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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/358,274	05/15/2014	Mark Y. Underwood	3155.118	5942

23598 7590 09/04/2020

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ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
09/04/2020	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MARK Y. UNDERWOOD and JAMES R. MOYER[1]

Appeal 2020-000685
Application 14/358,274
Technology Center 1600

Before RICHARD M. LEBOVITZ, DEBORAH KATZ, and JOHN A. EVANS, *Administrative Patent Judges*.

EVANS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) from the Examiner's Non-Final Rejection of Claims 1–4 and 6. Appeal Br. 4. We have jurisdiction over the pending claims under 35 U.S.C. § 6(b).

We AFFIRM.

INVENTION

The claims relate to apoaequorin-based compositions and methods for preconditioning neurons in a subject to reduce neuronal injury due to brain

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[1] We use the word "Appellant" to refer to "Applicants" as defined in 37 C.F.R. § 1.42(a). The Appeal Brief identifies Quincy Bioscience, LLC as the real party in interest. Appeal Br. 3.

ischemia. *See* Abstract. Claim 1, the sole independent claim, is reproduced below with some formatting added.

> 1. A method of preconditioning neurons to reduce neuronal injury when brain ischemia occurs in a subject, comprising preventatively administering apoaequorin to neurons in a subject, whereby the apoaequorin initiates a change in cytokine expression levels resulting in a reduction in neuronal injury when brain ischemia occurs in the subject at least 48 hours thereafter, as compared to neurons not administered the apoaequorin when brain ischemia occurs in the subject at least 48 hours thereafter.

PRIOR ART

Name[2]	Reference	Date
Underwood	WO 2009/114597 A1	Sept. 17, 2009

REJECTIONS[3] AT ISSUE[4]

1. Claims 1–4 and 6 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Final Act. 2–4.
2. Claims 1–4 and 6 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. Final Act. 4–6.

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[2] All citations herein to the reference are by reference to the first named inventor/author only.

[3] The present application was examined under the pre-AIA first to invent provisions. Final Act. 2.

[4] Throughout this Decision, we refer to the Appeal Brief ("Appeal Br.") filed April 30, 2019, the Reply Brief ("Reply Br.") (none filed), the Final Office Action ("Final Act.") mailed May 4, 2018, the Examiner's Answer mailed August 5, 2019, and the Specification ("Spec.") filed May 15, 2014.

3. Claims 1–4 and 6 stand rejected under 35 U.S.C. §102(b) as anticipated by Underwood. Final Act. 6–7.

ANALYSIS

We have reviewed the rejections of Claims 1–4 and 6 in light of Appellant's arguments that the Examiner erred. We have considered in this decision only those arguments Appellant actually raised in the Briefs. Any other arguments which Appellant could have made but chose not to make in the Briefs are deemed to be waived. *See* 37 C.F.R. § 41.37(c)(1)(iv). We adopt as our own the findings and reasons set forth in the rejection from which this appeal is taken and in the Examiner's Answer, to the extent consistent with our analysis below. We provide the following explanation to highlight and address specific arguments and findings primarily for emphasis.

CLAIMS 1–4 AND 6: INDEFINITENESS.

Claim 1, the sole independent claim, recites, *inter alia*, "preventatively administering apoaequorin to neurons in a subject, whereby the apoaequorin initiates a change in cytokine expression levels resulting in a reduction in neuronal injury when brain ischemia occurs in the subject at least 48 hours thereafter."

The Examiner finds the Specification fails to inform one of skill in the art how to determine when a stroke may happen such that the claimed apoaequorin may be administered "at least" (Claim 1), or "exactly" (Claim 6) 48 hours prior thereto. Final Act. 3. The Examiner repeats this finding in the Answer. Ans. 9.

Appellant contends the term "preventatively," as recited in the claims,

> is definite because it refers to "administering apoaequorin" prior to the occurrence of brain ischemia to prevent brain ischemia. Any alleged ambiguity in the claim term "preventatively" is resolved by the Applicant's quantitative metric that limits the nature of the administration of apoaequorin – "whereby the apoaequorin initiates a change in cytokine expression levels resulting in a reduction in neuronal injury when brain ischemia occurs in the subject at least 48 hours thereafter" – and therefore, provides a clear cut indication of the scope of the subject matter covered by the claim.

Appeal Br. 11. Appellant does not file a Reply Brief.

We find a person of ordinary skill in the medical arts would understand the clause "preventatively administering apoaequorin to neurons in a subject," as recited in Claim 1. The USPTO assesses indefiniteness pursuant to the Federal Circuit's guidance in *In re Packard*, 751 F.3d 1307, 1310 (Fed. Cir. 2014). *See Ex parte McAward*, Appeal 2015-006416 (PTAB Aug. 25, 2017) (precedential) ("[a] claim is indefinite when it contains words or phrases whose meaning is unclear").

In Claim 1, the "whereby" clause states the intended result of "administering apoaequorin." "A 'whereby' clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim." *Texas Instruments Inc. v. Int'l Trade Comm'n*, 988 F.2d 1165, 1172 (Fed. Cir. 1993).

In view of the foregoing, we decline to sustain the rejection of Claims 1–4 and 6 as indefinite.

CLAIMS 1–4 AND 6: ENABLEMENT.

The Examiner makes substantially similar findings as discussed above. *See* Final Act. 4–6.

Appellant proffers similar contentions and further argues Examples 1 and 2, as set forth in the Specification, satisfy the enablement requirement. Appeal Br. 13.

The Examiner finds the disclosure of Examples 1 and 2 relate to controlled, experimental settings where the timing of ischemia may be defined. Final Act. 11. The Examiner finds in real life, the timing of ischemic stroke is uncontrolled.[5] *Id.*

Similarly as discussed above, we find a person of ordinary skill in the medical arts, upon reading the Specification would understand how to effectuate the clause "preventatively administering apoaequorin to neurons in a subject," as recited in Claim 1. And similarly, we find the recited "whereby" clause of Claim 1 does not affect the patentability of the claims and does not render the claims indefinite.

In view of the foregoing, we decline to sustain the rejection of Claims 1–4 and 6 as lacking enablement.

CLAIMS 1–4 AND 6: ANTICIPATION BY UNDERWOOD.

Claim 1, the sole independent claim, recites, *inter alia*, "preventatively administering apoaequorin to neurons in a subject, whereby the apoaequorin initiates a change in cytokine expression levels resulting in a reduction in neuronal injury when brain ischemia occurs in the subject at least 48 hours thereafter."

[5] In regards to the Examiner's expressed concern, as relating to scheduled surgery, or perhaps a scheduled prize fight, the timing of an ischemic insult may be determined with relative certainty.

Appellant contends Underwood fails to disclose administering apoaequorin prior to an ischemic event. Appeal Br. 14.

The Examiner finds that "[u]nder the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. Ans. 14. (citing *In re King*, 801 F.2d 1324, 1326, (Fed. Cir. 1986)). The Examiner further finds Underwood "essentially discloses the same method, administering the same drug, apoaequorin, for the same duration, daily, which meets the limitation for 'at least 48 hours,' to the same patient population." *Id.*, citing Underwood ¶¶ 26, 27.

We agree with the Examiner that Underwood fully anticipates "preventatively administering apoaequorin to neurons in a subject," as recited in Claim 1 because administration of apoaequorin-containing compositions to a subject in order to correct or maintain the calcium balance in that subject, as taught in paragraph 26 of Underwood, will include administration to subjects who will suffer from brain ischemia at least 48 hours later. As discussed above, we find the recited "whereby" clause of Claim 1 does not affect the patentability of the claims.

In view of the foregoing, we sustain the rejection of Claims 1–4 and 6 under 35 U.S.C. § 102(b).

CONCLUSION

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–4, 6	112, second paragraph	Indefiniteness		1–4, 6
1–4, 6	112, first paragraph	Enablement		1–4, 6

1–4, 6	102(b)	Underwood	1–4, 6	
Overall Outcome			1–4, 6	

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED