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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* MURIEL Y. ISHIKAWA,
EDWARD K.Y. JUNG, NATHAN P. MYHRVOLD,
RICHA WILSON, and LOWELL L. WOOD, JR.[1]

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Appeal 2012-008962
Application 11/046,658
Technology Center 1600

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Before LORA M. GREEN, ALLEN R. MacDONALD, and JACQUELINE T. HARLOW, *Administrative Patent Judges.*

GREEN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's rejections of claims 51, 56, and 58–72. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part. We also enter a new ground of rejection of claims 56 and 66–72 under 35 U.S.C. § 112, second paragraph, for indefiniteness.

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[1] According to Appellants, the Real Party in Interest is Searete LLC. (App. Br. 4).

## STATEMENT OF THE CASE

Claims 51 and 56 are representative of the claims on appeal, and read as follows:

51. A system, comprising:

a computer readable recordable type medium including, but not limited to, a computer program for use with a computer system and wherein the computer program includes a plurality of instructions including:

one or more instructions for selecting one or more computable epitopes;

one or more instructions for predicting at least one pattern change as determined by analysis of past variations in the one or more computable epitopes;

one or more instructions for associating the at least one pattern change in the one or more computable epitopes with at least one timeline of therapy change;

one or more instructions for designating a course of action associated with the at least one pattern change in the one or more computable epitopes; and

one or more instructions for communicating the course of action to at least one system user.

56. A system, comprising:

circuitry for selecting one or more computable epitopes;

circuitry for predicting at least one pattern change as determined by analysis of past variations in the one or more computable epitopes;

> circuitry for associating the at least one pattern change in the one or more computable epitopes with at least one timeline of therapy change;
>
> circuitry for designating a course of action associated with the at least one pattern change in the one or more computable epitopes; and
>
> circuitry for communicati[ng] the course of action to at least one system user.

(App. Br. 57–58).

The following grounds of rejection are before us for review:

I. Claims 51 and 58–65 stand rejected under 35 U.S.C. § 101 as drawn to non-statutory subject matter (Ans. 6).

II. Claims 51, 56, and 58–72 stand rejected under 35 U.S.C. § 112, first paragraph as being non-enabled (Ans. 7).

We affirm rejection I, but reverse rejection II. We also enter new grounds of rejection.

ISSUE (Rejection I)

Has the Examiner established by a preponderance of the evidence that claims 51 and 58–65 are drawn to non-statutory subject matter?

*FINDINGS OF FACT*

We find that the following enumerated findings of fact (FF) are supported by at least a preponderance of the evidence. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

FF 1. The Specification teaches that the "present application relates, in general, to detection and/or treatment" (Spec. 4).

FF 2. The Specification teaches further "a system includes but is not limited to: a computer readable medium including, but not limited to, a computer program for use with a computer system" (*id.*).

FF 3. The Specification defines "epitope" as, including but not limited to:

> a sequence of at least 3 amino acids, a sequence of at least nine nucleotides, an amino acid, a nucleotide, a carbohydrate, a protein, a lipid, a capsid protein, a polysaccharide, a sugar, a lipopolysaccharide, a glycolipid, a glycoprotein, and/or at least a part of a cell. As used herein, the term "epitope" . . . may . . . be used interchangeably with antigen, paratope binding site, antigenic determinant, and/or determinant. As used herein, the term "determinant" can include an influencing element, determining element and/or factor, unless context indicates otherwise. In one aspect the term "epitope" … includes, but is not limited to, a peptide-binding site. As used herein, the term "epitope" … may include structural and/or functionally similar sequences found in the agent …. The term "epitope" … includes, but is not limited to, similar sequences observed in orthologs, paralogs, homologs, isofunctional homologs, heterofunctional homologs, heterospecific homologs, and/or pseudogenes of the agent ….

(*Id.* at 13).

FF 4. The Specification defines "immune response component" as including:

> but … not limited to, at least a part of a macrophage, a neutrophil, a cytotoxic cell, a lymphocyte, a T-lymphocyte, a killer T-lymphocyte, an immune response modulator, a helper T-lymphocyte, an antigen receptor, an antigen-presenting cell, a

> dendritic cell, a cytotoxic T-lymphocyte, a T-8 lymphocyte, a cluster differentiation (CD) molecule, a CD3 molecule, a CD1 molecule, a B lymphocyte, an antibody, a recombinant antibody, a genetically engineered antibody, a chimeric antibody, a monospecific antibody, a bispecific antibody, a multispecific antibody, a diabody, a chimeric antibody, a humanized antibody, a human antibody, a heteroantibody, a monoclonal antibody, a polyclonal antibody, a camelized antibody, a deimmunized antibody, an anti-idiotypic antibody, an antibody fragment, a synthetic antibody, and/or any component of the immune system that may bind to an antigen and/or an epitope thereof in a specific and/or a useful manner.

(*Id.* at 10).

FF 5. The Specification further teaches (emphasis added):

> In addition, those skilled in the art will appreciate that the mechanisms of the subject matter described herein are capable of being distributed as a *program product in a variety of forms*, and that an illustrative embodiment of the subject matter . . . described herein *applies equally regardless of the particular type of signal-bearing media used to actually carry out the distribution. Examples of a signal-bearing media include, but are not limited to*, the following: *recordable type media such as* floppy disks, hard disk drives, DVD/CD-ROMs, digital tape, computer memory devices of various types; and *data transmission type-media such as digital and analog communication links* using TDM or IP-based communication links (e.g., packetized data links).

(*Id.* at 41).

*PRINCIPLES OF LAW*

During prosecution before the Office, claims are to be given their broadest reasonable interpretation consistent with the Specification as it would be interpreted by one of ordinary skill in the art. *In re American*

*Academy Of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). In addition, the claims are not to be confined to the embodiments found in the Specification, and it is improper to import limitations from the Specification into the claims. *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007).

"An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process." *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989). Moreover, it is during prosecution that applicants have "the opportunity to amend the claims to obtain more precise claim coverage." *American Academy*, 367 F.3d at 1364.

It is well established that laws of nature, natural phenomena, and abstract ideas are not patentable subject matter under 35 U.S.C. § 101. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1290 (2012).

*ANALYSIS*

The Examiner rejects claims 51, and 58–65 as being drawn to non-statutory subject matter because the claims "are directed to a system comprising a computer readable recordable type medium including a computer program with instructions." (Ans. 6). The Examiner reasons that, because the Specification "does not supply a limiting definition of a computer readable recordable type medium," this claim limitation is "not sufficient to distinguish the claimed medium from a signal" and therefore the claims cover "both transitory and non-transitory embodiments" (*id.*).

Appellants first argue that the rejection is improper because it is not a new rejection, but rather has the "same thrust" as a prior rejection which was expressly withdrawn. (App. Br. 26–27). Appellants contend that the Examiner's reinstatement of a previous rejection with "no new explanation" is improper because it "[creates] a confusing record," amounts to "the unnecessary and costly waste of USPTO and Appellant's resources," and violates the principles of "[f]airness and equity" and the "USPTO's policy of compact prosecution." (*Id.* at 28–29; Reply Br. 3).

That argument is not persuasive of reversible error. Appellants have not identified any authority or case law that prevents an Examiner from reconsidering the patentability of claims during prosecution. As the Examiner explains, the rejection of claim 51 under § 101 was expressly withdrawn in the March 1, 2010 Official Action, but was reconsidered in light of Subject Matter Eligibility Guidelines of Computer Readable Media (hereinafter "Guidelines") published in February 2010. (Ans. 13). Appellants contend, however, that the Guidelines "*already existed* when [the Examiner] explicitly withdrew the prior rejection in the March 2010 Office Action," and that the Examiner was presumably aware of the Guidelines when the rejection was withdrawn. (Reply Br. 6).

That argument is also not persuasive. The rejection of claim 51 under § 101 was withdrawn in an Official Action mailed Monday, March 1, 2010. The Guidelines were published six days before, on Tuesday, February 23, 2010. Appellants' contention seems to suggest that the Examiner was aware of and applied the Guidelines to claim 51, and then processed an Official Action to enable its mailing within six days of the Guideline's publication.

We do not find that position reasonable. However, even if Appellants' position had some merit, Appellants still have not identified how the Examiner erred by reconsidering the patentability of claim 51 while prosecution was ongoing. Thus, we discern no reversible error committed by the Examiner in reconsidering the previous withdrawal of the § 101 rejection of claim 51.

Next, Appellants argue that the broadest reasonable interpretation of the recited "computer readable recordable type medium" in claim 51, and its dependent claims 58–65, is "sufficient to distinguish the claimed medium from a signal" because the claimed language "would be read by one of ordinary skill in the art to include tangible medium [sic], specifically 'recordable type' tangible media." (App. Br. 35).

We are not persuaded. In claim 51, the recited "computer readable recordable type medium" is not claimed as non-transitory, and the Specification does not expressly and unambiguously limit that medium to solely non-transitory forms via a definition or similar limiting language. Rather, the Specification merely provides non-limiting examples of recordable type media, which include "data transmission type-media such as digital and analog communication links using TDM or IP-based communication links (e.g., packetized data links)" (*see* FF 5). Therefore, the claimed medium encompasses transitory forms and is ineligible under § 101.

*CONCLUSION OF LAW*

We conclude that the Examiner has established by a preponderance of the evidence that claims 51 and 58–65 are directed to non-statutory subject matter.

Accordingly, we affirm the Examiner's § 101 rejection of claims 51 and 58–65.

ISSUE (Rejection II)

Has the Examiner established by a preponderance of the evidence that the Specification fails to enable the claimed systems?

*FINDINGS OF FACT*

FF 6. The Examiner's statement of the enablement rejection may be found at pages 7–12 of the Answer.

FF 7. The Examiner finds that "[t]he claims are broad in that they require associating at least one pattern change in one or more computable epitopes with at least one timeline of therapy change, and are not limited to a particular therapy for a particular disease, nor to any particular epitopes." (Ans. 12).

FF 8. The Examiner also finds that the Specification does not provide specific guidance or working examples of a computer program for associating at least one pattern change in one or more computable epitopes with at least one timeline of therapy change, and also finds that the nature of the invention is complex (*id.* at 10).

FF 9. The Examiner further finds that the level of skill in the art is high, but that the prior art does not teach "anything related to a machine with

hardware and software components for associating a pattern change in one or more computable epitopes with a timeline of therapy change" (*id.* at 11).

FF 10. The Examiner appears to cite De Groot[2] and Moore[3] as evidence of the state of the art (*id.*).

FF 11. The Examiner notes that while De Groot "teaches bioinformatics tools for designing epitope-based treatments for HIV . . . [De Groot] does not teach associating pattern changes in epitopes with a timeline of therapy change" (*id.*).

FF 12. The Examiner notes that although "Moore teaches a program (Epipop) for performing association testing between the presence of HIV residue polymorphisms and HLA alleles in a population . . . [Moore] does not teach associating pattern changes in epitopes with a timeline of therapy change" (*id.*).

FF 13. Thus, according to the Examiner:

> The skilled practitioner would first turn to the instant specification for guidance in making and using the claimed invention. However, the specification does not disclose any computer hardware components and integrated software or any method capable of predictably associating at least one pattern change in one or more computable epitopes with at least one timeline of therapy change, as in claims 51 and 56. As such, the skilled practitioner would turn to the prior art for guidance, but

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[2] A.S. De Groot et al., *Designing HIV-1 vaccines to reflect viral diversity and the global context of HIV/AIDS*, 1 AIDSCIENCE 1–16 (2001) ("De Groot").

[3] Corey B. Moore et al., *Evidence of HIV-1 Adaptation to HLA-Restricted Immune Responses at a Population Level*, 296 SCIENCE 1439–1443 (2002) ("Moore").

> the prior art does not discuss these limitations. Finally, said practitioner would turn to trial and error experimentation to make and use the claimed invention. Due to the high degree of unpredictability, coupled to the lack of guidance in either the prior art or instant specification, it would require undue experimentation to perform the instructions recited in the claims.

(*Id.* at 12).

*PRINCIPLES OF LAW*

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application." *In re Wright*, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993).

> [A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

*In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971) (emphasis added). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *Id.* at 224.

Although "working examples are *desirable* in complex technologies . . . examples are not *required* to satisfy section 112, first paragraph." *In re Strahilevitz*, 668 F.2d 1229, 1232 (CCPA 1982) (emphasis in original).

"'The enablement requirement is met if the description enables any mode of making and using the invention.'" *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (quoting *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991)). Furthermore, "[e]nablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003).

*ANALYSIS*

Appellants argue that the Specification "provides further support and context for the claim recitations as a whole," and thus, "[o]ne of skill in the art could implement these portions of the specification, *inter alia*, in relation to programming a computer system to utilize Appellant[s'] claims 51 and 56, or for utilizing such a programmed computer system" (App. Br. 42, 44). Appellants further argue that the Examiner has not demonstrated "a reasonable basis to question the enablement of Appellant[s'] claims" (*id.* at 44–45). Appellants assert that the Specification "provides clear 'direction or guidance' [to] one of skill in the art to practice Appellant[s'] claims without undue experimentation. Table 1 . . . lists multiple examples from the specification that provide support for claims 51 and 56" (*id.* at 49–50).

Appellants further assert that the statement of the rejection "did not describe the relationship of the cited [De Groot and Moore] references to the actual claims at issue and therefore does not establish a reasonable basis to determine any 'undue experimentation' that may be required to use Appellant[s'] claims" (*id.* at 52).

We agree with Appellants that the Examiner has not established a prima facie case that the Specification fails to enable the claimed systems. In particular, although we acknowledge that the Specification does not provide working examples of such systems, it does provide guidance as to how the ordinary skilled artisan could make or use a system with an integrated hardware or software component for associating a pattern change in one or more computable epitopes with a timeline of therapy change. (*See, e.g.*, Spec. 21–22, and 30–33).

We have also considered the Moore and De Groot references cited by the Examiner, but they do not persuade us otherwise. The fact that the references do not discuss associating a pattern change in one or more computable epitopes with a timeline of therapy change is not evidence that the instant claims are not enabled, or even that they are enabled. That is, Moore and De Groot do not appear to be relevant to the issue of whether the instantly claimed systems are enabled.

*CONCLUSION OF LAW*

We conclude that the Examiner has not established by a preponderance of the evidence that the Specification fails to enable the claimed systems. We, thus, reverse the Examiner's enablement rejection

under 35 U.S.C. § 112, first paragraph, of claims 51, 56, and 58–72, as failing to comply with the enablement requirement.

NEW GROUND OF REJECTION

Pursuant to our authority under 37 C.F.R. § 41.50(b), we enter a new ground of rejection for claims 56 and 66–72 under 35 U.S.C. § 112, second paragraph, for indefiniteness.

Specifically, we construe each of the "circuitry for" limitations recited in independent claim 56 as "means-plus-function" limitations subject to 35 U.S.C. § 112, sixth paragraph, and conclude that claim 56 and each of its dependent claims are rendered indefinite under 35 U.S.C. § 112, second paragraph, due to the Specification's failure to disclose corresponding structure for performing either of the recited functions. Claims 66–72[4] depend from claim 56, and, thus, those claims are rejected as well.

*FINDINGS OF FACT*

FF 14. As to "systems" the Specification teaches (emphasis added):

> In one or more various aspects, related systems include but are not limited to circuitry and/or programming for effecting the herein-referenced method aspects; *the circuitry* and/or programming *can be virtually any combination of hardware*, software, and/or firmware *configured to effect the herein-referenced method aspects depending upon the design choices of the system designer*.

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[4] We note that the dependent claims 66 and 69–72 also contain "circuitry for" limitations, but determine there is no need to separately address those added limitations for purposes of this new ground of rejection.

(Spec. 5).

FF 15. The Specification teaches (emphasis added):

> The foregoing detailed description has set forth various embodiments of the devices and/or processes via the use of block diagrams, flowcharts, and/or examples. *Insofar as such block diagrams, flowcharts, and/or examples contain one or more functions and/or operations*, it will be understood by those within the art that *each function and/or operation within such block diagrams, flowcharts, or examples can be implemented, individually and/or collectively, by a wide range of hardware, software, firmware, or virtually any combination thereof.* In one embodiment, several portions of the subject matter described herein may be implemented via Application Specific Integrated Circuits (ASICs), Field Programmable Gate Arrays (FPGAs), digital signal processors (DSPs), other integrated formats, or other extensively-integrated formats. However, those skilled in the art will recognize that some aspects of the embodiments disclosed herein, in whole or in part, can be equivalently implemented in *standard integrated circuits*, as one or more computer programs running on one or more computers (e.g., as one or more programs running on one or more computer systems), as one or more programs running on one or more processors (e.g., as one or more programs running on one or more microprocessors), as firmware, or as virtually any combination thereof, and that *designing the circuitry* and/or writing the code for the software and[/]or firmware *would be well within the skill of one of skill in the art* in light of this disclosure.

(*Id.* at 40).

FF 16. The Specification teaches further (emphasis added):

> In a general sense, those skilled in the art will recognize that the various aspects described herein which can be implemented, individually and/or collectively, by a wide range of hardware, software, firmware, or any combination thereof can be viewed as being composed of various types of "electrical circuitry." Consequently, as used herein "electrical circuitry" includes, but is not limited to, electrical circuitry having at least

> one discrete electrical circuit, electrical circuitry having at least one integrated circuit, electrical circuitry having at least one application-specific integrated circuit, *electrical circuitry forming a general-purpose computing device configured by a computer program* (*e.g., a general-purpose computer configured by a computer program* which at least partially carries out processes and/or devices described herein, or a microprocessor configured by a computer program which at least partially carries out processes and/or devices described herein), electrical circuitry forming a memory device (e.g., forms of random access memory), and/or electrical circuitry forming a communications device (e.g., a modem, communications switch, or optical-electrical equipment).

(*Id.* at 41).

FF 17. The Specification teaches further (emphasis added):

> Those skilled in the art will recognize that it is common within the art to describe devices and/or processes in the fashion set forth herein, and thereafter use *standard engineering practices* to integrate such described devices and/or processes into data-processing systems. That is, at least a portion of the devices and/or processes described herein can be integrated into a data-processing system via a reasonable amount of experimentation. Those having skill in the art will recognize that a typical data processing system generally includes one or more of a system unit housing, a display device, a video display device, a memory such as volatile and/or non-volatile memory, processors such as microprocessors and digital signal processors, computational entities such as operating systems, drivers, user interfaces (e.g., graphical), and applications programs, one or more interaction devices, such as a touch-pad or screen, and/or control systems including feedback loops and control motors .... A typical data processing system may be implemented utilizing *any suitable commercially available components, such as those typically found in digital data computing/communication and/or network computing/ communication systems.*

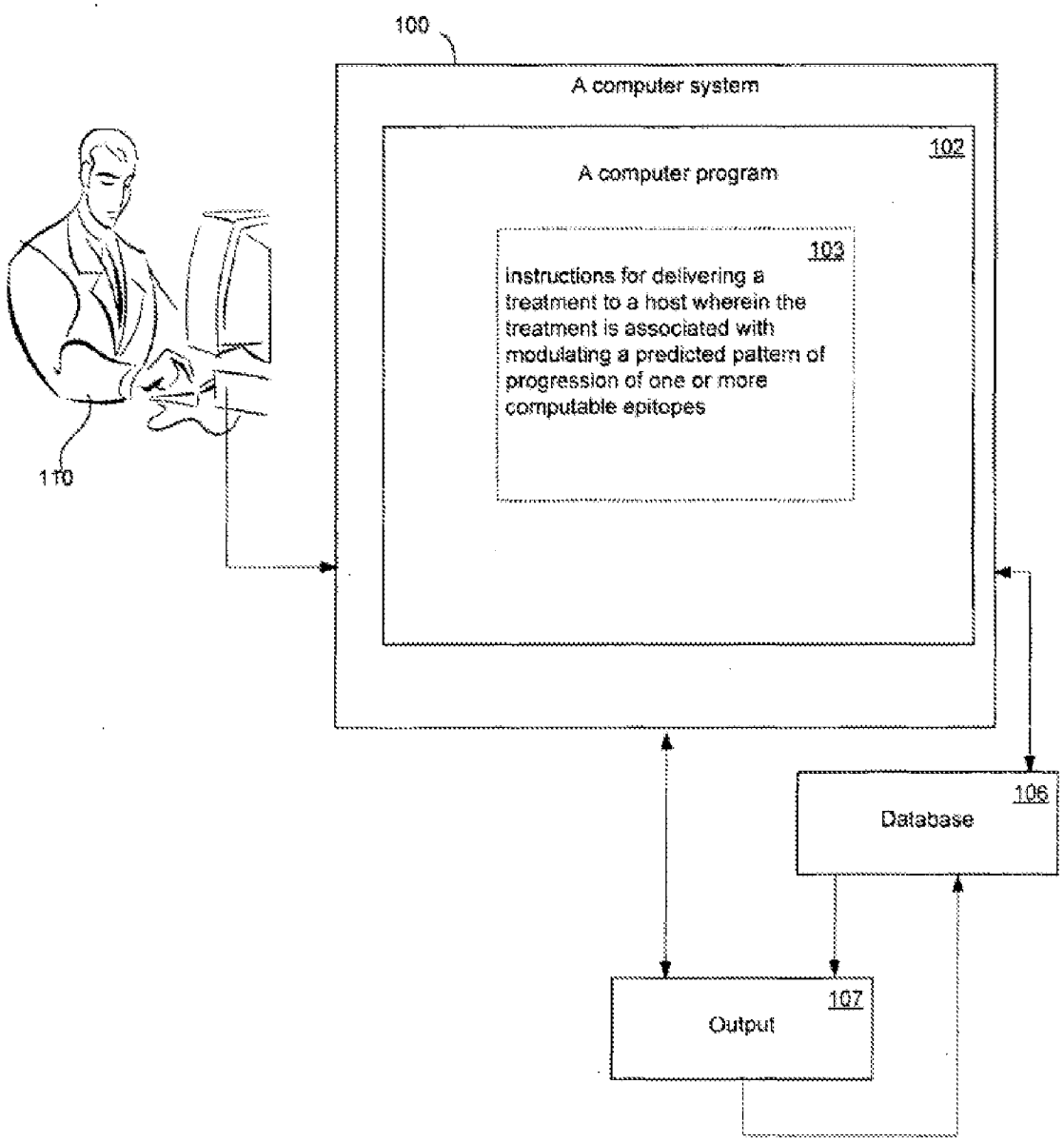
(*Id.* at 41–42).

FF 18. The Specification teaches further (emphasis added):

> The herein described aspects depict different components contained within, or connected with, different other components. It is to be understood that such depicted architectures are merely exemplary, and that in fact *many other architectures can be implemented which achieve the same functionality*. In a conceptual sense, any arrangement of components to achieve the same functionality is effectively "associated" such that the desired functionality is achieved. Hence, any two components herein combined to achieve a particular functionality can be seen as "associated with" each other such that the desired functionality is achieved, irrespective of architectures or intermedial components. Likewise, any two components so associated can also be viewed as being "operably connected", or "operably coupled", to each other to achieve the desired functionality, and any two components capable of being so associated can also be viewed as being "operably couplable", to each other to achieve the desired functionality.

(*Id.* at 42).

FF 19. Figure 1 is reproduced below:



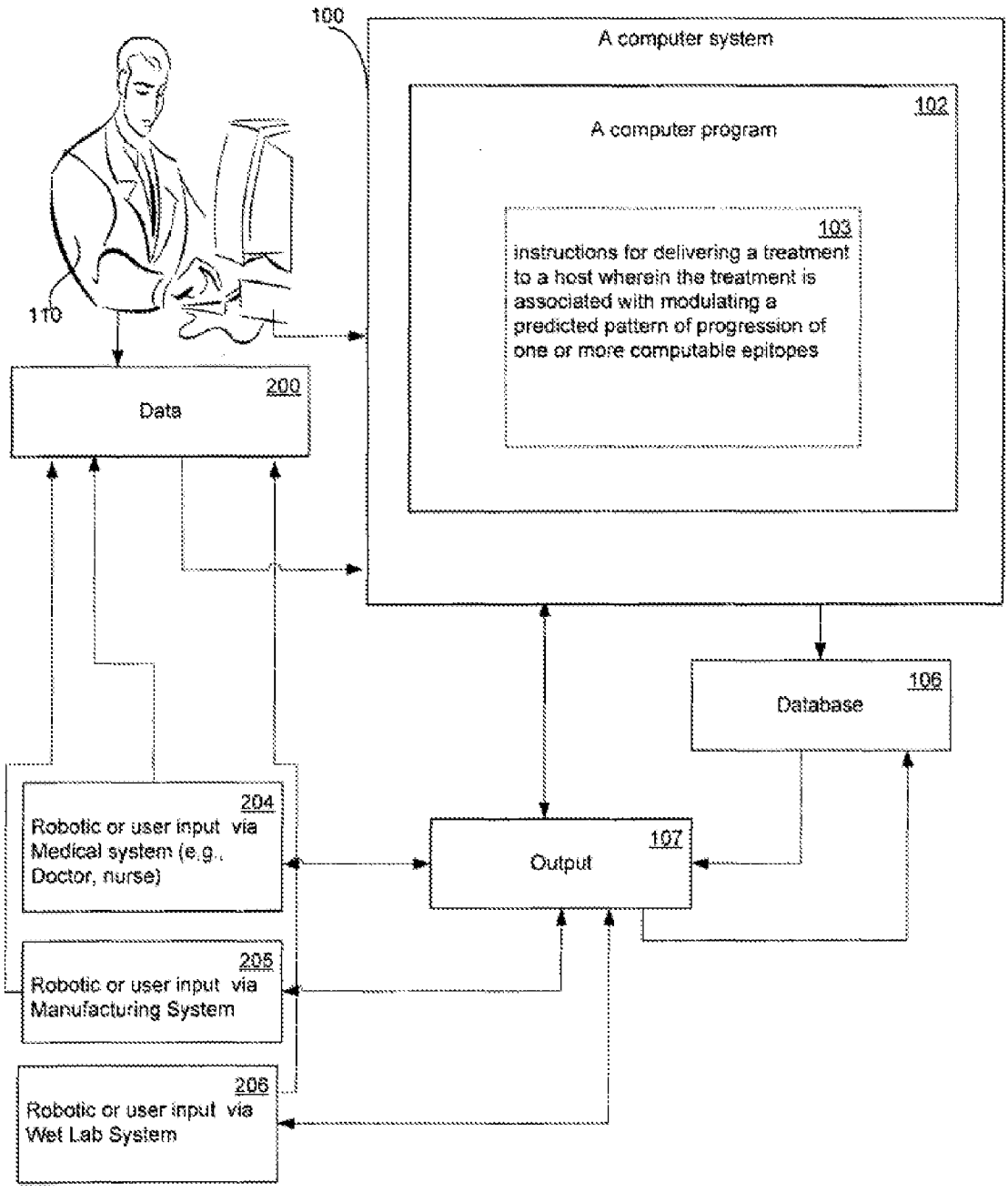

"Figure 1 depicts a partial view of a system that may serve as an illustrative environment of and/or for subject matter technologies." (*Id.* at 5).

FF 20. Regarding Figure 1, the Specification teaches:

> One or more users 110 may use a computer system 100 including a computer program 102, for example, for providing and/or delivering a treatment associated with a disease, disorder, or condition. The computer program 102 may include one or more instructions, for example, instructions for delivering a treatment to a host wherein the treatment is associated with modulating a predicted pattern of progression of one or more computable epitopes 103. The instructions may be such that, when they are loaded to *a general-purpose computer* or microprocessor programmed to carry out the instructions, they create a new machine, because *a general purpose computer in effect may become a special-purpose computer once it is programmed to perform particular functions pursuant to instructions from program software.* That is, *the instructions of the software program may electrically change the general-purpose computer by creating electrical paths within the device. These electrical paths, in some implementations, may create a special-purpose machine having circuitry for carrying out the particular program.* The computer program 102 may include instructions that give rise to circuitry for delivering a treatment to a host wherein the treatment is associated with modulating a predicted pattern of progression of one or more computable epitopes 103. The treatment, may be provided based on, for example, including, but not limited to, information specific to the host and/or agent. In one aspect, the treatment, may include a plan and/or a protocol for treating a person. The treatment may include, and is not limited to, the treatment of a disease, disorder, condition, management of health in a healthy individual, and/or the management of health in an at-risk individual.

(*Id.* at 7–8).

FF 21. Figure 2 is reproduced below:




"Figure 2 depicts a partial view of a system that may serve as an illustrative environment of and/or for subject matter technologies." (*Id.* at 5).

FF 22. Regarding Figure 2, the Specification teaches:

> The database 106, data 200, and/or the output 107 may be accessed by various input mechanisms, for example, mechanisms including but not limited to, robotic and/or user input via medical system 204, robotic and/or user input via manufacturing system 205, or robotic and/or user input via wet lab system 206. Access to the data 200 may be provided, for example, for further manipulation of the data.

(*Id.* at 8).

*PRINCIPLES OF LAW*

Special rules of claim construction allow for claim limitations drafted in functional language and are set forth in 35 U.S.C. § 112, sixth paragraph, which provides for:

> [a]n element in a claim for a combination may be expressed as a means or step for performing a specified function *without the recital of structure, material, or acts in support thereof*, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112, sixth paragraph (emphasis added). While this provision permits a claim limitation to be set forth using solely functional language, it operates to restrict such claim limitations to those structures, materials, or acts disclosed in the specification (or their equivalents) that perform the claimed function. *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998).

The Federal Circuit has established that use of the term "means" is central to the analysis of whether a claim limitation should be interpreted in accordance with 35 U.S.C. § 112, sixth paragraph: use of the word "means"

creates a rebuttable presumption that the inventor intended to invoke § 112, sixth paragraph, whereas failure to use the word "means" creates a rebuttable presumption that the inventor did not intend the claims to be governed by § 112, sixth paragraph. *Id.* at 703–04. However, this presumption against its invocation can be overcome, and therefore § 112, sixth paragraph will apply, if the "claim term fails to 'recite [] sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'" *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (quoting *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed. Cir. 2000)).

For a computer-implemented claim limitation interpreted under § 112, sixth paragraph, the corresponding structure must include the algorithm needed to transform the general purpose computer or processor disclosed in the specification into the special purpose computer programmed to perform the disclosed algorithm. *Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008); *see also Function Media, L.L.C. v. Google, Inc.*, 708 F.3d 1310, 1318 (Fed. Cir. 2013). Thus, the specification must sufficiently disclose an algorithm to transform the general purpose computer or processor to a special purpose processor programmed to perform the disclosed algorithm. *Aristocrat*, 521 F.3d at 1338. An algorithm is defined, for example, as "a finite sequence of steps for solving a logical or mathematical problem or performing a task." MICROSOFT Computer Dictionary 23 (5th ed. 2002). An applicant may express the algorithm in any understandable terms including as a mathematical formula, in prose, in a flow chart, or "in any other manner that provides sufficient

structure." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008).

An indefiniteness rejection under § 112, second paragraph, is appropriate if the specification discloses no corresponding algorithm associated with a computer or processor. *Aristocrat*, 521 F.3d at 1337–38. Mere reference to a general purpose computer or processor with appropriate programming without providing an explanation of the appropriate programming or to "software" without providing detail about the means to accomplish the software function is not an adequate disclosure. *Id.* at 1334; *Finisar*, 523 F.3d at 1340–41. In addition, simply reciting the claimed function in the specification, while saying nothing about how the computer or processor ensures that those functions are performed, is not a sufficient disclosure for an algorithm which, by definition, must contain a sequence of steps. *Blackboard, Inc. v. Desire2Learn, Inc.*, 574 F.3d 1371, 1384 (Fed. Cir. 2009).

*ANALYSIS*

Claim 56 is directed to "[a] system, comprising:
circuitry for selecting one or more computable epitopes;
circuitry for predicting at least one pattern change . . . ;
circuitry for associating the at least one pattern change . . . ;
circuitry for designating a course of action . . . ; and
circuitry for communicati[ng] the course of action . . . ."

Appellants' failure to use the word "means" in each "circuitry for" limitation creates a rebuttable presumption that the inventor did not intend this claim limitation to be governed by § 112, sixth paragraph. *Personalized*

*Media*, 161 F.3d at 703–704. However, this presumption may be overcome if one or more of the "circuitry for" limitations "recites 'function without reciting sufficient structure for performing that function'." *Williamson*, 792 F.3d at 1348 (quoting *Watts*, 232 F.3d at 880).

We conclude that the presumption against invoking § 112, sixth paragraph has been overcome, and thus § 112, sixth paragraph does apply, because the claimed circuitry limitations recite specific functions without reciting sufficient structure for performing those functions. In particular, we note that the Specification recites that the circuitry "can be virtually any combination of hardware, software, and/or firmware configured to effect" the claimed functions, and that "designing the circuitry and/or writing the code for the software and[/]or firmware" is within the skilled of the ordinary skilled artisan (*see* FFs 14 and 15). The Specification also describes that when the instructions are loaded onto a general purpose computer, the instructions may transform the general purpose computer into a "special-purpose computer" by "creating electrical paths within the device" (FF 20). The Specification also states that "standard engineering practices" may be used to integrate such devices into data processing systems which are "implemented utilizing any suitable commercially available components" (FF 17).

However, the Specification fails to provide instructions on how the claimed circuitry, which could be part of a general purpose computer, is actually capable of performing the claimed functions. Despite providing several general references to "instructions" for carrying out the claimed functions (Spec. 4, 7–8, FFs 19–21), the Specification is silent regarding the

algorithm, or sequence of steps, specifying precisely how to carry out the various claimed functions of the circuitry. Rather, the Specification simply recites the claimed functions and provides no guidance about how the claimed circuitry ensures that those functions are performed. *See Advanced Ground Info. Sys. v. Life360*, 2016 WL 4039771, at *6 (Fed. Cir. July 28, 2016) ("A patentee cannot claim a means for performing a specific function and subsequently disclose a 'general purpose computer as the structure designed to perform that function' because this 'amounts to purely functional claiming.'" (quoting *Aritocrat*, 521 F.3d at 1333)).

*CONCLUSION OF LAW*

Accordingly, we conclude that Appellants have not disclosed sufficient structure for performing the functions recited in independent claim 56. Thus, claim 56 is indefinite under 35 U.S.C. § 112, second paragraph as to the functional aspects of the recited "circuitry." Dependent claims 66–72 are likewise indefinite under 35 U.S.C. § 112, second paragraph in view of their dependence from claim 94.

TIME PERIOD FOR RESPONSE

Regarding the affirmed rejection(s), 37 CFR § 41.52(a)(1) provides that "Appellant may file a single request for rehearing within two months from the date of the original decision of the Board."

In addition to affirming the examiner's rejection(s) of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides: "A new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .
>
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should the Appellants elect to prosecute further before the Examiner pursuant to 37 CFR § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the

prosecution before the Examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the Appellants elect prosecution before the Examiner and this does not result in allowance of the application, abandonment, or a second appeal, this case should be returned to the Patent Trial and Appeal Board for final action on the affirmed rejection, including any timely request for rehearing thereof.

AFFIRMED-IN-PART; 37 C.F.R. §41.50(b)