Appl. No.   : 17/194,823   Confirmation No. 1007
Applicant   : Brian Haney
Filed   : 03-08-2021
Examiner   : Pablo Whaley
Customer No. : 172663

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Mr. Whaley,

I am disappointed to have received your final rejection of my patent application. Based on your final rejection letter, I have made some final amendments to my applications. The amendments are intended to address and remedy the stated reasons for your rejection. These final amendments have been made in full compliance with 35 U.S.C. 112.

I have filed along with this response a substitute specification and a substitute specification with markup; along with a substitute claim and a claim with markup.

Respectfully,

Brian Haney

Grammatical Objection

First, you objected to the claim language on the ground that it should be thyroxin instead of Thyroxin. The correct spelling is thyroxine; however, I have amended the claim to be lowercase – thyroxine – which satisfies your objection.

Rejection under 35 USC 112 – First Paragraph

In your final rejection letter attached, it is extremely clear that you failed to diligently read the amendments I made. You state the reason for rejection is that only a "generic A.I. computer program" is mentioned in paragraphs 0008-0009 and 0013; and more is required to reach standards of patentability. However, you did not mention at all paragraphs 0021-0022, as well as paragraph 0055, which specifically provide mathematical algorithms for embodiments of the claimed AI program. For example, paragraph 0055 states,

> "In certain embodiments, the disclosure is a process using the following algorithm, where ai^* is the optimal administration of thyroxine. The algorithm is a minimization function, comparing the measured thyroid concentration, tc^m to the optimal thyroid concentration tc^* and minimizing the difference to identify the optimal dose administration.

> (3) $$ai^* = \min_{tc} tc^m - tc^*$$

> Here, in **Equation 3**, the value of thyroid concentration at which is the minimum of the difference between the optimal and measured amount is the amount to be delivered."

Ultimately, I disagree with your decision as parts of the specification directly answer and address your stated reasons for objection under 35 USC 112. Specifically, parts of the specification that provide specific mathematical algorithms for artificial intelligence programs that predict and control administration of thyroid hormone were apparently ignored. Indeed, one skilled in the art, would certainly be able to make and use the invention described therein.

You state,

> "There must be an explanation or discussion of algorithms that transform a general purpose computer to a special purpose computer programmed to perform the specialized claimed functions."

Such explanation was added with mathematical detail in 0052. However, I have taken note of your comments and have added additional explanation and discussion of such algorithms that transform the general-purpose computer to a special purpose computer are discussed in paragraphs 0056 – 0068. This explanation is sufficient, such that one skilled in the art can make or use the invention.

Rejection under 35 USC 112 – Second Paragraph

You state,

> "Claim 9 is directed to a "method" comprising a plurality of positive process steps as well as a "thyroid hormone sensor". In this case, however, the hormone sensor limitation is problematic because the sensor is not being "used" in any of the process limitation."

You further state,

> "clarification is requested via amendment, by deleting the aforementioned "sensor" limitation and amending one of the process limitations to use the sensor for a specified purpose."

I have appropriately amended the claim.

Finally, you state,

> "If applicant intends for the computer program to perform these steps, the claim should be amended accordingly."

I have appropriately amended the claim.

<u>Revised Claim</u>

Markup

9. A method for ~~curing~~ <u>treating</u> <u>congenital</u> hypothyroidism <u>with thyroxine drug administration,</u> the method comprising ~~a synthetic thyroid,~~

measuring ~~thyroid hormone~~ <u>thyroxine</u> in the ~~blood~~ <u>human body</u> using <u>a thyroid hormone sensor,</u>

<u>sending the measurement data to a microchip computer processor,</u>

<u>the microchip computer processor further comprising</u> ~~using~~ <u>an embedded</u> artificial intelligence <u>computer</u> program <u>comprising instructions, defined by medical experts, to perform the following functions:</u>

<u>calculating optimum levels of thyroxine in the human body,</u>

<u>comparing the optimum calculated levels of thyroxine to the measured levels of thyroxine,</u>

predicting needed delivery dosage <u>between a range of four micrograms and three-hundred-and-one micrograms,</u>

<u>sending the predicted needed delivery dosage to a second computer program,</u>

<u>wherein the second computer program commands drug administration to the human body from a stored thyroid hormone supply,</u>

~~delivering~~ <u>administering</u> ~~thyroid hormone~~ <u>thyroxine once every twelve hours,</u>

according to the dosage defined by the artificial intelligence computer program <u>comprising a set of logical instructions defined by medical experts,</u>

<u>helping the patient</u> maintain metabolic homeostasis~~,~~ <u>by measuring and administering</u> thyroid ~~human~~ <u>hormone</u> in the <u>human body</u> ~~bloodstream~~.

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9. A method for treating congenital hypothyroidism with thyroxine drug administration, the method comprising

measuring thyroxine in the human body using a thyroid hormone sensor,

sending the measurement data to a microchip computer processor,

the microchip computer processor further comprising an embedded artificial intelligence computer program comprising instructions, defined by medical experts, to perform the following functions:

calculating optimum levels of thyroxine in the human body,

comparing the optimum calculated levels of thyroxine to the measured levels of thyroxine,

predicting needed delivery dosage between a range of four micrograms and three-hundred-and-one micrograms,

sending the predicted needed delivery dosage to a second computer program,

wherein the second computer program commands drug administration to the human body from a stored thyroid hormone supply,

administering thyroxine once every twelve hours,

according to the dosage defined by the artificial intelligence computer program comprising a set of logical instructions defined by medical experts,

helping the patient maintain metabolic homeostasis by measuring and administering thyroid hormone in the human body.

Final Remarks

Thank you for your time and consideration. At this time, I respectfully request a notice of allowance.

Respectfully,

Brian Haney