II. Amendments to the Claims

Please amend claim 9 as follows.

9. A method for ~~curing~~ treating congenital hypothyroidism with Thyroxine drug administration,
the method comprising ~~a synthetic thyroid,~~
a thyroid hormone sensor,
measuring ~~thyroid hormone~~ Thyroxine in the ~~blood~~ human body,
sending the measurement data to a microchip computer processor,
the microchip computer processor further comprising ~~using~~ an embedded artificial intelligence computer program comprising a set of logical instructions defined by medical experts,
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,
~~delivering~~ administering ~~thyroid hormone~~ 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 ~~human~~ hormone in the human body ~~bloodstream~~.

Please cancel claim 10.

~~10. The method of claim 9, wherein the artificial intelligence program is a convolutional neural network, further comprising an input layer, two hidden layers, and output layer, predicting needed dosage.~~

Please cancel claim 11.

~~11. The method of claim 9, wherein the first artificial intelligence program is an embedded intelligence, calculating the needed dosage using statistical analysis, using intelligence from a human expert.~~

Please cancel claim 12.

~~12. The method of claim 9, wherein the thyroid hormone composition is purified Thyroxine (T_4).~~

Please cancel claim 13.

~~13. The method of claim 9, wherein the thyroid hormone is a composition containing Thyroxine (T_4) and Triiodothyronine (T_3).~~

Please cancel claim 14.

~~14. The method of claim 9, wherein the thyroid hormone is a composition containing Thyroxine (T_4), Triiodothyronine (T_3), and Free Thyroxine (FT_4) other thyroid hormone.~~

Please cancel claim 15.

~~15. The method of claim 9, wherein the synthetic thyroid further compromises a carbon nanotube, concealing a thyroid hormone supply, delivering to the blood through a timed-release drug delivery system, according to commands from a micro computing chip, signaling delivery time according to programmed commands.~~

II. Discussion of the Claims

This section provides a formal response to the rejections authored on June 29, 2023.

Regarding the examiner's three objections to the claims:

1. Rejection under 35 U.S.C. 101.

35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

"Claims 9-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more."

To overcome this objection, claim 9 has been amended. The remaining claims have been canceled.

Here, the claims meet the statutory subject matter under 35 §101 as a new and useful process. Specifically, the process is for treating congenital hypothyroidism through direct thyroxine administration. The process is new insofar as the only existing treatment available for patients with congenital hypothyroidism is oral drug therapy daily. The process is useful insofar as it creates a way for patients to be able to treat congenital hypothyroidism more efficiently and effectively. It is also useful because it offers a solution to the problem of having to take daily medication, patient failures in medication compliance, and possible side effects associated with patients receiving non-purified thyroxine.

2. Rejection 35 U.S.C. 112(a).

The statute states:

"The following is a quotation of 35 U.S. C. 112 (pre-AIA), first paragraph:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The examiner made the following three objections under 112(a):

A. "Claims 9-15 under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention."

Additional matter has been added to the specification specifically relating to the claims. See paragraphs 26-55 of the specification. One skilled in the art would be able to read the specification and be able to make or use the invention. Indeed, one has sufficient information to assemble component mechanisms and program a logical process for administration of thyroxine to the body on a 12-hour or 24-hour basis.

B. "Given the breadth of the claims, applicant must provide a sufficient number of well-defined mathematical algorithms (ie.virtual models) capable of performing the claimed functions and bearing a reasonable correlation to the entire scope of the claim."

The claim has been narrowed such that the functions are more specifically detailed. Additionally, a new model has been introduced in drawing 4 to provide more specific guidance on the functionality of the artificial intelligence computer program. Additionally, the following algorithm has been added in the specification, defining the mechanism for identifying the optimal delivery dosage.

$$\underline{ai^* = \text{ai} \min_{tc} tc^m - tc^*}$$

C. "The specification also fails to provide any evidence that applicant had knowledge specific dosages of specific thyroid hormones useful for curing hypothyroidism as claimed."

The specific dosages have been added to both the body of the claim and to the specification. The specific dosage ranges between a range of 4 and 301 micrograms.

3. Claim rejections - 35 USC § 112 (b)

"The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

"Claims 9-15 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. Claims that depend directly or indirectly from claims) is/are also rejected due to said dependency."

The claim has been significantly narrowed to describe the invention more meticulously and to directly address the indefinite objection. The preamble has been narrowed to directly focus on a method for treating congenital hypothyroidism with Thyroxine drug administration. In the body, the specific thyroid hormone Thyroxine now further defines the nature of the invention, the time duration of twelve hours for administration narrows the claim and the dosages between four micrograms and three-hundred-and-one micrograms also limit the claim further.

"Claim 9 recites "using an artificial intelligence program, predicting needed delivery dosage, delivering thyroid hormone, according to the dosage defined by the artificial intelligence program, maintaining metabolic homeostasis, controlling thyroid human in the bloodstream." This phrase is problematic for the following reasons: (1) With regards to the "using" phrase, the claim does not set forth any steps involved in the method/process of use. As a result, it is unclear what method/process applicant is intending to encompass, i.e. is the claimed "Al program" an independent step, is it being "used" to perform all of the subsequent steps, or otherwise? A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced."

The phrase using has been removed. Additionally, the functional parts of the artificial intelligence program: receiving, calculating, comparing, predicting, and sending have been added. The purpose for this narrowing of the claim is to make clear the process encompassed and may be practiced.

V. Remarks

At this time, I believe my invention to be sufficiently and described such that one skilled in the art would be able to make and use the invention. As such, I respectfully request a timely notice of allowance.

Respectfully,

/Brian Haney/

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