classification procedure for deciding which of its mechanistic or apparent-order labels applies to a dissolving dosage form.

### **IX.C.2. The claimed kinetic classifications**

- 12 — Zero order — col. 8, ll. 41–45 ("rate=k"; constant and independent of reactant concentration)
- 13 — Pseudo zero order — col. 7, ll. 8–13 ("appears to follow zero order kinetics, but is actually a result of a first order reaction with a large excess of one of the reactants")
- 14 — First order — col. 5, ll. 63–67 ("rate=k[A]")
- 15 — Pseudo first order — col. 7, ll. 14–20 ("a second order or bimolecular reaction that is made to behave like a first-order reaction")
- 16 — Second order — col. 7, ll. 21–28 ("rate=k[A]<sup>2</sup>" or k[A][B])

Ground 3A reaches all five alternative dependent claims (§ VII.D); Ground 3B, in the alternative, reaches Claims 12 and 16. The § 112 and § 103 challenges are pleaded in the alternative.

### **IX.C.3. Ground 3A — the patent's own prototype data demonstrate method dependence**

The specification describes the 10 mg prototype, including batch 030448-008, as exhibiting "pseudo zero order kinetics" under one-stage dissolution (Table

9; FIG. 6; col. 97) and describes the two-stage data, which include the same batch (Table 10), as showing "more of a first-order release profile with a large burst due to the acid-stage" (FIG. 7; col. 98). Which classification controls depends on a method the claims and specification never specify. The two-stage description is inconsistent with treating the one-stage "pseudo zero order" label as an intrinsic property of batch 030448-008. Ex. 1015 ¶ 36. The same prototype, tested two ways, falls under Claim 13 or Claim 14 depending on the environment chosen. *Nautilus*, 572 U.S. at 910; *Dow*, 803 F.3d at 634–35.

The omission is structural. The specification uses three dissolution conditions: pH 7.2 phosphate buffer, USP Apparatus II at 75 rpm for FIGS. 2–5; 900 mL of pH 6.8 buffer at 50 rpm for FIG. 6; the two-stage acid-then-buffer method for FIG. 7, and designates none as controlling, while observing that minoxidil "likely has pH sensitive solubility." Ex. 1015 ¶¶ 33–34. That the specification attributes the divergence to an acid-stage burst explains why the methods differ; it does not say which method decides whether a formulation "exhibits" a claimed order, and confirms that the choice is outcome-determinative (¶¶ 33–34). It identifies no controlling apparatus, medium, agitation rate, assessment window, model, goodness-of-fit criterion, or rule for comparing fits. Ex. 1015 ¶ 33. Even the two-stage description specifies no apparatus or agitation rate and reports no discriminating-power assessment or model-fitting protocol (Ex.

1015 ¶ 34). Nor does the specification define the period over which a claimed order must hold: Claim 12 in particular specifies no duration over which zero order must be maintained (¶ 37). A profile that is first-order over a 24-hour test may fit a zero-order model comparably over a shorter, unstated interval, leaving the boundary between Claims 12 and 14 undeterminable. Hydrophilic-matrix profiles may fit adjacent empirical models comparably depending on the selected method and interval. Ex. 1015 ¶ 33.

#### **IX.C.4. Ground 3A — the reaction-kinetics definitions add ambiguity rather than an operational boundary**

The specification's equations describe chemical-reaction kinetics in concentration units, while the claims concern drug release from a dosage form. The patent does not explain how its rate expressions map onto cumulative mass released in a dissolution vessel, and never translates them into a dissolution-based criterion. Ex. 1015 ¶ 33.

The pseudo-order definitions also combine mechanistic and apparent classifications. "Pseudo zero order" is defined as behavior that appears zero order but is actually attributed to a first-order reaction under excess-reactant conditions; "pseudo first order" similarly depends on an asserted underlying bimolecular mechanism. Yet the patent gives no procedure for identifying that underlying mechanism in a tablet. The overlap is not itself the legal defect; it confirms that an

appearance-based curve fit alone does not determine which claimed category applies. The definitions turn on mechanism ("appears to follow ... but is actually ...") while the only evidence a POSITA has is an empirical profile. This showing rests on the intrinsic record and reaches all of Claims 12–16.

#### **IX.C.5. Ground 3B — Claims 12 and 16 are not enabled at "about 4.5 mg"**

Claim 12: Constant-rate zero-order release is not the default behavior of the simple hydrophilic cellulose matrix the specification discloses; it is typically pursued with osmotic or other specially designed architectures. Ex. 1015 ¶¶ 32, 35. The '184 recites zero-order release only inside an omnibus string listing all five kinetic orders as alternatives (e.g., col. 13, ll. 14–20; col. 50, embodiment XX; col. 55, embodiment KKKKK), attached to no composition, dose, dissolution condition, or result; no embodiment is characterized as producing it. Its prototypes are HPMC hydrophilic matrix tablets (Table 8), and the two-stage profiles release faster early and then slow toward a plateau. Ex. 1015 ¶¶ 32, 35. The only zero-order-labeled data are the method-dependent 10 mg matrix data (§ IX.C.3). The ground is not that zero-order release was unknown (Cardinal, Ex. 1012 ¶ [0038], defines a "zero-order release pattern"); it is that the patent does not teach how to obtain it at about 4.5 mg with Claim 1's envelope. The incorporation of U.S. Pub. No. 2020/0108008 (cols. 16–17, 44) establishes that osmotic platforms for approximately zero-order release were known. On its face, that publication (Ex.

1053) reports such performance for olaparib, which it describes as "an insoluble drug" requiring "solubilization treatment," at unit doses of "20 to 400 mg," roughly four to ninety times the claimed dose, in worked examples for olaparib alone; it does not disclose an about-4.5-mg minoxidil formulation, demonstrate zero-order release of minoxidil under a governing assessment method, or show that any such formulation produces Claim 1's C<sub>max</sub> and T<sub>max</sub> combination (Ex. 1053 ¶ [0021] ("an insoluble drug"); *id.* at 16 (release models), 18–19 (Example 1, 100 tablets), 25 (unit dose)). The '184 reproduces that publication's dosage-form taxonomy with minoxidil substituted for olaparib (§ IX.A.4). The specification supplies no worked, dose-specific minoxidil osmotic embodiment, no dissolution result for one, and no formulation-to-pharmacokinetic correlation (Ex. 1015 ¶¶ 24, 32). Petitioner submits that what is missing is how to practice the complete Claim 12 method: select an architecture, formulate and test candidates, choose a classification method, and determine whether the result provides Claim 1's envelope.

Claim 16: Second-order release is rarely a designed oral release profile. Ex. 1015 ¶ 32. The specification recites it only as the last alternative in the same omnibus string (col. 50, embodiment XX; col. 55, embodiment KKKKK), tied to no composition, dose, or result at any dose. The only controlled-release teaching the specification adopts from outside itself, U.S. Pub. No. 2020/0108008,

enumerates four release models, "zero-order, first-order, Higuchi or Ritger-Peppas," and does not contemplate second-order release at all. FIGS. 6 and 7 carry only "Pseudo Zero Order" and "Pseudo First Order" reference labels; the patent identifies no architecture or rule that produces its defined second-order behavior. Claim 16 cannot be practiced at the recited dose without de novo development the specification does not guide.

| <i>Wands</i> factor             | Claim 12 (zero order)                                                                                                                                                              |
|---------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1) Quantity of experimentation | A drug- and dose-specific osmotic or other specially designed embodiment developed on an established platform, then classified under an unfixed method (Ex. 1015 ¶¶ 32–33, 35, 37) |
| (2) Direction or guidance       | Generic osmotic enumeration; no minoxidil embodiment or dissolution data (Ex. 1001, cols. 16–17; Ex. 1015 ¶ 32)                                                                    |
| (3) Working examples            | None; only method-dependent matrix data (Ex. 1015 ¶ 33)                                                                                                                            |
| (4) Nature of the invention     | Result-defined order, no structural disclosure                                                                                                                                     |
| (5) State of the prior art      | Platforms known, not connected to minoxidil at this dose                                                                                                                           |

|                     |                                                                                                                                                                                 |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Wands</i> factor | Claim 12 (zero order)                                                                                                                                                           |
| (6) Level of skill  | Cannot supply missing minoxidil-specific guidance                                                                                                                               |
| (7) Predictability  | Low; constant-rate release is not the default behavior of the disclosed HPMC matrix absent additional design controls, and the specification supplies none (Ex. 1015 ¶¶ 32, 35) |
| (8) Breadth         | Every zero-order architecture at about 4.5 mg meeting Claim 1                                                                                                                   |

|                                 |                                                             |
|---------------------------------|-------------------------------------------------------------|
| <i>Wands</i> factor             | Claim 16 (second order)                                     |
| (1) Quantity of experimentation | Non-matrix architecture with no conventional model, de novo |
| (2) Direction or guidance       | None                                                        |
| (3) Working examples            | None                                                        |
| (4) Nature of the invention     | Same                                                        |
| (5) State of the prior art      | Rarely a designed oral release profile (Ex. 1015 ¶ 32)      |

|                     |                                                                 |
|---------------------|-----------------------------------------------------------------|
| <i>Wands</i> factor | Claim 16 (second order)                                         |
| (6) Level of skill  | Same                                                            |
| (7) Predictability  | Low; no disclosed architecture produces it                      |
| (8) Breadth         | Every second-order architecture at about 4.5 mg meeting Claim 1 |

The factors weigh decisively against enablement of each claim. *Wands*, 858 F.2d at 737.

#### **IX.C.6. Ground 3 conclusion**

Ground 3A: Claims 12–16 identify no dissolution method, interval, model, or fit criterion by which their alternative orders are determined, and the patent's own two labels for batch 030448-008 show why those omissions decide claim membership. They are indefinite under § 112(b). Ground 3B, in the alternative: Claims 12 and 16 are not enabled at the recited dose under § 112(a). The claims fall individually, and each is more likely than not unpatentable.

#### **IX.D. GROUND 4 — Claims 1, 3–7, 9, 11, 13–15, 18 are obvious under § 103 over Sinclair-535 in view of Reynolds 2002**

A POSITA would have been motivated to select an about-4.5-mg dose within Sinclair-535's low-dose oral-minoxidil teachings and to employ Reynolds's

tunable HPMC controlled-release matrix to moderate and delay systemic exposure, and, on the documentary showing at § IX.D.0, would reasonably have expected the resulting modified-release formulation to provide the recited Cmax and Tmax ranges.

#### **IX.D.0. Governing principles, prior-art status, and the reasonable expectation of success shared by Grounds 4–6**

The '184 itself acknowledges, immediately after reproducing Fleishaker's data in Table 3, that its 20 ng/mL "Cmax exposure limit" "is based on a set of previous studies" (Ex. 1001, cols. 69–70); Petitioner does not rely on that acknowledgment for motivation. Every one of those inputs is prior art: the 20 ng/mL threshold (Ex. 1003 ¶¶ [0145], [0164]), the immediate-release data (Ex. 1006, Table I), and the modified-release means of holding a peak beneath a ceiling (Ex. 1004). The result-effective variable is the matrix release rate, and Cmax is its recognized response: the Loniten label reports that immediate-release plasma levels "reach maximum within the first hour and decline rapidly" (Ex. 1007 at 2), and Reynolds teaches the matrix variables that set the release rate (Ex. 1004 at 457, 460–62). Dr. Omidian confirms that the established matrix toolkit supplied conventional means to reduce Cmax and move Tmax later (Ex. 1015 ¶ 38).

Obviousness turns on the scope and content of the prior art, its differences from the claims, the level of ordinary skill, and objective indicia. *Graham v. John*

*Deere Co.*, 383 U.S. 1, 17–18 (1966); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416–17 (2007). Optimizing a variable the art recognizes as result-effective is "normally obvious." *Pfizer Inc. v. Sanofi Pasteur Inc.*, 94 F.4th 1341, 1348 (Fed. Cir. 2024) (quoting *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977)); rejecting the argument that optimization applies only where a prior-art range overlaps the claimed one); *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1341 (Fed. Cir. 2020); *E.I. du Pont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018). The expectation "need only be reasonable, not absolute." *Pfizer*, 94 F.4th at 1352; *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1062 (Fed. Cir. 2024) (reasonable expectation of success for a claimed daily dose no reference had tested, drawn from neighboring reported regimens; "certainty and absolute predictability are not required").

Sinclair-535 itself reports swallowed-oral minoxidil at 2.5 mg producing a peak serum concentration of 18.5 ng/mL "[a]t one hour post-dose," and at 5 mg 41 ng/mL (Ex. 1003 ¶ [0146]); the published immediate-release literature reports the same pattern (accord Ex. 1006, Table I: 16.8 ng/mL at 2.5 mg, 37.2 ng/mL at 5 mg; t<sub>max</sub> 0.566/0.389/0.419 h). Because the immediate-release peak at 5 mg lies above the threshold and the peak at 2.5 mg lies just below it (Ex. 1003 ¶ [0146]; Ex. 1006, Table I), a POSITA would have expected an immediate-release dose between them to approach or exceed the threshold; Fleishaker reports "[n]o

significant effects" of dose on "dose normalized C<sub>max</sub>" across 2.5, 5, and 10 mg and concludes that the data "support dose-independent" kinetics (Ex. 1006 at 162), so the expectation of a proportionally higher immediate-release peak at a higher dose is a reported finding. Slowing release is the conventional answer. The expectation Grounds 4–6 require is that a conventional matrix would place the peak and its timing within windows spanning 0.25–20 ng/mL and 30–360 minutes, windows that already contain the 2.5 mg immediate-release values. By the patentee's own reading of the same data, the 5 mg immediate-release excursion above 20 ng/mL lasted "around 1 h" (Ex. 1001, col. 69), and the 2.5 mg dose produced none (Ex. 1006, Table I; Ex. 1003 ¶ [0146]). A form that releases over an extended period (Ex. 1004 at 460–62; Ex. 1012 ¶ [0002]), for a drug whose immediate-release form peaks within the first hour (Ex. 1007 at 2) and is eliminated with a reported half-life of approximately 1.1–4.2 hours (Ex. 1006, Table I; Ex. 1007 at 2), lowers the peak relative to immediate release; that fluctuation reduction is the stated purpose of controlled release (Ex. 1012 ¶ [0002]). Dr. Omidian confirms the direction, though not with certainty: a conventional matrix could be made to reduce C<sub>max</sub> and move T<sub>max</sub> later relative to immediate release (Ex. 1015 ¶¶ 38, 53). What the claim requires is that the peak fall below about 20 ng/mL (§ VII.A) and not that it land at a value. Dr. Omidian's ¶ 50 addresses a different question, whether routine formulation tools alone make a

particular bounded result predictable without quantitative data for that endpoint; he says they do not, and Petitioner does not rely on him for the window. The window showing rests on the documents alone: the published ceiling (Ex. 1003 ¶ [0145]), the immediate-release peaks on either side of the claimed dose (Ex. 1006, Table I; Ex. 1003 ¶ [0146]), and the stated purpose and direction of matrix release (Ex. 1012 ¶ [0002]; Ex. 1004 at 460–62). The specification, by contrast, supplies no measured result for any modified-release formulation (§ IX.A.3). This is not *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 676 F.3d 1063, 1069–70 (Fed. Cir. 2012), where the profile was targetable but no pharmacokinetic-pharmacodynamic relationship was known from which a targeted profile could be expected to be therapeutically effective; here the threshold that fixes the ceiling was published (Ex. 1003 ¶ [0145]), hair-growth efficacy was reported for swallowed oral minoxidil in clinical use (¶ [0150]; accord Ex. 1005) and at serum levels far below the ceiling (¶ [0143]), and Claim 1 recites no therapeutic-equivalence limitation. Petitioner does not attribute that showing to Dr. Omidian, who offers no opinion on the precise concentration, percentage reduction, or Tmax any particular formulation would produce (Ex. 1015 ¶ 53) and does not opine that the cited formulation art, without additional quantitative PK evidence, establishes Claim 1's numerical limitations (¶ 58(c)); the quantitative question is the one the enablement showing at § IX.A.7 concerns. Sinclair reports

that the 20 ng/mL threshold was established from "[t]welve hour steady state intravenous infusions" (Ex. 1003 ¶ [0145], citing Ferry 1996). It is a serum-concentration threshold, and Sinclair itself applies it to peak concentrations after sublingual and topical dosing (¶¶ [0148], [0164]). The 5 mg immediate-release dose exceeds that threshold on either reported value (Ex. 1003 ¶ [0146]; accord Ex. 1006, Table I).

Dr. Omidian's expectation is stated "though not with certainty": a conventional hydrophilic-matrix formulation could be made to reduce the peak and move Tmax later relative to immediate release (Ex. 1015 ¶ 53). The Office reached the same architecture, an oral-minoxidil reference in view of Reynolds, in rejecting the '184's sibling (Ex. 1029 at 5); Petitioner cites that non-final action as corroboration only and not as a theory of inherency.

Prior-art status of each reference:

- Sinclair-535 (Ex. 1003): oral minoxidil for hair loss; dose, serum, and threshold context; published Sept. 5, 2019; § 102(a)(1).
- Reynolds 2002 (Ex. 1004): HPMC matrix architecture and release-rate control; § 102(a)(1).
- Vañó-Galván 2021 (Ex. 1005): pre-priority clinical use and indications; § 102(a)(1).

- Fleishaker 1989 (Ex. 1006): immediate-release oral minoxidil pharmacokinetics; § 102(a)(1).
- Loniten label (Ex. 1007): oral dosage forms, dosing, and pharmacology; revised January 2015; § 102(a)(1).
- Cardinal (Ex. 1012): sustained-release matrix platform naming minoxidil; published June 24, 2010; § 102(a)(1).
- Beach 2021 (Ex. 1019): indication-specific clinical-use evidence; § 102(a)(1).

#### **IX.D.1. The references' complementary teachings**

Sinclair-535 discloses minoxidil for treating hair loss and the recited indications (Ex. 1003 ¶¶ [0001], [0008], [0030]); one-hour serum concentrations of 18.5 and 41 ng/mL at swallowed-oral doses of 2.5 and 5 mg (¶ [0146]); swallowed-oral minoxidil in clinical use for androgenetic alopecia (¶ [0150]); daily administration (¶ [0016]); and a "lipid matrix tablet" among its dosage forms (¶ [0017]). Its 0.25–10 ng/mL range (¶ [0013]) is cited only as a stated blood-concentration objective for its oral-mucosal embodiments.

Reynolds teaches controlled release of soluble drugs (promethazine HCl, diphenhydramine HCl, propranolol HCl) from HPMC matrix tablets, with release rate empirically tunable by tablet surface-area-to-volume ratio and the effect of

HPMC content established in the literature Reynolds cites (Ex. 1004 at 457–58; Ex. 1015 ¶ 40).

**IX.D.2. A POSITA had reason to combine Sinclair's oral-minoxidil method with Reynolds's matrix platform**

Sinclair reported that the 5 mg conventional dose produced a one-hour serum concentration above its own stated threshold while the 2.5 mg dose did not (Ex. 1003 ¶¶ [0145], [0146]). Reynolds offered a familiar matrix-tablet means of moderating that early input through adjustable formulation and geometry (Ex. 1004 at 457, 460–62). Minoxidil, a well-absorbed drug (Ex. 1007; Ex. 1015 ¶ 46), presents a conventional reason to consider a hydrophilic matrix (Ex. 1015 ¶ 40).

The proposed combination is specific: approximately 4.5 mg of minoxidil in a Reynolds-type HPMC matrix tablet for once-daily treatment of the conditions Sinclair identifies, with the known release-controlling variables adjusted toward the desired input profile. The motivation arises from Sinclair's treatment, dose, and concentration disclosures together with Reynolds's express matrix teachings, not from the challenged patent's later protocol. The dose is the routine adjustment two facts point to: Sinclair's 5 mg swallowed dose at 41 ng/mL exceeds the threshold while its 2.5 mg dose at 18.5 ng/mL does not (Ex. 1003 ¶¶ [0145], [0146]). An intermediate swallowed dose between the two Sinclair reports, within the construed 4.05–4.95 mg band (§ VII.A), is optimization of a recognized result-

effective relationship. *Pfizer*, 94 F.4th at 1348; *Genentech*, 946 F.3d at 1341; *KSR*, 550 U.S. at 416–17.

### **IX.D.3. Reasonable expectation of meeting Claim 1's two limitations; anticipated rebuttals**

The reasonable expectation is shown at § IX.D.0 on the documents.

Sinclair's preference for oromucosal delivery (§ [0008]) is a preference for one known solution and not a discouragement of another: Sinclair itself reports swallowed-oral minoxidil in clinical use (§ [0150]) and frames the same 20 ng/mL constraint that drives this combination (§§ [0145], [0164]). Its enumerated ranges reach 3 mg (§ [0014]); for swallowed dosing it reports the conventional 2.5 and 5 mg doses (§ [0146]). Its comparative statements prefer sublingual dosing on efficacy and first-pass grounds (§§ [0165]–[0166], [0169]) while reporting swallowed efficacy (§§ [0150], [0165]); § [0170] attributes sublingual 0.45 mg's advantage over oral 1 mg to "greater hair follicle bio-availability," a comparison of doses and routes and not a statement that a swallowed modified-release form cannot meet the stated ceiling; a preferred alternative is not a teaching away.

*Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 964 (Fed. Cir. 2014). The '184 identifies no criticality at 4.5 mg (Ex. 1015 § 44) and reports no modified-release human result from which an unexpected result could be shown (Ex. 1001, cols. 65–66; Ex. 1015 §§ 54, 57). Grounds 5 and 6 rely on this paragraph equally.

#### IX.D.4. Claim 1 mapping

|                                                                                                       |                                                                                 |
|-------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| Claim 1 limitation                                                                                    | Sinclair-535 + Reynolds 2002                                                    |
| Method of treating hair loss by orally administering to a human subject who is experiencing hair loss | Ex. 1003 ¶¶ [0001], [0008], [0030], [0146], [0150]                              |
| Modified-release pharmaceutical formulation                                                           | Ex. 1004 at 457–59 (HPMC matrix tablet); Ex. 1003 ¶ [0017] (motivation only)    |
| About 4.5 mg minoxidil                                                                                | Ex. 1003 ¶ [0146] (2.5 and 5 mg swallowed doses); § IX.D.2 (optimization)       |
| C <sub>max</sub> about 0.25–20 ng/mL                                                                  | Ex. 1003 ¶¶ [0145], [0146], [0164]; Ex. 1004 at 460–62; see § IX.D.0            |
| T <sub>max</sub> about 30–360 minutes                                                                 | Ex. 1003 ¶ [0146] ("[a]t one hour post-dose"); Ex. 1004 at 460–62; see § IX.D.0 |

#### IX.D.5. Dependent claims

Claims 3 and 4 recite a release modifier and a filler, glidant, or lubricant; Reynolds teaches HPMC as the release-controlling polymer with conventional matrix-tablet excipients (Ex. 1004 at 459). Claims 5–7 and 9 recite female pattern hair loss, alopecia areata, telogen effluvium, and lichen planopilaris, each identified by Sinclair (Ex. 1003 ¶ [0030]). Claim 11 recites hair regrowth; Sinclair reports oral minoxidil used to treat androgenetic alopecia with a terminal-hair increase in a head-to-head study (¶ [0150]; see ¶ [0146]). Claim 18 recites administration at least once daily; Sinclair states that "the dose of minoxidil is administered daily" (¶ [0016]).

Claims 13–15 recite pseudo-zero-order, first-order, and pseudo-first-order release. To the extent Claims 13–15 are found definite (contrary to Ground 3A), their kinetic-order limitations are met by the conventional matrix profiles the references report, as follows. Reynolds reports the release profiles of conventional HPMC matrices (Ex. 1004 at 460–62), and the characteristic behavior of HPMC hydrophilic matrices lies in the first-order, pseudo-first-order, and pseudo-zero-order regime (Ex. 1015 ¶ 32); under any construction giving these claims determinable scope, Petitioner submits that a POSITA adjusting a Reynolds matrix would have expected a profile within that regime. Claims 13–15 are alternatives; a POSITA tuning a Reynolds matrix in the ordinary way would obtain a profile the '184 would label with one of the three, and the choice among them describes the result rather than a separate design objective.

#### **IX.D.6. Ground 4 conclusion**

Sinclair-535 and Reynolds 2002 supply every limitation of Claims 1, 3–7, 9, 11, 13–15, and 18, a reason to combine, and a reasonable expectation of success (§ IX.D.0); those claims are more likely than not unpatentable.

**IX.E. GROUND 5A — Claims 1, 5–7, 9, 11, 18, 19, and 20 are obvious under § 103 over Vañó-Galván 2021 in view of Sinclair-535, Fleishaker 1989, the Loniten label, and Reynolds 2002; GROUND 5B — Claims 8 and 10 are obvious over the Ground 5A combination further in view of Beach 2021**

Ground 5A: Vañó-Galván 2021 establishes the clinical use and general tolerability of low-dose oral minoxidil for hair loss; Sinclair-535 states the low-dose exposure objective and the 20 ng/mL hemodynamic threshold; Fleishaker 1989 supplies measured human immediate-release minoxidil pharmacokinetics at neighboring doses; the Loniten label supplies established oral-minoxidil dosing and safety knowledge; and Reynolds 2002 teaches a tunable HPMC controlled-release matrix. A POSITA seeking to retain hair-growth exposure while reducing the early plasma peak would have had reason to combine those teachings, with the reasonable expectation shown at § IX.D.0.

Ground 5B: Beach 2021 additionally documents oral minoxidil prescribed for the hair-loss conditions recited in Claims 8 and 10 (central centrifugal cicatricial alopecia; traction alopecia), supplying the disease-specific reason to apply the Ground 5A method to those patients.

(The declaration addresses Grounds 5A and 5B together as a single six-reference Ground 5 (Ex. 1015 ¶ 41); the petition cites ¶ 41 for the Ground 5A

combination and, separately, for Beach's documented clinical use under Ground 5B.)

#### **IX.E.1. The references have defined, claim-specific roles**

- Vañó-Galván documents pre-priority low-dose oral minoxidil use in 1,404 patients, principally for androgenetic alopecia (82.4%) and also for telogen effluvium, alopecia areata, and lichen planopilaris, at doses of 0.03–15 mg (Ex. 1005 at 1645; *id.*, Table I).
- Fleishaker reports immediate-release oral minoxidil pharmacokinetics over 2.5–10 mg, described as supporting dose-independent pharmacokinetics for dose-normalized C<sub>max</sub> and t<sub>max</sub>, with significant differences in oral clearance and elimination rate constant between 2.5 mg and the higher doses (Ex. 1006 at 162; *id.* at 164, Table I): mean C<sub>max</sub> 16.8 ng/mL and t<sub>max</sub> 0.566 h at 2.5 mg (Ex. 1006, Table I).
- The Loniten label confirms FDA-approved oral tablets in 2.5 mg and 10 mg strengths, adult dosing from 5 mg/day, and peak plasma concentration within the first hour (Ex. 1007 at 1, 2, 10).
- Beach (Ground 5B only) supplies indication-specific evidence for central centrifugal cicatricial alopecia and traction alopecia (Ex. 1019, Table I, p. 761). Its small numbers, n=2 and n=3, are cited as documented clinical use and not as efficacy evidence.

### **IX.E.2. Reason to combine**

Sinclair and Reynolds function as in Ground 4 (§ IX.D.1). A POSITA developing an oral minoxidil product for the practice Vañó-Galván documents had reason to apply Reynolds's platform to a dose near the upper portion of the low-dose clinical range, for the reason stated at § IX.D.0, the reported 5 mg immediate-release peak lies above the threshold Sinclair identifies (Ex. 1003 ¶¶ [0145], [0146]; accord Ex. 1006, Table I). Dr. Omidian identifies the role each Ground 5A reference plays (Ex. 1015 ¶ 41), states that combining Sinclair's minoxidil teaching with Reynolds's HPMC-matrix teaching was within ordinary skill (¶ 39), and states that reducing the peak and moving T<sub>max</sub> later by adjusting established matrix variables was routine formulation work (¶¶ 38, 52, 53).

Vañó-Galván's generally favorable tolerability findings must be addressed, not ignored. They can reduce the urgency of solving a safety problem for immediate-release low-dose therapy, as can Sinclair's report that 5–100 mg oral doses "had minimal effect on the blood pressure of normotensive individuals" while noting reflex tachycardia (Ex. 1003 ¶ [0145]). The combination remains motivated by product-profile objectives, a moderated peak, extended input, and a conventional once-daily oral product, and Petitioner does not contend that Vañó-Galván itself demanded modified release. That immediate-release low-dose minoxidil was tolerable in practice does not remove the motivation to reduce the

peak: Sinclair states the threshold, and Fleishaker, while calling them clinically unremarkable, detected significant treatment effects on supine blood pressure and pulse rate after single 2.5–10 mg immediate-release doses (Ex. 1006 at 162).

### IX.E.3. Claim 1 mapping

| Claim 1 limitation                                                                                    | Ground 5A                                                                                                 |
|-------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
| Method of treating hair loss by orally administering to a human subject who is experiencing hair loss | Ex. 1005 at 1644–45; Ex. 1003 ¶¶ [0001], [0030], [0146], [0150]; Ex. 1007 at 1–2                          |
| Modified-release pharmaceutical formulation                                                           | Ex. 1004 at 457–59; Ex. 1003 ¶ [0017] (motivation only)                                                   |
| About 4.5 mg minoxidil                                                                                | Ex. 1005 at 1650 (proposed 2.5–5 mg titration); Ex. 1003 ¶ [0146]; Ex. 1007 at 1; § IX.D.2 (optimization) |
| Cmax about 0.25–20 ng/mL                                                                              | Ex. 1006, Table I (16.8 ng/mL at 2.5 mg); Ex. 1003 ¶¶ [0145], [0146]; Ex. 1004 at 460–62; see § IX.D.0    |
| Tmax about 30–360 minutes                                                                             | Ex. 1006, Table I (tmax 0.566 h at 2.5 mg); Ex. 1007 at 1–2; Ex. 1004 at 460–62; see § IX.D.0             |

### IX.E.4. Dependent claims; Claims 19–20 under Patent Owner's narrowing construction

Claims 5–7 and 9 recite conditions documented by Sinclair and Vañó-Galván (Ex. 1003 ¶ [0030]; Ex. 1005 at 1644–45). Claim 8 (central centrifugal cicatricial alopecia) and Claim 10 (traction alopecia) rest on Ground 5B: Beach tabulates confirmed pre-priority prescriptions for each (Ex. 1019, Table I, p. 761), and that documented practice supplied the reason to extend the same method to

those patients (Ex. 1015 ¶ 41, cited for clinical use only). Claim 11 rests on Sinclair's regrowth report (Ex. 1003 ¶¶ [0146], [0150]). Claim 18 rests on Sinclair's daily administration (¶ [0016]) and the Loniten label's once- or twice-daily dosing (Ex. 1007 at 10).

Claims 19 and 20 are challenged under this Ground only if the Board adopts Patent Owner's anticipated narrowing construction of "no cardiac effects" as "no clinically significant cardiac effects" (§ IX.B); Ground 2 is the principal challenge. The alternative rests on the design logic of Sinclair's threshold: Sinclair reports a 0.45 mg sublingual peak of 1.42 ng/mL as "well below the minimum dose threshold for any hemodynamic effect (20 ng/ml)" (Ex. 1003 ¶ [0143]; accord ¶ [0164]), and the claimed C<sub>max</sub> ceiling is set at that threshold. A POSITA seeking oral minoxidil for hair loss without hemodynamic effect had reason to design a modified-release 4.5 mg formulation whose peak stays at or below that benchmark; Claim 19 therefore recites, under that construction, the design objective Sinclair states rather than a separate result; Claim 20's enumerated effects fall within the same objective. Petitioner does not contend that peaks below 20 ng/mL were known to be free of all measurable hemodynamic change (§ IX.B.4; Ex. 1001, Example 2); under Patent Owner's construction the limitation reduces to the design objective Sinclair states, and the prior art supplied the objective and the means. If measurable change below the benchmark instead counts as a "cardiac effect," the

categorical construction and Ground 2 govern. Petitioner's expert does not opine that a particular Cmax causes or avoids cardiovascular effects or that reducing Cmax produces a particular clinical outcome (Ex. 1015 ¶ 49); his observation on Claim 19 is confined to the documents and offers no clinical-cardiology opinion (¶ 56).

#### **IX.E.5. Grounds 5A/5B conclusion**

The Ground 5A combination renders Claims 1, 5–7, 9, 11, and 18 more likely than not unpatentable, and Claims 19 and 20 likewise under Patent Owner's narrowing construction (§ IX.E.4); further in view of Beach, Claims 8 and 10 are likewise unpatentable.

#### **IX.F. GROUND 6 — Claims 1–7, 9, 11, 13–15, 17, and 18 are obvious under § 103 over Sinclair-535 in view of Cardinal and Fleishaker 1989**

(The declaration numbers this combination Ground 7 (Ex. 1015 ¶ 43); the petition does not plead the declaration's Ground 6.)

This Ground rests on references that each name minoxidil. Ground 6 is the only § 103 route to Claims 2 and 17.

### **IX.F.1. Cardinal is a matrix-platform reference that names minoxidil and not a worked minoxidil formulation**

Sinclair supplies oral minoxidil for hair loss, the indications, adjacent 2.5 mg and 5 mg oral doses, the stated blood-concentration objective, and the threshold (Ex. 1003 ¶¶ [0001], [0008], [0013], [0030], [0145], [0146], [0150]). Fleishaker supplies the immediate-release pharmacokinetics (Ex. 1006, Table I).

Cardinal teaches sustained-release matrix systems, lists minoxidil among many possible drug substances, and separately identifies HPMC grades including K4M and K200M among matrix materials (Ex. 1012 ¶¶ [0064], [0115]). It describes delivery "over an extended period of time lasting from about four hours up to about twenty-four hours," maintenance of desired blood levels, and reduction of immediate-release fluctuation (¶ [0002]); pH-dependent near-linear and first-order release patterns designable by manipulating matrix components (¶¶ [0003], [0027]–[0030]; claims 4–10); and enteric coatings (¶ [0155]). Cardinal discloses no worked minoxidil matrix tablet. This Ground is therefore a minoxidil-listed matrix-platform path and not a minoxidil-specific worked-embodiment path.

### **IX.F.2. Reason to combine**

A POSITA would have had reason to apply Cardinal's oral extended-release platform, a generic hydrophilic-matrix platform that expressly identifies minoxidil as a candidate active ingredient (Ex. 1012), to Sinclair-535's low-dose oral-

minoxidil hair-loss method, using Fleishaker's measured human immediate-release pharmacokinetics as the formulation baseline. Sinclair reported a 5 mg one-hour concentration above its stated threshold (Ex. 1003 ¶¶ [0145], [0146]); Cardinal's background states the purposes of controlled release, maintaining desired blood levels and reducing fluctuation (Ex. 1012 ¶ [0002]). A POSITA pursuing oral minoxidil at about 4.5 mg would have reason to consult matrix art naming both the drug and the relevant HPMC grades (Ex. 1015 ¶ 43).

The number of possible actives in Cardinal's list affects the weight of the teaching but does not erase it, because Sinclair's specific drug and treatment disclosure is combined with Cardinal's identification of the same drug. The dose selection is the routine adjustment stated at § IX.D.2. Efficacy is retained: Sinclair reports swallowed-oral efficacy in clinical use (¶ [0150]) and efficacy at serum levels far below the threshold (¶ [0143]); its stated concentration objective (¶ [0013]) and the claimed range's own floor are likewise below it. Combining Sinclair's minoxidil teaching with Cardinal's HPMC-matrix teaching was within ordinary skill, each element performing its established function (Ex. 1015 ¶ 39), and the matrix work itself was routine (¶ 53). The reasonable expectation as to C<sub>max</sub> and T<sub>max</sub> is shown at § IX.D.0. *Allergan*, 754 F.3d at 964–66.

### IX.F.3. Claim 1 mapping

| Claim 1 limitation                                                                                    | Ground 6                                                                       |
|-------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Method of treating hair loss by orally administering to a human subject who is experiencing hair loss | Ex. 1003 ¶¶ [0001], [0008], [0030], [0146], [0150]                             |
| Modified-release pharmaceutical formulation                                                           | Ex. 1012 ¶¶ [0002], [0064], [0115]; Ex. 1003 ¶ [0017] (motivation only)        |
| About 4.5 mg minoxidil                                                                                | Ex. 1003 ¶ [0146]; Ex. 1006, Table I; § IX.D.2 (optimization)                  |
| Cmax about 0.25–20 ng/mL                                                                              | Ex. 1003 ¶¶ [0145], [0146]; Ex. 1006, Table I; Ex. 1012 ¶ [0002]; see § IX.D.0 |
| Tmax about 30–360 minutes                                                                             | Ex. 1006, Table I; Ex. 1003 ¶ [0146]; Ex. 1012 ¶¶ [0002]–[0003]; see § IX.D.0  |

### IX.F.4. Dependent claims

Claim 2 recites a blood level of about 1–20 ng/mL maintained for at least about eight hours. Cardinal's stated purpose, to "maintain desired blood levels" while avoiding immediate-release fluctuation, and its release durations of about four to about twenty-four hours, including release over a period greater than about eight hours (Ex. 1012 ¶ [0002]; claim 8), and its claim to a formulation whose pharmacological effect lasts at least about eight hours (claim 12), both depending from claim 2, are cited as the design objective and the means Cardinal discloses; Petitioner does not equate in-vitro release duration with in-vivo blood-level duration, and the expectation as to Claim 2 rests on Cardinal itself. Dr. Omidian is

cited only for Cardinal's stated purpose and release patterns (Ex. 1015 ¶ 43) and for the direction of the matrix effect (¶ 53); Petitioner does not attribute the eight-hour expectation to him.

Claims 3 and 4 are met by Cardinal's HPMC release-controlling materials and conventional matrix-tablet excipients (Ex. 1012 ¶¶ [0115], [0145]–[0148]); Claims 5–7 and 9 by Sinclair's express indications (Ex. 1003 ¶ [0030]); Claim 11 by Sinclair's regrowth report (¶¶ [0146], [0150]); Claim 18 by Sinclair's daily administration (¶ [0016]) and Cardinal's reduced dosing frequency through extended release (Ex. 1012 ¶ [0002]; claims 10, 14).

To the extent Claims 13–15 are found definite (contrary to Ground 3A), their kinetic-order limitations are met by the conventional matrix profiles the references report, as follows. Cardinal defines its "first-order release pattern" by the formula  $F = Kt^{1/2}$  (Ex. 1012 ¶ [0026]), a label that is not the '184's rate law (§ VII.D), and Petitioner does not equate them. The mapping is that Cardinal teaches selecting matrix components to obtain a chosen release pattern across that family (¶¶ [0003], [0027]–[0030]), so that, Petitioner submits, a POSITA adjusting a Cardinal HPMC matrix would have expected a profile within the first-order, pseudo-first-order, and pseudo-zero-order regime characteristic of such matrices (Ex. 1015 ¶¶ 32, 43). Under the rate-law construction (§ VII.D), that regime comprises Claim 14's first-order and Claims 13 and 15's pseudo-orders; that mapping is Petitioner's. Claims

13–15 are alternatives; a POSITA tuning a Cardinal matrix in the ordinary way would obtain a profile the '184 would label with one of the three, and the choice among them describes the result rather than a separate design objective.

Claim 17 requires an enteric coating, which Cardinal expressly teaches for delayed release (§ [0155]). A POSITA seeking to hold the early peak beneath the ceiling had a conventional reason to defer release with such a coat; Claim 1's Tmax window extends to 360 minutes, and whether a coated embodiment's peak falls inside it is the same routine adjustment § IX.D.0 describes. Petitioner does not contend that every coated embodiment would.

#### **IX.F.5. Ground 6 conclusion**

Sinclair, Cardinal, and Fleishaker render Claims 1–7, 9, 11, 13–15, 17, and 18 more likely than not unpatentable.

### **X. SECONDARY CONSIDERATIONS DO NOT OUTWEIGH THE EVIDENCE OF OBVIOUSNESS**

Objective indicia are weighed with the other *Graham* factors, but carry substantial weight only where a nexus connects the evidence to the claimed invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373–75 (Fed. Cir. 2019). A presumption of nexus arises only for a specific product that is "essentially the claimed invention"; otherwise Patent Owner must show directly that the

evidence resulted from the claimed invention's unique characteristics. *Id.* at 1373–74. Patent Owner's 2026 announcements (Exs. 1048, 1050–1052) may bear on objective indicia although they postdate October 25, 2022; they cannot supply the written description the specification lacked at filing (§ IX.A), and they establish neither presumed nor direct nexus.

#### **X.A. No presumed or direct nexus**

The public record does not show that any study on which Patent Owner might rely practiced the claimed dose-and-envelope combination. Study 302 evaluated VDPHL01 at 8.5 mg once or twice daily in males (Ex. 1050 at 1–2; Ex. 1052 at 2–3), outside "about 4.5 mg" (§ VII.A). Study 207 evaluated 4.5 mg once or twice daily in women (Ex. 1051 at 2–4; Ex. 1052 at 2) but reports no C<sub>max</sub> or T<sub>max</sub> measured in that study. Study 109 reports C<sub>max</sub> values for a 4.5 mg extended-release formulation in healthy volunteers but no numerical T<sub>max</sub>, and does not establish that the Study 207 formulation produced the same profile (Ex. 1048 at printed p. 112). Nor does the record tie any reported outcome to the claimed dose-and-envelope combination rather than to minoxidil's known activity, total daily dose, dosing frequency, or patient selection.

**X.B. No long-felt unmet need shown to have been satisfied by the claimed invention**

A long-felt need must have been recognized and unresolved, and the claimed invention must be shown to have satisfied it. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1332–33 (Fed. Cir. 2016). Low-dose oral minoxidil was in wide clinical use for hair loss before the priority date (Ex. 1005: 1,404 patients). Patent Owner's asserted needs, an FDA-approved, non-hormonal oral treatment, particularly for women, with improved tolerability (Exs. 1048, 1050–1052), are not limitations of Claim 1, and VDPHL01 remained an unapproved investigational candidate as of this Petition; on this record any satisfaction of that need is not attributable to the features that distinguish Claim 1 from prior low-dose oral minoxidil use.

**X.C. No unexpected result attributable to the claimed combination**

Unexpected results must be shown relative to the prior art and be commensurate with claim scope. *In re Peterson*, 315 F.3d 1325, 1330–31 (Fed. Cir. 2003). Study 302 was placebo-controlled but at 8.5 mg; results at 8.5 mg cannot be presumed at about 4.5 mg, still less attributed to the recited Cmax and Tmax ranges. Study 207 was an open-label study in which 28 women received 4.5 mg once or twice daily and 21 men received 8.5 mg twice daily, with no placebo arm and no dose-matched immediate-release arm (Ex. 1051 at 2–4); it cannot show that the reported hair growth was unexpected relative to the known efficacy of low-

dose oral minoxidil, or that any benefit came from modified release or the claimed envelope, and it reports no study-specific pharmacokinetics. Study 109 administered 4.5 mg extended-release VDPHL01 to healthy female volunteers and, after washout, 20 mg immediate-release minoxidil; the reported geometric-mean C<sub>max</sub> values were 6.417 and 7.735 ng/mL for the 4.5 mg extended-release doses against 135.1 ng/mL for 20 mg immediate release (Ex. 1048 at printed p. 112). A lower peak and fewer dose-related effects at 4.5 mg than at a dose more than four times larger do not isolate any effect of the claimed release profile; the comparison is confounded by dose. Study QSC300720 compared an 8.5 mg prototype with an observed 2.5 mg and an estimated 5 mg immediate-release profile (Ex. 1048 at printed pp. 106, 110): a dose outside Claim 1 against a modeled baseline.

The claimed envelope itself is not shown to be a critical or unexpected boundary. Fleishaker's measured 2.5 mg immediate-release C<sub>max</sub> of 16.8 ng/mL, matching the 2.5 mg value in the specification's own Table 3, lies within the claimed 0.25–20 ng/mL range (Ex. 1001, col. 67; Ex. 1006, Table I), and the specification identifies the 20 ng/mL ceiling as a preselected design constraint (col. 63, n. b: no selected dose "will be expected to result in a geometric mean C<sub>max</sub> >20 ng/ml or exceed 30 mg based on impurity limits") while admitting that no modified-release human study had been conducted (cols. 65–66; § IX.A.3). Petitioner cites the post-filing Study 109 values only to rebut a contention of

criticality and not to supply any element or to show what was predictable in October 2022.

#### **X.D. No commercial success**

VDPHL01 is an investigational candidate with no marketed product (Ex. 1052); there are no sales from which commercial success could be inferred; financing events are not sales.

#### **X.E. No skepticism or failure of others**

The record identifies no contemporaneous skepticism and no failed attempt by another; pre-priority clinical use of low-dose oral minoxidil (Ex. 1005) is inconsistent with either.

#### **X.F. No copying, independent praise, or licensing**

Copying requires evidence of actual copying efforts, not mere similarity. *Liqwd, Inc. v. L'Oréal USA, Inc.*, 941 F.3d 1133, 1137–38 (Fed. Cir. 2019); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004); *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010). The record contains none; Patent Owner's releases quote its own affiliates (Exs. 1050–1052) and are not independent praise, and no license attributable to the claimed combination is identified.

## **XI. CONCLUSION**

For the foregoing reasons, Petitioner respectfully requests that the Board institute post-grant review of Claims 1–20 of U.S. Patent No. 12,491,184 on each ground presented and, following trial, issue a final written decision determining that Claims 1–20 are unpatentable.

Dated: September 1, 2026

Respectfully submitted,

FAIRCHILD LAW LLC

By: /Steven R. Fairchild/

Steven R. Fairchild, Reg. No. 70,800

170 Parkside Avenue, 3F, Brooklyn, NY 11226

(703) 994-0193 · [steve@fairchildlegal.com](mailto:steve@fairchildlegal.com)

Counsel for Petitioner Anagen LLC

## **CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24**

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Petition contains 18,677 words, as determined by the word-count function of Microsoft Word, excluding the table of contents, mandatory notices under 37 C.F.R. § 42.8, this certificate, the certificate of service, the appendix of exhibits, and the claim listing, as permitted by 37 C.F.R. § 42.24(a)(1). The Petition complies with the 18,700-word limit of 37 C.F.R. § 42.24(a)(1)(ii).

/Steven R. Fairchild/

Steven R. Fairchild, Reg. No. 70,800

## **CLAIM LISTING APPENDIX — CLAIMS 1–20 OF U.S. PATENT NO.**

**12,491,184 (37 C.F.R. § 42.24(a)(1); excluded from the word count)**

Claims 1–20 of U.S. Patent No. 12,491,184 (verbatim; Ex. 1001, cols. 99–100):

1. A method of treating hair loss, comprising orally administering to a human subject who is experiencing hair loss a modified release pharmaceutical formulation comprising about 4.5 mg of minoxidil or a molar equivalent amount of the pharmaceutically acceptable salt thereof; wherein the modified release pharmaceutical formulation provides: a Cmax of minoxidil that is about 0.25 ng/ml to about 20 ng/ml; and a Tmax of minoxidil that is about 30 to about 360 minutes.

2. The method of claim 1, wherein a blood level of minoxidil is maintained in a range of about 1 ng/ml to about 20 ng/ml for at least about 8 hours.

3. The method of claim 1, wherein the modified release pharmaceutical formulation further comprises a release modifier.

4. The method of claim 1, wherein the modified release pharmaceutical formulation further comprises a filler, a glidant, a lubricant, or a combination thereof.

5. The method of claim 1, wherein the hair loss comprises female pattern hair loss.

6. The method of claim 1, wherein the hair loss comprises alopecia areata.

7. The method of claim 1, wherein the hair loss comprises telogen effluvium.
8. The method of claim 1, wherein the hair loss comprises central centrifugal cicatricial alopecia.
9. The method of claim 1, wherein the hair loss comprises lichen planopilaris.
10. The method of claim 1, wherein the hair loss comprises traction alopecia.
11. The method of claim 1, wherein the oral administration results in hair regrowth.
12. The method of claim 1, wherein the modified release pharmaceutical formulation exhibits a zero order release of minoxidil.
13. The method of claim 1, wherein the modified release pharmaceutical formulation exhibits a pseudo zero order release of minoxidil.
14. The method of claim 1, wherein the modified release pharmaceutical formulation exhibits a first order release of minoxidil.
15. The method of claim 1, wherein the modified release pharmaceutical formulation exhibits a pseudo first order release of minoxidil.
16. The method of claim 1, wherein the modified release pharmaceutical formulation exhibits a second order release of minoxidil.
17. The method of claim 1, wherein the modified release pharmaceutical formulation comprises an enteric coating.

18. The method of claim 1, wherein the modified release pharmaceutical formulation is administered at least once daily.

19. The method of claim 1, wherein the oral administration of the modified release pharmaceutical formulation results in no cardiac effects.

20. The method of claim 19, wherein the cardiac effects are selected from tachycardia, hypotension, premature ventricular contractions, and other tachyarrhythmias.

## PETITIONER'S EXHIBIT LIST (37 C.F.R. § 42.63(e))

| Ex. # | Document                                                                                                                                                                                                                                                                                         |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1001  | U.S. Patent No. 12,491,184 B2 (the challenged patent)                                                                                                                                                                                                                                            |
| 1002  | U.S. Patent No. 12,268,688 B2 (the "'688 patent"; issued April 8, 2025)                                                                                                                                                                                                                          |
| 1003  | U.S. Patent Application Publication No. 2019/0269684 A1 (Samson Clinical Pty Ltd.), published September 5, 2019 ("Sinclair-535"; the U.S. national-phase publication of WO 2019/010535). All Sinclair paragraph citations in this Petition use the paragraph numbering of this U.S. publication. |
| 1004  | Reynolds et al., "Investigation of the effect of tablet surface area/volume on drug release from hydroxypropylmethylcellulose controlled-release matrix tablets," <i>Drug Dev. Ind. Pharm.</i> 28(4):457–466 (2002)                                                                              |
| 1005  | Vañó-Galván et al., "Safety of low-dose oral minoxidil for hair loss: A multicenter study of 1404 patients," <i>J. Am. Acad. Dermatol.</i> 84(6):1644–51 (2021)                                                                                                                                  |
| 1006  | Fleishaker et al., "The pharmacokinetics of 2.5- to 10-mg oral doses of minoxidil in healthy volunteers," <i>J. Clin. Pharmacol.</i> 29:162–167 (1989)                                                                                                                                           |
| 1007  | Loniten® (minoxidil tablets) FDA-approved prescribing information (Reference ID 3685475; LAB-0168-0.x, revised January 2015)                                                                                                                                                                     |
| 1008  | Williams, U.S. Patent Application Publication No. 2010/0104639 A1, published April 29, 2010                                                                                                                                                                                                      |
| 1009  | Biovail, International Publication No. WO 2004/058229                                                                                                                                                                                                                                            |
| 1010  | Certified copy of U.S. Provisional Application No. 63/419,155 (filed October 25, 2022), from the WIPO file of PCT/US2023/035920                                                                                                                                                                  |
| 1011  | Certified copy of U.S. Provisional Application No. 63/433,203 (filed December 16, 2022), from the WIPO file of PCT/US2023/035920                                                                                                                                                                 |
| 1012  | Cardinal, U.S. Patent Application Publication No. 2010/0159001 A1, published June 24, 2010                                                                                                                                                                                                       |
| 1013  | Bokhari et al., "Sublingual minoxidil for the treatment of male and female pattern hair loss: a randomized, double-blind, placebo-controlled, phase 1B clinical trial," <i>J. Eur. Acad. Dermatol. Venereol.</i> 36(1):e62–e66 (2022; published online August 30, 2021)                          |

| Ex. # | Document                                                                                                                                                                                             |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1014  | Panchaprateep et al., "Efficacy and safety of oral minoxidil 5 mg once daily in the treatment of male patients with androgenetic alopecia," <i>Dermatol. Ther. (Heidelb.)</i> 10(6):1345–1357 (2020) |
| 1015  | Declaration of Hossein Omidian, Ph.D. (filed herewith)                                                                                                                                               |
| 1016  | Reserved                                                                                                                                                                                             |
| 1017  | Gottlieb et al., "Pharmacokinetic studies of minoxidil," <i>Clin. Pharmacol. Ther.</i> 13(3):436–441 (1972)                                                                                          |
| 1018  | Lowenthal & Affrime, "Pharmacology and Pharmacokinetics of Minoxidil," <i>J. Cardiovasc. Pharmacol.</i> 2(Suppl 2):S93–S106 (1980)                                                                   |
| 1019  | Beach et al., "Low-dose oral minoxidil for treating alopecia: A 3-year North American retrospective case series," <i>J. Am. Acad. Dermatol.</i> 84(3):761–763 (2021)                                 |
| 1020  | Reserved                                                                                                                                                                                             |
| 1021  | Buhl et al., "Minoxidil Sulfate Is the Active Metabolite that Stimulates Hair Follicles," <i>J. Invest. Dermatol.</i> 95:553–557 (1990)                                                              |
| 1022  | Reserved                                                                                                                                                                                             |
| 1023  | Written Opinion of the International Searching Authority (Form PCT/ISA/237) for PCT/US2023/035920 (USPTO as ISA; February 27, 2024)                                                                  |
| 1024  | Reserved                                                                                                                                                                                             |
| 1025  | Reserved                                                                                                                                                                                             |
| 1026  | Reserved                                                                                                                                                                                             |
| 1027  | Reserved                                                                                                                                                                                             |
| 1028  | Reserved                                                                                                                                                                                             |
| 1029  | Non-Final Office Action in U.S. Application No. 19/094,703, mailed March 16, 2026                                                                                                                    |
| 1030  | Reserved                                                                                                                                                                                             |
| 1031  | Reserved                                                                                                                                                                                             |
| 1032  | Reserved                                                                                                                                                                                             |
| 1033  | Reserved                                                                                                                                                                                             |
| 1034  | Sinha, U.S. Patent Application Publication No. 2024/0374594 A1, published November 14, 2024 (national phase of PCT/US2022/044912, filed September 27, 2022, published as WO 2023/055740)             |

| Ex. # | Document                                                                                                                                                                                                                                                                                                                               |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1035  | File history of U.S. Application No. 19/094,716 (Patent Center records, downloaded August 19, 2026), 93 pages: Non-Final Office Action (Apr. 28, 2025), response and terminal disclaimer, information disclosure statements (June 27, Sept. 15, Sept. 18, 2025), PTO-892, and Notices of Allowability (June 18, Aug. 8, Oct. 21, 2025) |
| 1036  | Reserved (the three Notices of Allowability appear in Ex. 1035 at 81–89; 37 C.F.R. § 42.6(d))                                                                                                                                                                                                                                          |
| 1037  | Reserved                                                                                                                                                                                                                                                                                                                               |
| 1038  | Reserved                                                                                                                                                                                                                                                                                                                               |
| 1039  | Follica/Barman, U.S. Patent Application Publication No. 2019/0381296 A1                                                                                                                                                                                                                                                                |
| 1040  | Bazzano, International Publication No. WO 83/02558 A1, published August 4, 1983                                                                                                                                                                                                                                                        |
| 1041  | Samson Clinical, International Publication No. WO 2016/065426 A1, published May 6, 2016                                                                                                                                                                                                                                                |
| 1042  | Reserved                                                                                                                                                                                                                                                                                                                               |
| 1043  | Certified copy of U.S. Provisional Application No. 63/250,009 (filed September 29, 2021), from the WIPO file of PCT/US2022/044912                                                                                                                                                                                                      |
| 1044  | Reserved                                                                                                                                                                                                                                                                                                                               |
| 1045  | Follica/Barman, U.S. Patent No. 11,207,511 B2                                                                                                                                                                                                                                                                                          |
| 1046  | Reserved                                                                                                                                                                                                                                                                                                                               |
| 1047  | Reserved                                                                                                                                                                                                                                                                                                                               |
| 1048  | Veradermics, Incorporated, Prospectus (Form 424B4), dated February 3, 2026, filed with the U.S. Securities and Exchange Commission (EDGAR Accession No. 0001628280-26-005505); 338 pages, filed in two parts (Part 1, pp. 1–169; Part 2, pp. 170–338); cited by printed folio — e.g., printed p. 112 is exhibit-stamped p. 166 of 338  |
| 1049  | Curriculum Vitae of Hossein Omidian, Ph.D.                                                                                                                                                                                                                                                                                             |
| 1050  | Veradermics, Inc. press release, "Veradermics' Oral VDPHL01 Achieved Early, Consistent, and Robust Hair Growth in Positive Phase 2/3 '302' Clinical Trial in Male Pattern Hair Loss" (April 27, 2026), filed as Exhibit 99.1 to Form 8-K (EDGAR Accession No. 0001628280-26-027354)                                                    |

| Ex. # | Document                                                                                                                                                                                                                                                                                            |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1051  | Veradermics, Inc. press release, "Veradermics' Oral VDPHL01 Delivers Positive Study '207' Phase 2 Clinical Trial Results in Female Pattern Hair Loss Ahead of Upcoming Phase 2/3 Study '306' Readout" (July 15, 2026), filed as Exhibit 99.1 to Form 8-K (EDGAR Accession No. 0001827635-26-000023) |
| 1052  | Veradermics, Inc. press release, "Veradermics Reports Second Quarter 2026 Financial Results and Highlights Recent Corporate and Clinical Progress" (August 11, 2026), filed as Exhibit 99.1 to Form 8-K (EDGAR Accession No. 0001827635-26-000028)                                                  |
| 1053  | U.S. Patent Application Publication No. 2020/0108008 A1 (Shanghai Institute of Materia Medica), published April 9, 2020 (incorporated by reference in the '184 patent at cols. 17 and 44)                                                                                                           |
| 1054  | <i>Teva Pharms. Int'l GmbH v. Eli Lilly &amp; Co.</i> , No. 2024-1094 (Fed. Cir. Apr. 16, 2026) (slip opinion; copy provided per 37 C.F.R. § 42.13(d))                                                                                                                                              |
| 1055  | <i>Wyeth LLC v. AstraZeneca Pharms. LP</i> , No. 2024-2325 (Fed. Cir. July 9, 2026) (slip opinion; copy provided per 37 C.F.R. § 42.13(d))                                                                                                                                                          |
| 1056  | <i>Enviro Tech Chem. Servs., Inc. v. Safe Foods Corp.</i> , No. 2024-2160 (Fed. Cir. May 4, 2026) (slip opinion; copy provided per 37 C.F.R. § 42.13(d))                                                                                                                                            |

## **CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.205(a), the undersigned certifies that on September 1, 2026, contemporaneously with the filing of this Petition, a complete copy of (1) the Petition for Post-Grant Review of Claims 1–20 of U.S. Patent No. 12,491,184, (2) the Power of Attorney, (3) Petitioner's Exhibit List, and (4) every exhibit and item of supporting evidence filed with the Petition was served by Priority Mail Express® on Patent Owner at the correspondence address of record for U.S. Patent No. 12,491,184, as confirmed in USPTO Patent Center on the date of service:

Procopio, Cory, Hargreaves & Savitch LLP (attorney of record per Ex. 1001, field (74)), 525 B Street, Suite 2200, San Diego, CA 92101

Priority Mail Express® No. 9481 7301 0935 5001 3011 69

and additionally, as an address likely to effect service, on:

Veradermics, Incorporated, 470 James Street, New Haven, Connecticut

06513 (address of principal executive offices per its Form 8-K filed August 11, 2026)

Priority Mail Express® No. 9481 7301 0935 5001 3011 76

/Steven R. Fairchild/

Steven R. Fairchild, Reg. No. 70,800