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(54) **SYSTEM AND METHOD RELATED TO AUGMENTING AN IMMUNE SYSTEM**

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(57) **ABSTRACT**

The present application relates, in general, to a system and/or method for detection and/or treatment.

FIG. 1

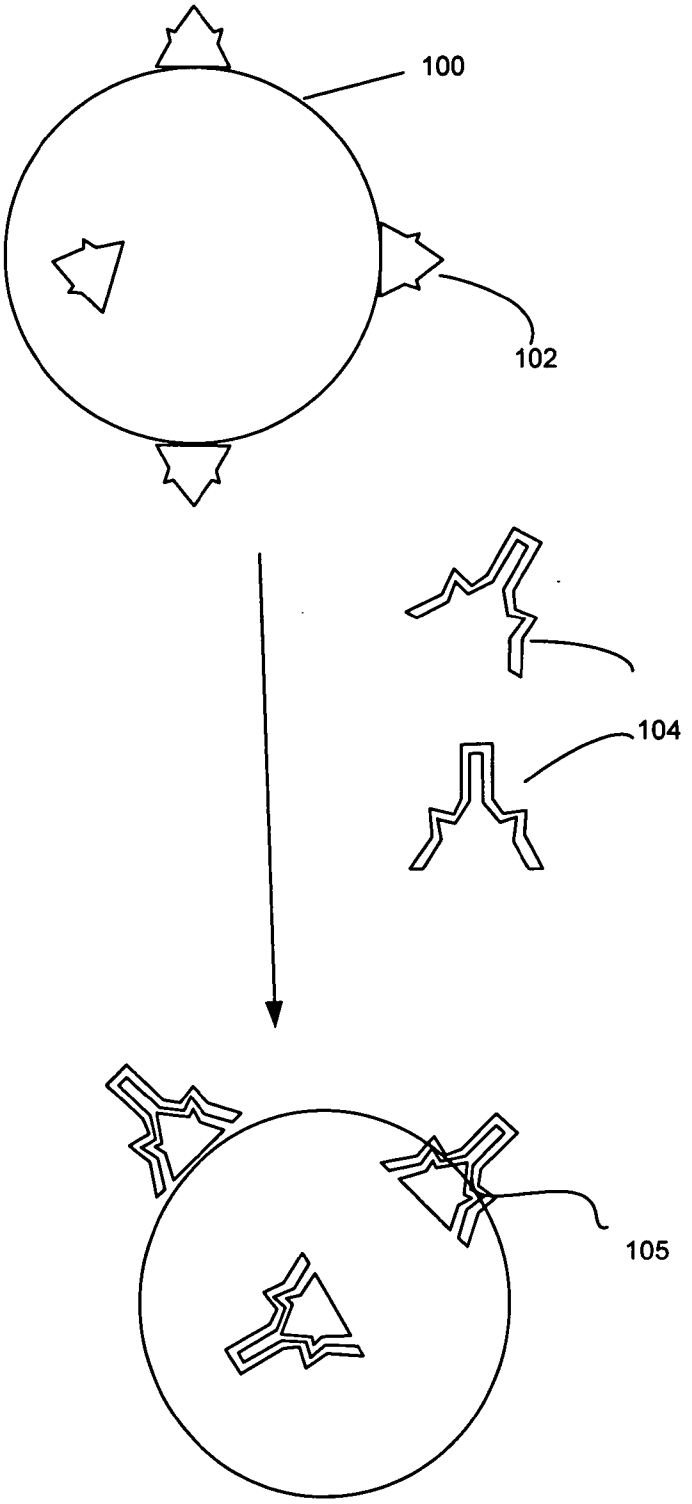

FIG. 2

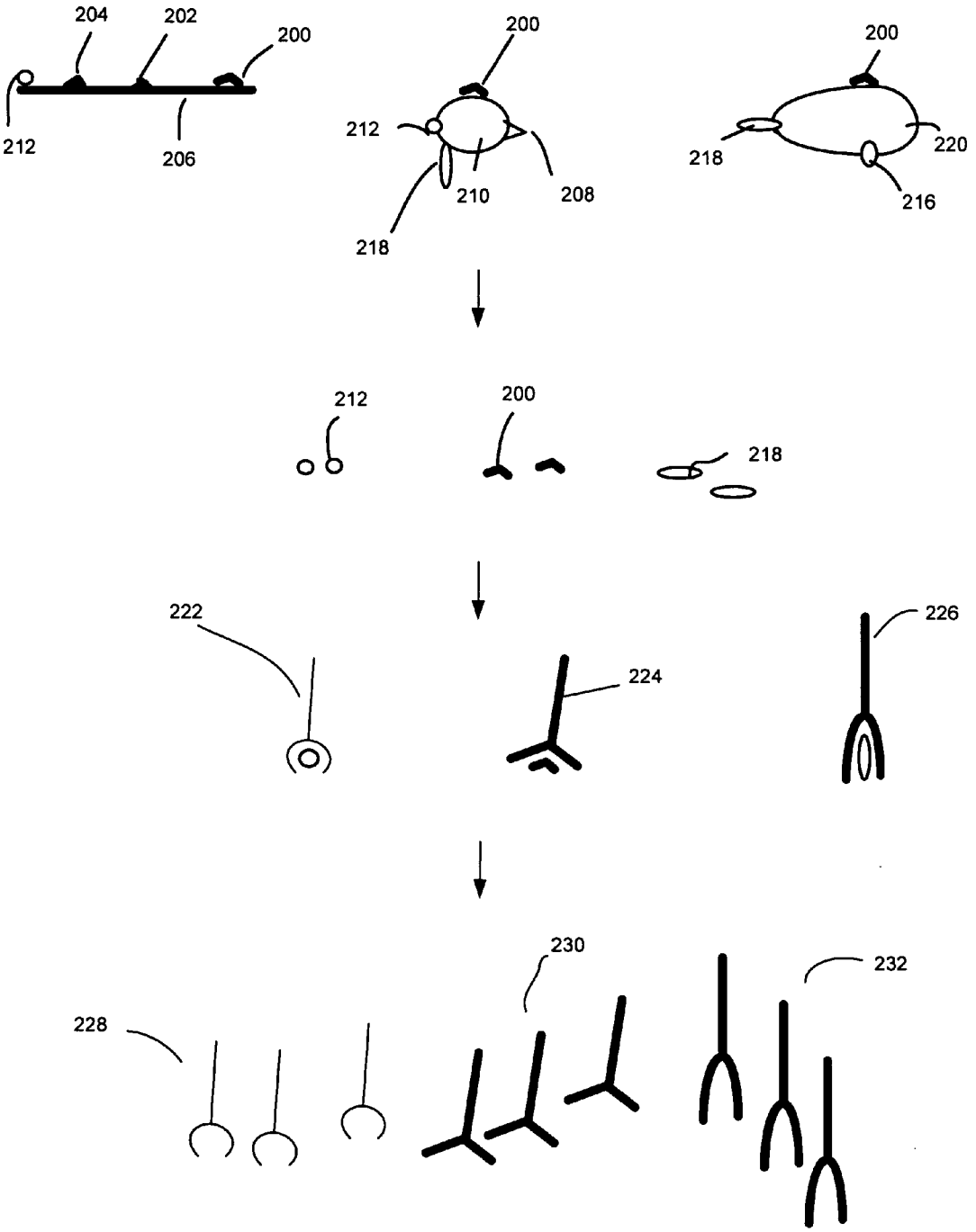
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FIG. 3

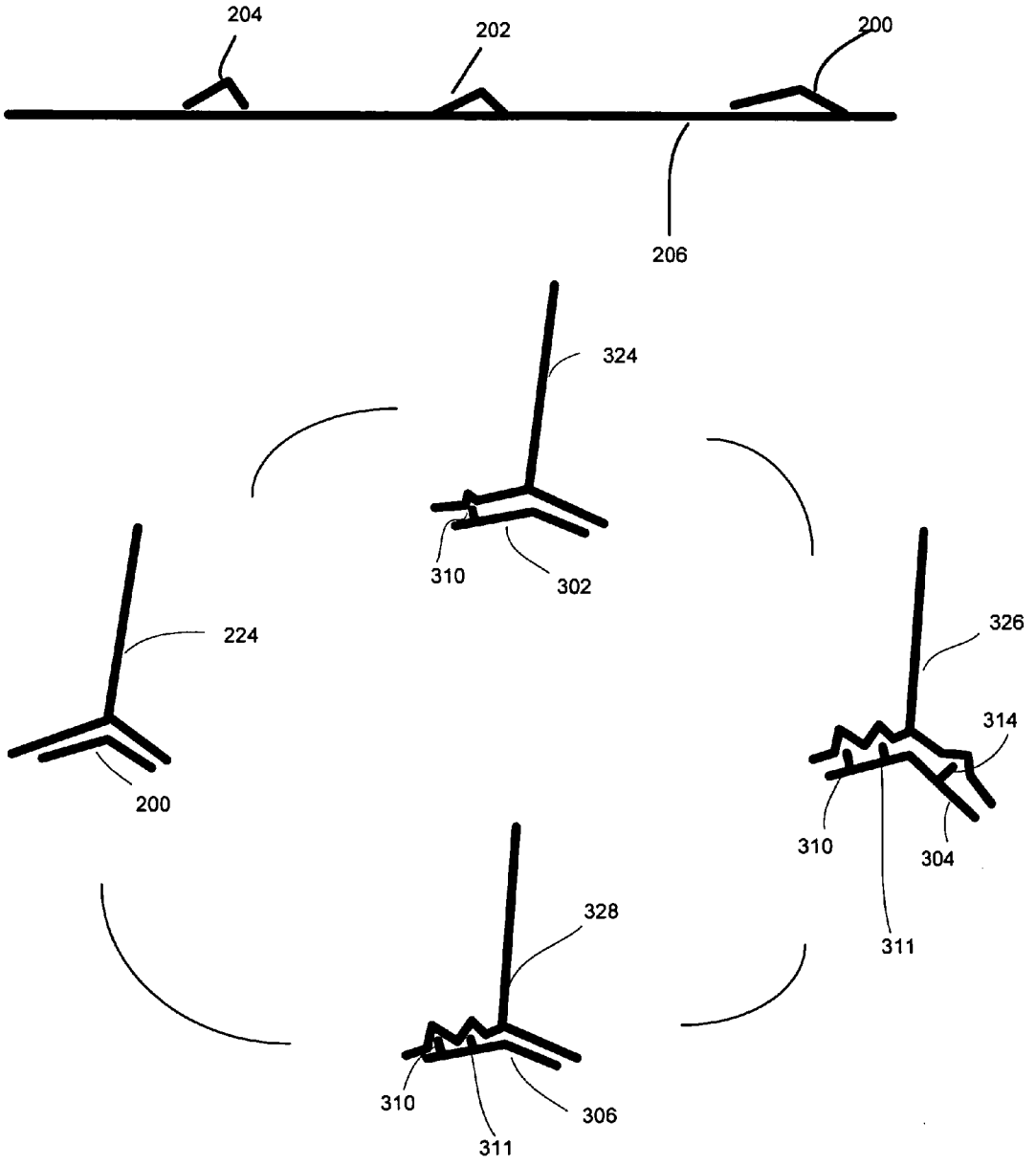

204
202
200
206
324
310
302
224
200
326
314
310
304
311
328
310
306
311

FIG. 4

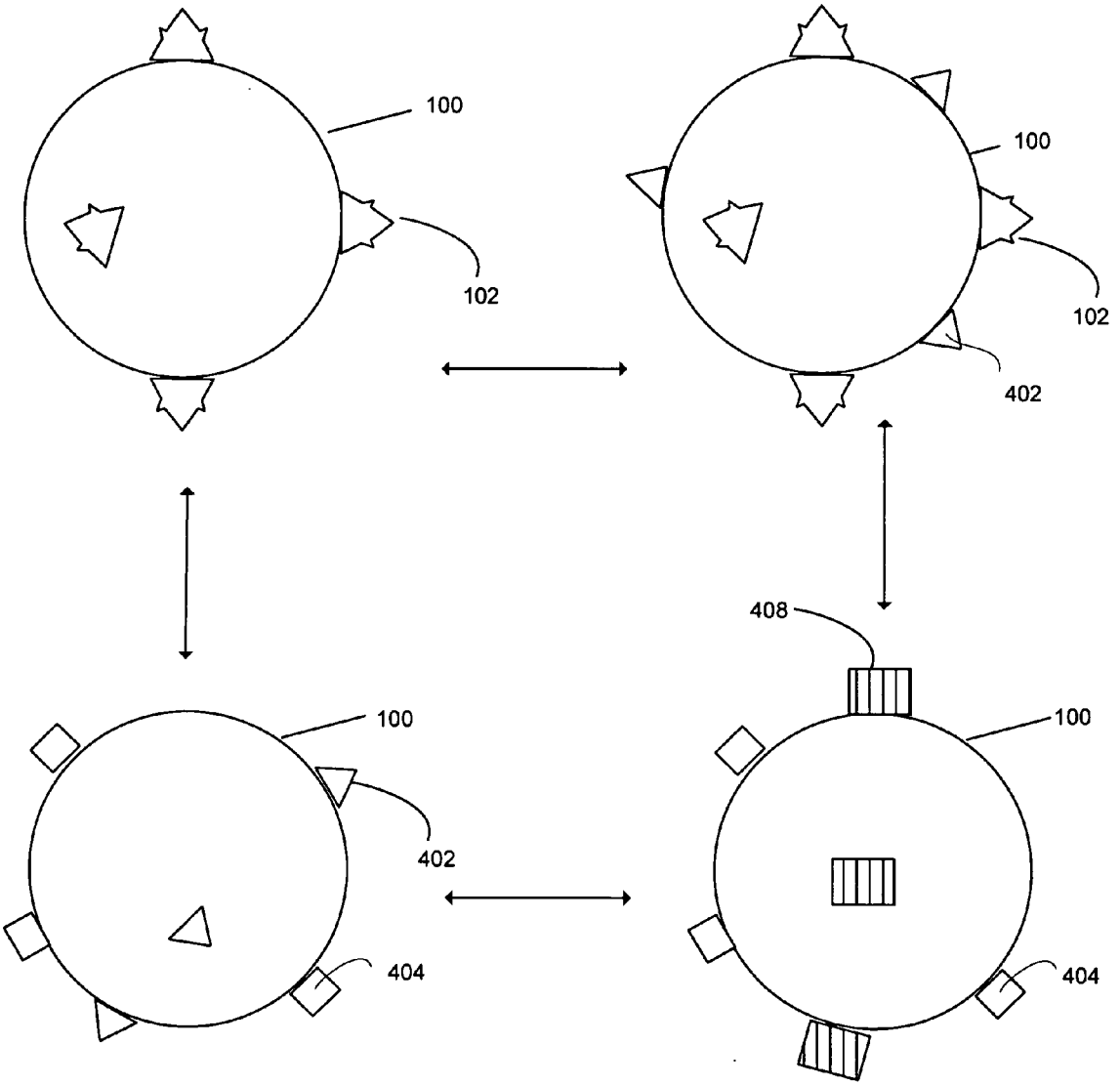


FIG. 5

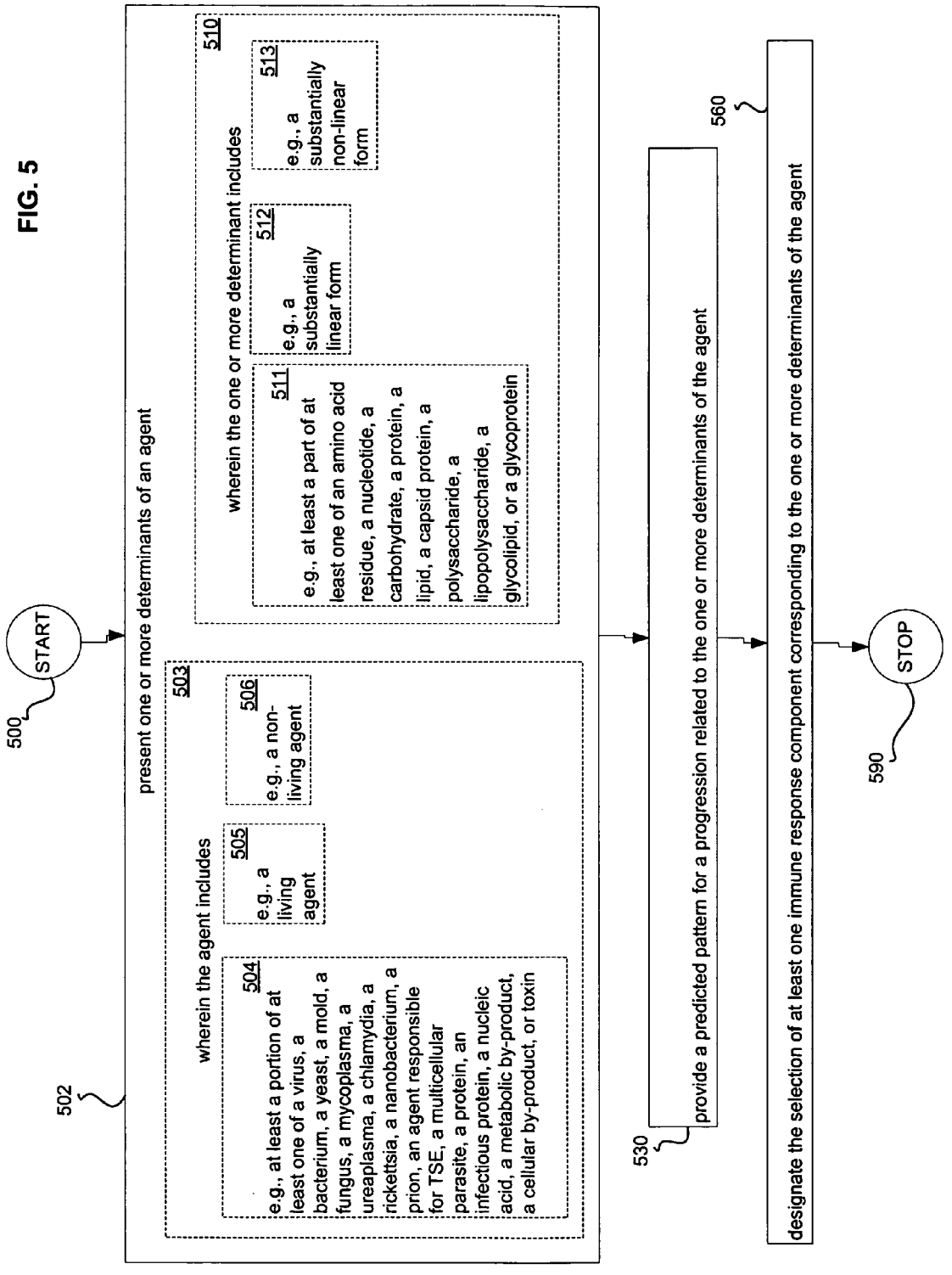

500
START
502
present one or more determinants of an agent
503
wherein the agent includes
504
e.g., at least a portion of at least one of a virus, a bacterium, a yeast, a mold, a fungus, a mycoplasma, a ureaplasma, a chlamydia, a rickettsia, a nanobacterium, a prion, an agent responsible for TSE, a multicellular parasite, a protein, an infectious protein, a nucleic acid, a metabolic by-product, a cellular by-product, or toxin
505
e.g., a living agent
506
e.g., a non-living agent
510
wherein the one or more determinant includes
511
e.g., at least a part of at least one of an amino acid residue, a nucleotide, a carbohydrate, a protein, a lipid, a capsid protein, a polysaccharide, a lipopolysaccharide, a glycolipid, or a glycoprotein
512
e.g., a substantially linear form
513
e.g., a substantially non-linear form
530
provide a predicted pattern for a progression related to the one or more determinants of the agent
560
designate the selection of at least one immune response component corresponding to the one or more determinants of the agent
590
STOP

FIG. 6

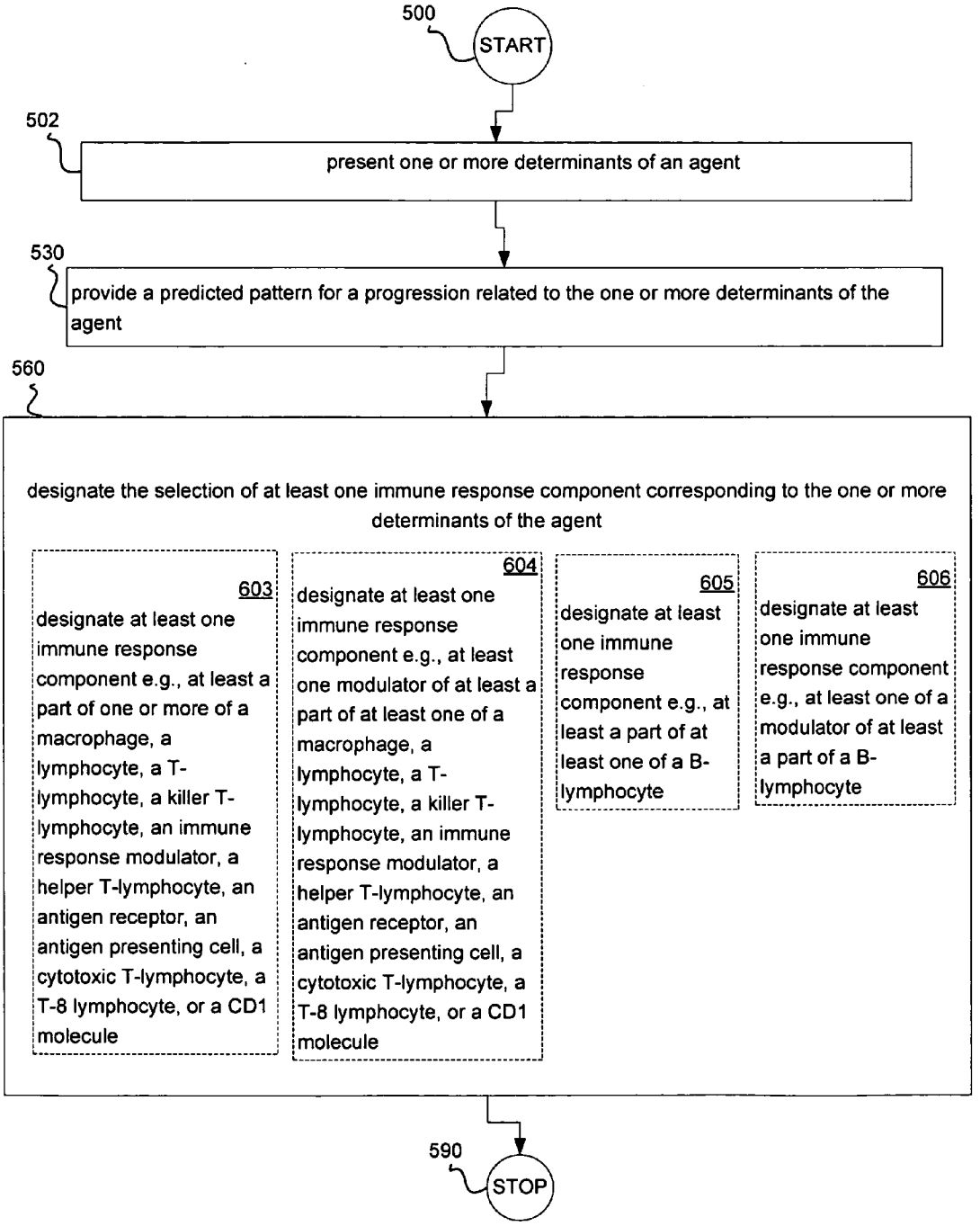

500
START
502
present one or more determinants of an agent
530
provide a predicted pattern for a progression related to the one or more determinants of the agent
560
designate the selection of at least one immune response component corresponding to the one or more determinants of the agent
603
designate at least one immune response component e.g., at least a part of one or more of a macrophage, 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 cytotoxic T-lymphocyte, a T-8 lymphocyte, or a CD1 molecule
604
designate at least one immune response component e.g., at least one modulator of at least a part of at least one of a macrophage, 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 cytotoxic T-lymphocyte, a T-8 lymphocyte, or a CD1 molecule
605
designate at least one immune response component e.g., at least a part of at least one of a B-lymphocyte
606
designate at least one immune response component e.g., at least one of a modulator of at least a part of a B-lymphocyte
590
STOP

FIG. 7

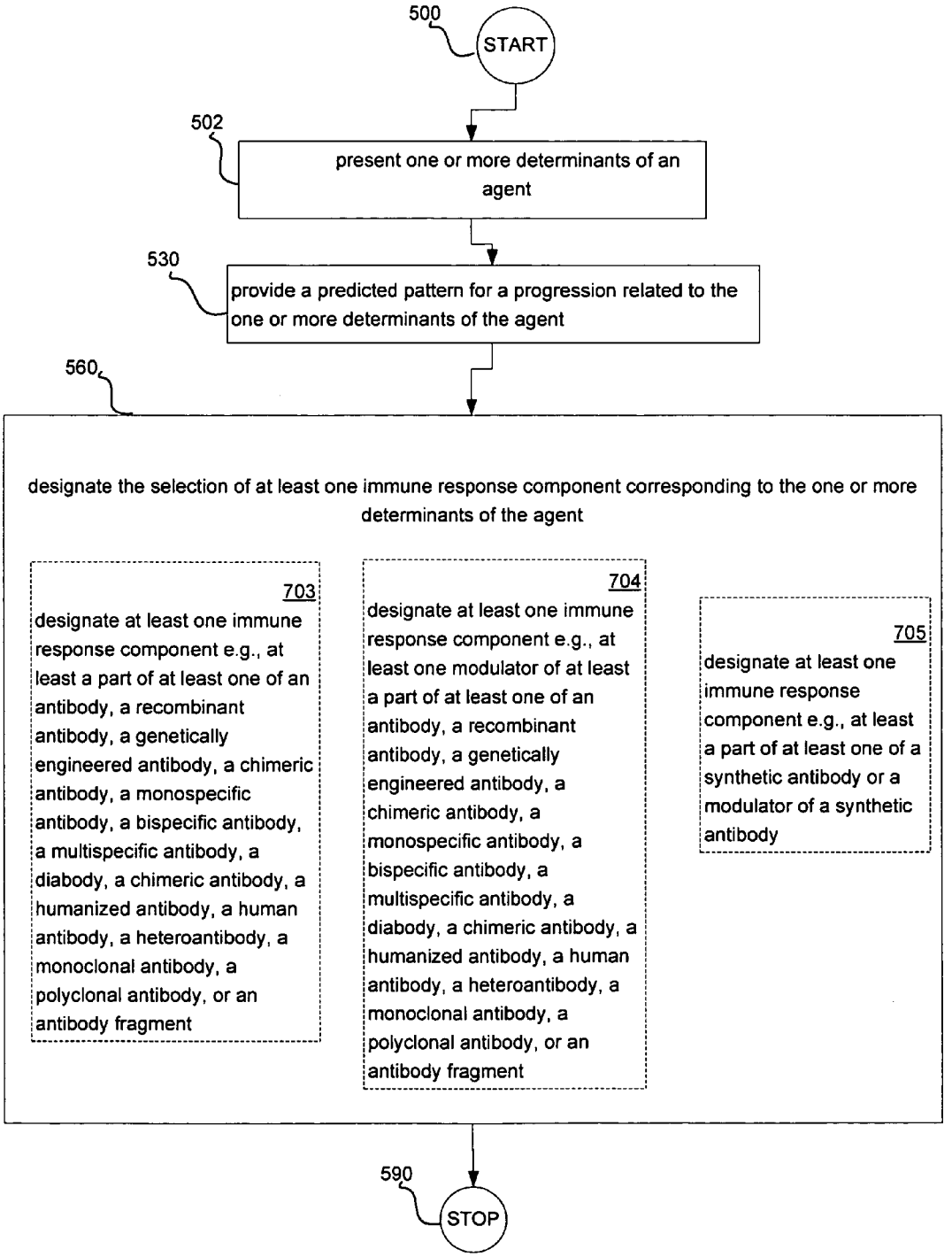

500
START
502
present one or more determinants of an agent
530
provide a predicted pattern for a progression related to the one or more determinants of the agent
560
designate the selection of at least one immune response component corresponding to the one or more determinants of the agent
703
designate at least one immune response component e.g., at least a part of at least one of 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, or an antibody fragment
704
designate at least one immune response component e.g., at least one modulator of at least a part of at least one of 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, or an antibody fragment
705
designate at least one immune response component e.g., at least a part of at least one of a synthetic antibody or a modulator of a synthetic antibody
590
STOP

FIG. 8

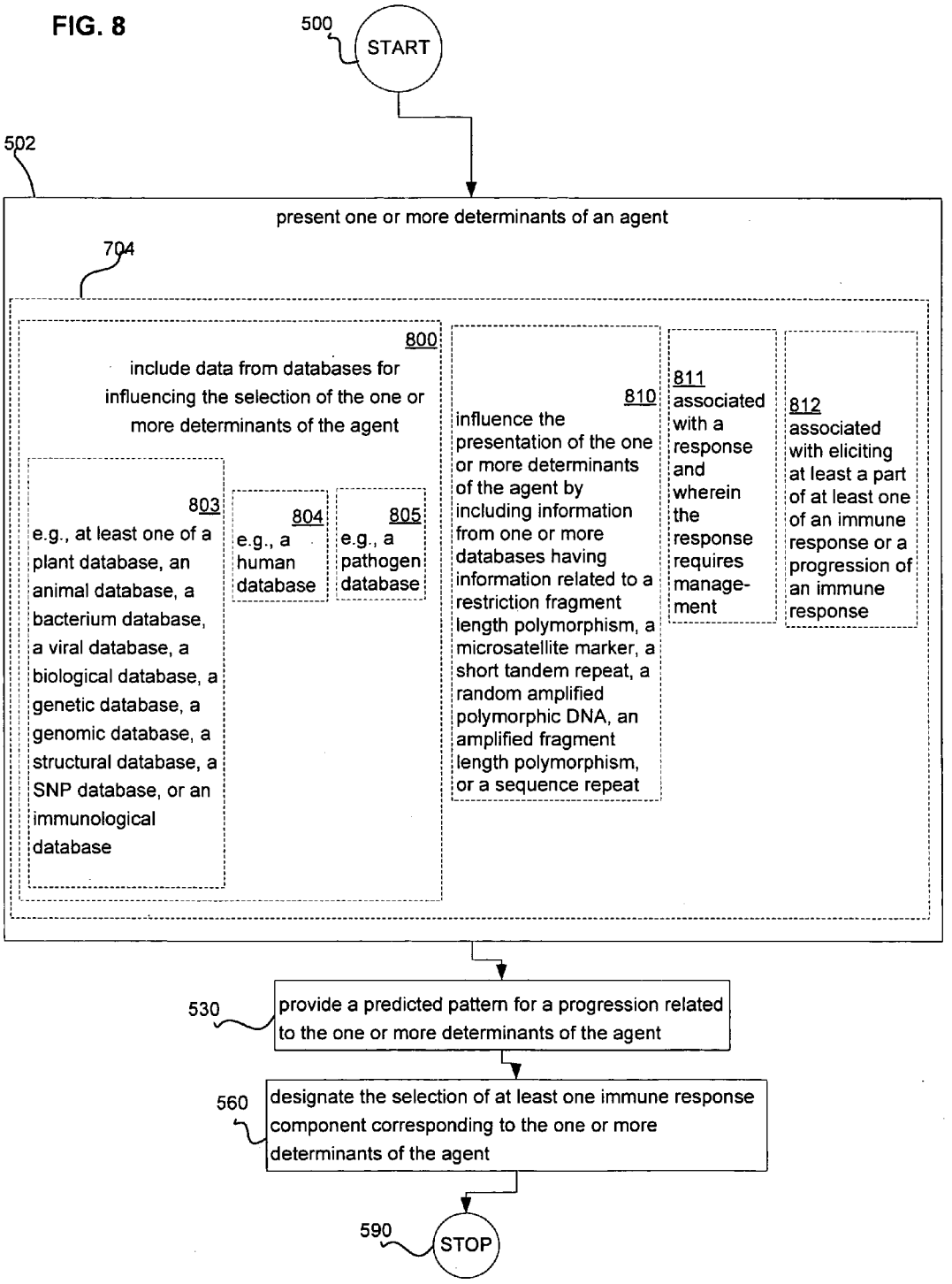

500
START
502
present one or more determinants of an agent
704
800
include data from databases for influencing the selection of the one or more determinants of the agent
803
e.g., at least one of a plant database, an animal database, a bacterium database, a viral database, a biological database, a genetic database, a genomic database, a structural database, a SNP database, or an immunological database
804
e.g., a human database
805
e.g., a pathogen database
810
influence the presentation of the one or more determinants of the agent by including information from one or more databases having information related to a restriction fragment length polymorphism, a microsatellite marker, a short tandem repeat, a random amplified polymorphic DNA, an amplified fragment length polymorphism, or a sequence repeat
811
associated with a response and wherein the response requires management
812
associated with eliciting at least a part of at least one of an immune response or a progression of an immune response
530
provide a predicted pattern for a progression related to the one or more determinants of the agent
560
designate the selection of at least one immune response component corresponding to the one or more determinants of the agent
590
STOP

FIG. 9

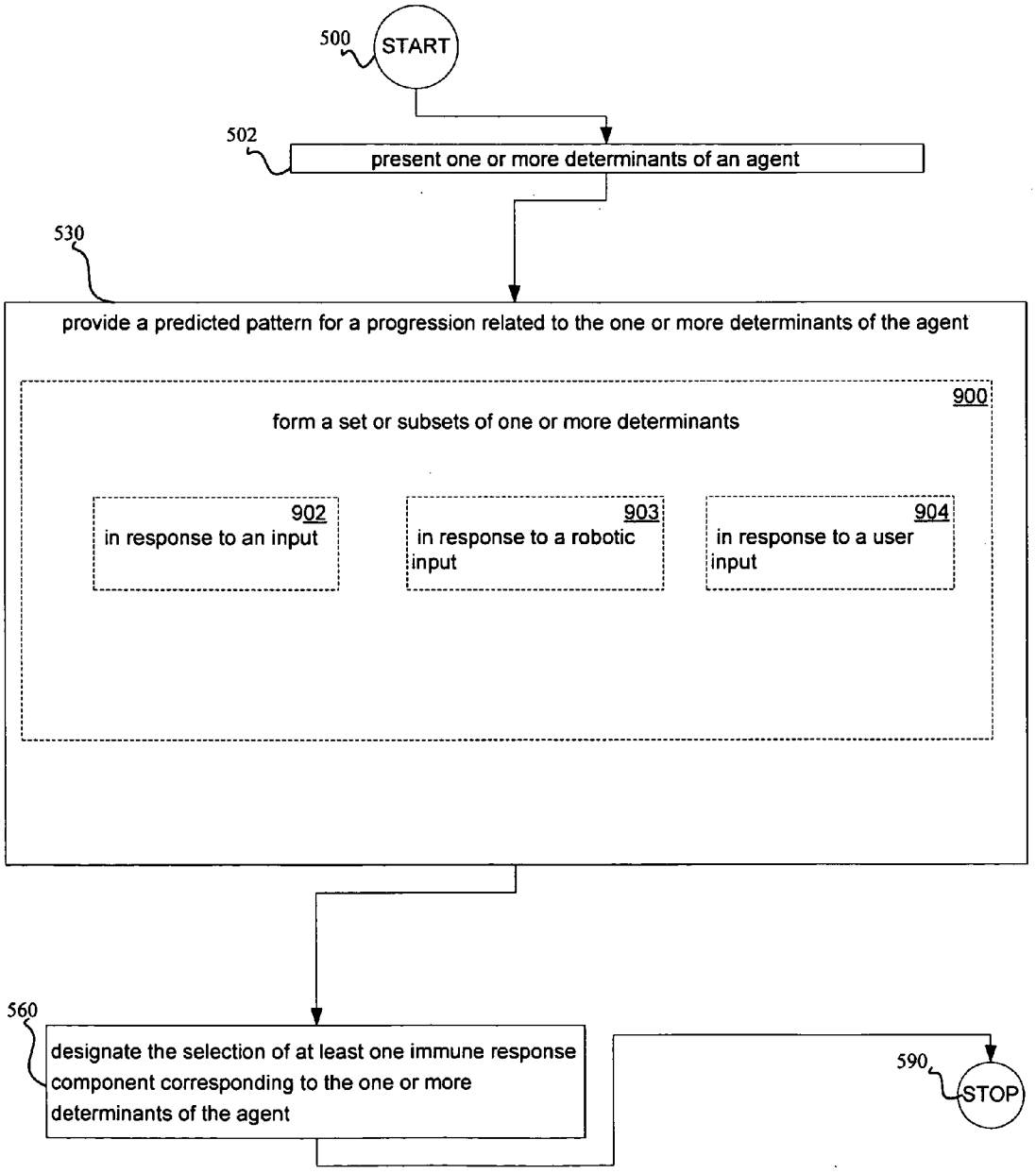

500
START
502
present one or more determinants of an agent
530
provide a predicted pattern for a progression related to the one or more determinants of the agent
900
form a set or subsets of one or more determinants
902
in response to an input
903
in response to a robotic input
904
in response to a user input
560
designate the selection of at least one immune response component corresponding to the one or more determinants of the agent
590
STOP

FIG. 10A

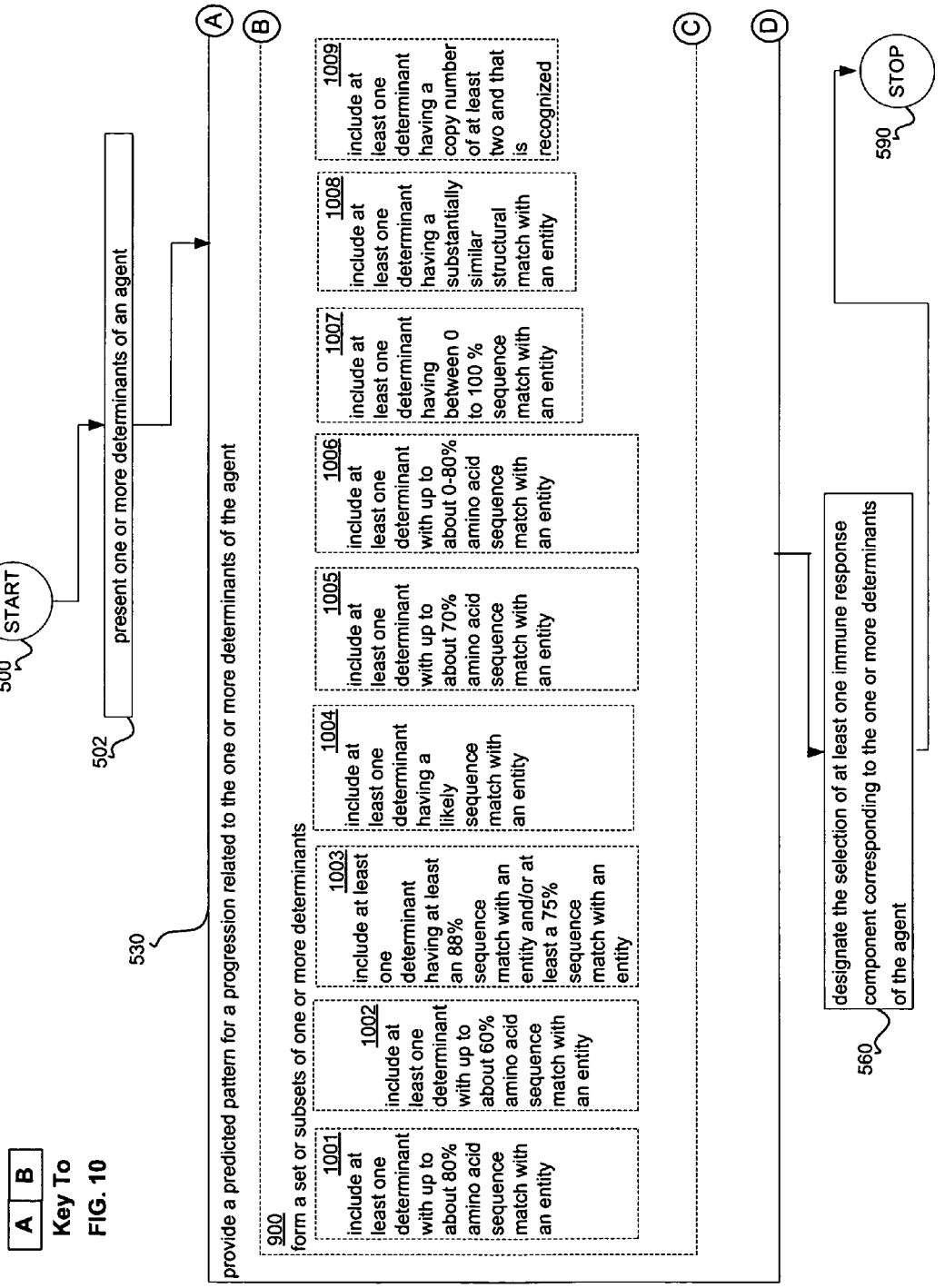

A
B
Key To
FIG. 10
500
START
502
present one or more determinants of an agent
530
provide a predicted pattern for a progression related to the one or more determinants of the agent
900
form a set or subsets of one or more determinants
1001
include at least one determinant with up to about 80% amino acid sequence match with an entity
1002
include at least one determinant with up to about 60% amino acid sequence match with an entity
1003
include at least one determinant having at least an 88% sequence match with an entity and/or at least a 75% sequence match with an entity
1004
include at least one determinant having a likely sequence match with an entity
1005
include at least one determinant with up to about 70% amino acid sequence match with an entity
1006
include at least one determinant with up to about 0-80% amino acid sequence match with an entity
1007
include at least one determinant having between 0 to 100 % sequence match with an entity
1008
include at least one determinant having a substantially similar structural match with an entity
1009
include at least one determinant having a copy number of at least two and that is recognized
C
D
560
designate the selection of at least one immune response component corresponding to the one or more determinants of the agent
590
STOP

FIG. 10B

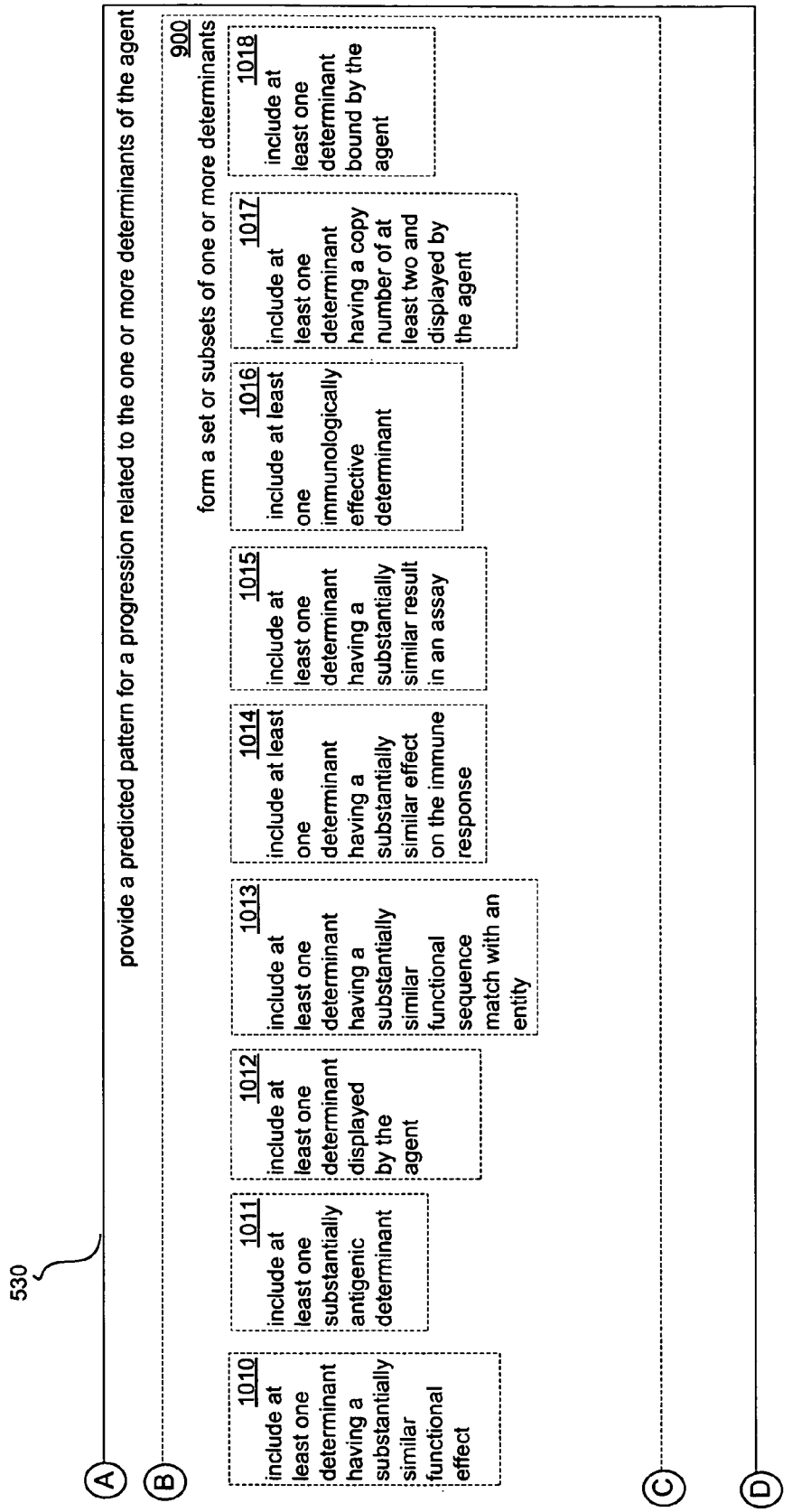

A
B
Key To
FIG. 10
530
provide a predicted pattern for a progression related to the one or more determinants of the agent
900
form a set or subsets of one or more determinants
1010 include at least one determinant having a substantially similar functional effect
1011 include at least one substantially antigenic determinant
1012 include at least one determinant displayed by the agent
1013 include at least one determinant having a substantially similar functional sequence match with an entity
1014 include at least one determinant having a substantially similar effect on the immune response
1015 include at least one determinant having a substantially similar result in an assay
1016 include at least one immunologically effective determinant
1017 include at least one determinant having a copy number of at least two and displayed by the agent
1018 include at least one determinant bound by the agent
A
B
C
D

FIG. 11

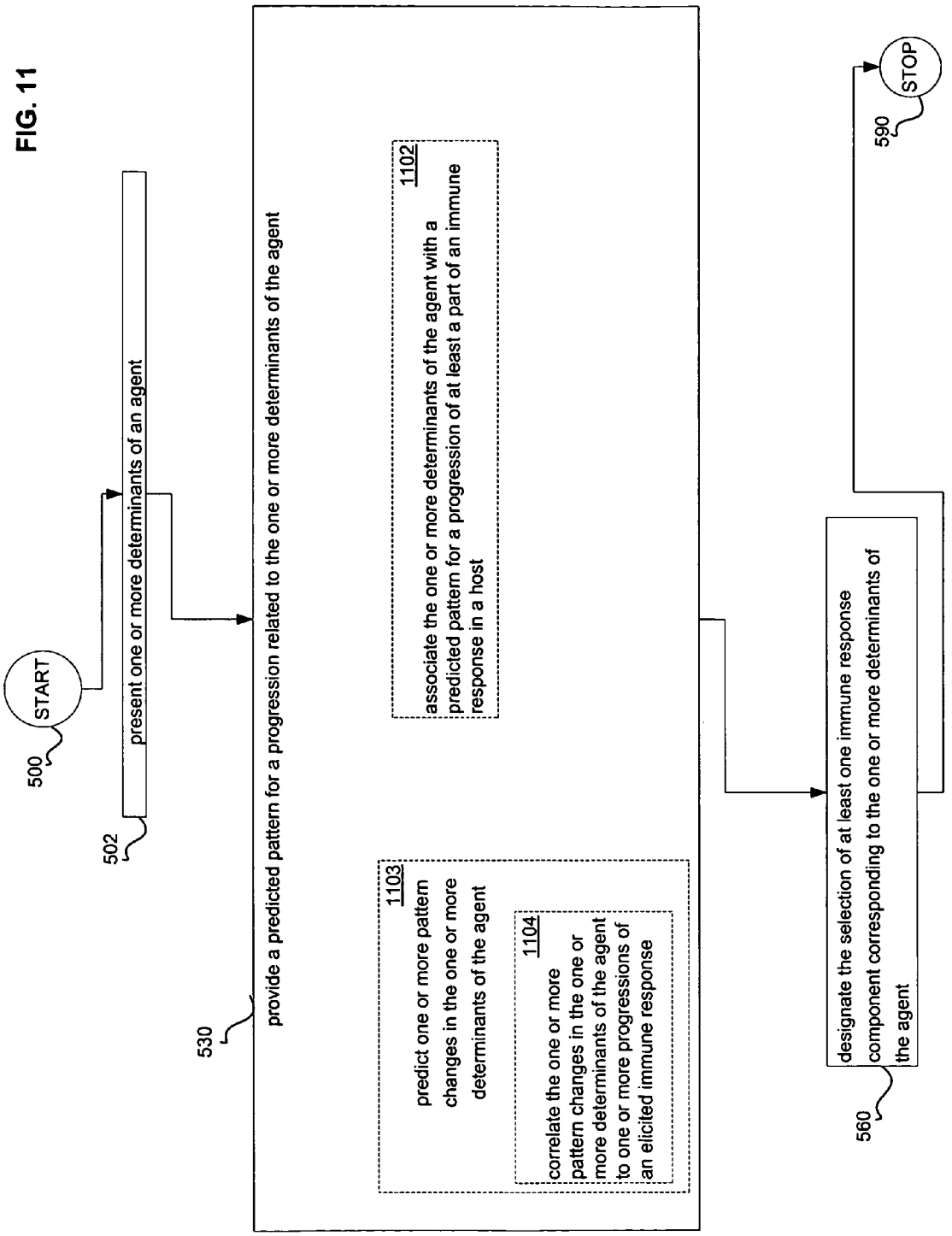

START
500
present one or more determinants of an agent
502
provide a predicted pattern for a progression related to the one or more determinants of the agent
530
1102
associate the one or more determinants of the agent with a predicted pattern for a progression of at least a part of an immune response in a host
1103
predict one or more pattern changes in the one or more determinants of the agent
1104
correlate the one or more pattern changes in the one or more determinants of the agent to one or more progressions of an elicited immune response
designate the selection of at least one immune response component corresponding to the one or more determinants of the agent
560
STOP
590

FIG. 12

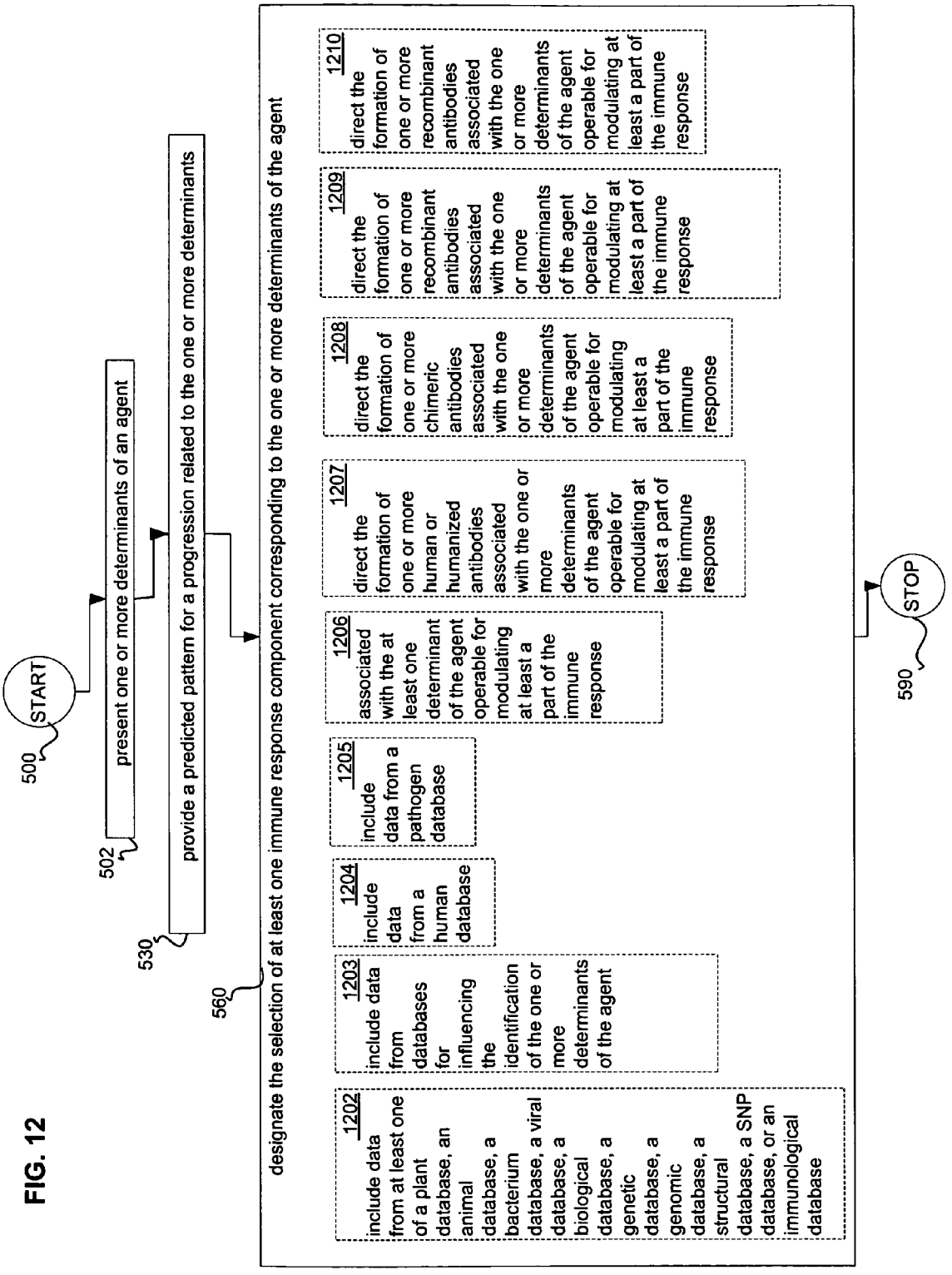

500
START
present one or more determinants of an agent
502
provide a predicted pattern for a progression related to the one or more determinants
530
designate the selection of at least one immune response component corresponding to the one or more determinants of the agent
560
1202 include data from at least one of a plant database, an animal database, a bacterium database, a viral database, a biological database, a genetic database, a genomic database, a structural database, a SNP database, or an immunological database
1203 include data from databases for influencing the identification of the one or more determinants of the agent
1204 include data from a human database
1205 include data from a pathogen database
1206 associated with the at least one determinant of the agent operable for modulating at least a part of the immune response
1207 direct the formation of one or more human or humanized antibodies associated with the one or more determinants of the agent operable for modulating at least a part of the immune response
1208 direct the formation of one or more chimeric antibodies associated with the one or more determinants of the agent operable for modulating at least a part of the immune response
1209 direct the formation of one or more recombinant antibodies associated with the one or more determinants of the agent operable for modulating at least a part of the immune response
1210 direct the formation of one or more recombinant antibodies associated with the one or more determinants of the agent operable for modulating at least a part of the immune response
590
STOP

FIG. 13

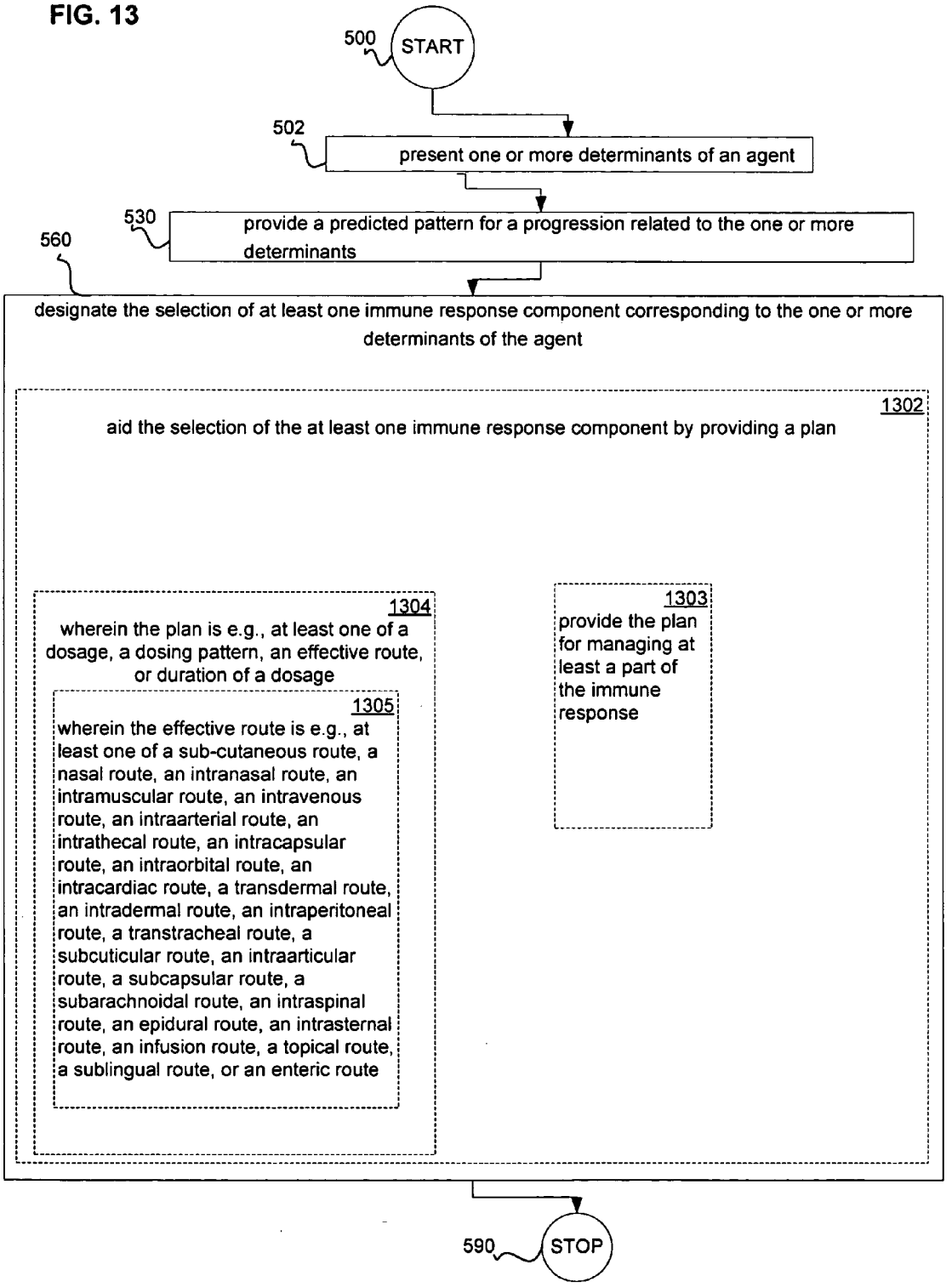

500
START
502
present one or more determinants of an agent
530
provide a predicted pattern for a progression related to the one or more determinants
560
designate the selection of at least one immune response component corresponding to the one or more determinants of the agent
1302
aid the selection of the at least one immune response component by providing a plan
1304
wherein the plan is e.g., at least one of a dosage, a dosing pattern, an effective route, or duration of a dosage
1305
wherein the effective route is e.g., at least one of a sub-cutaneous route, a nasal route, an intranasal route, an intramuscular route, an intravenous route, an intraarterial route, an intrathecal route, an intracapsular route, an intraorbital route, an intracardiac route, a transdermal route, an intradermal route, an intraperitoneal route, a transtracheal route, a subcuticular route, an intraarticular route, a subcapsular route, a subarachnoidal route, an intraspinal route, an epidural route, an intrasternal route, an infusion route, a topical route, a sublingual route, or an enteric route
1303
provide the plan for managing at least a part of the immune response
590
STOP

FIG. 14

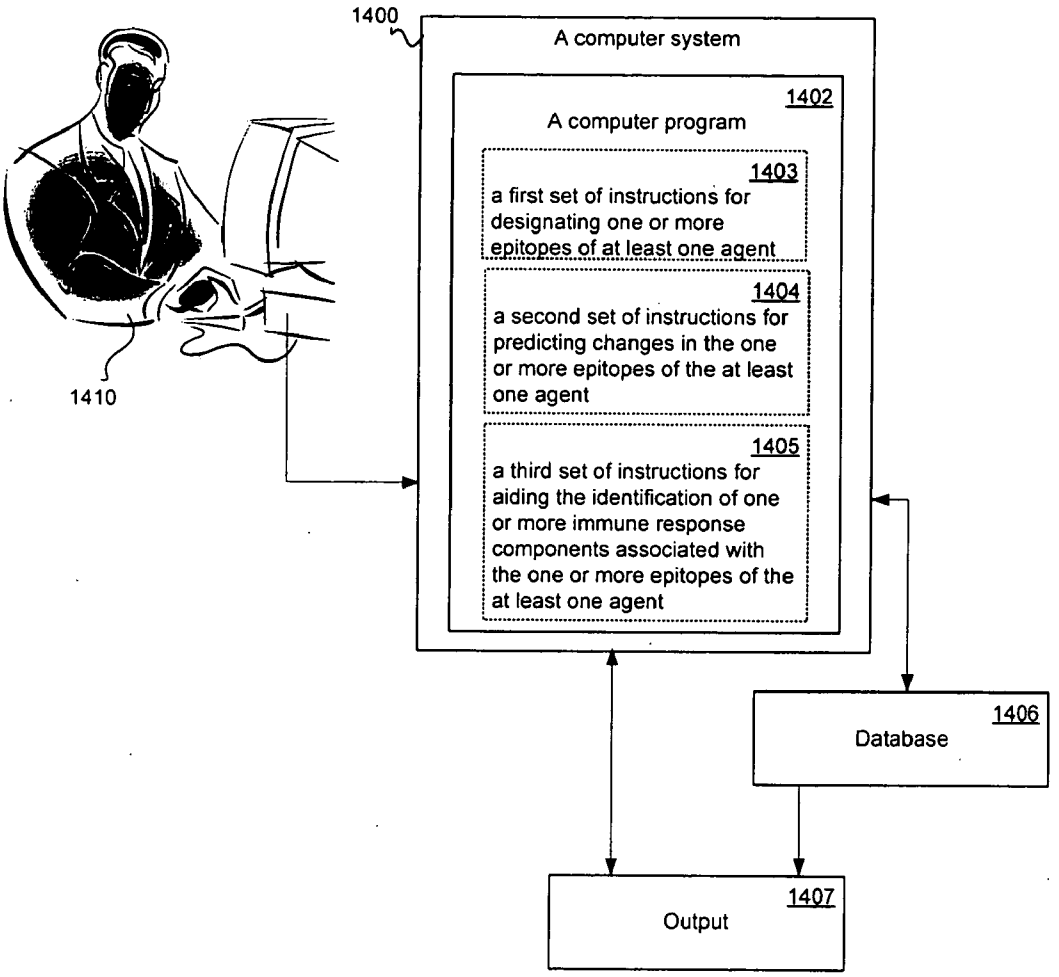
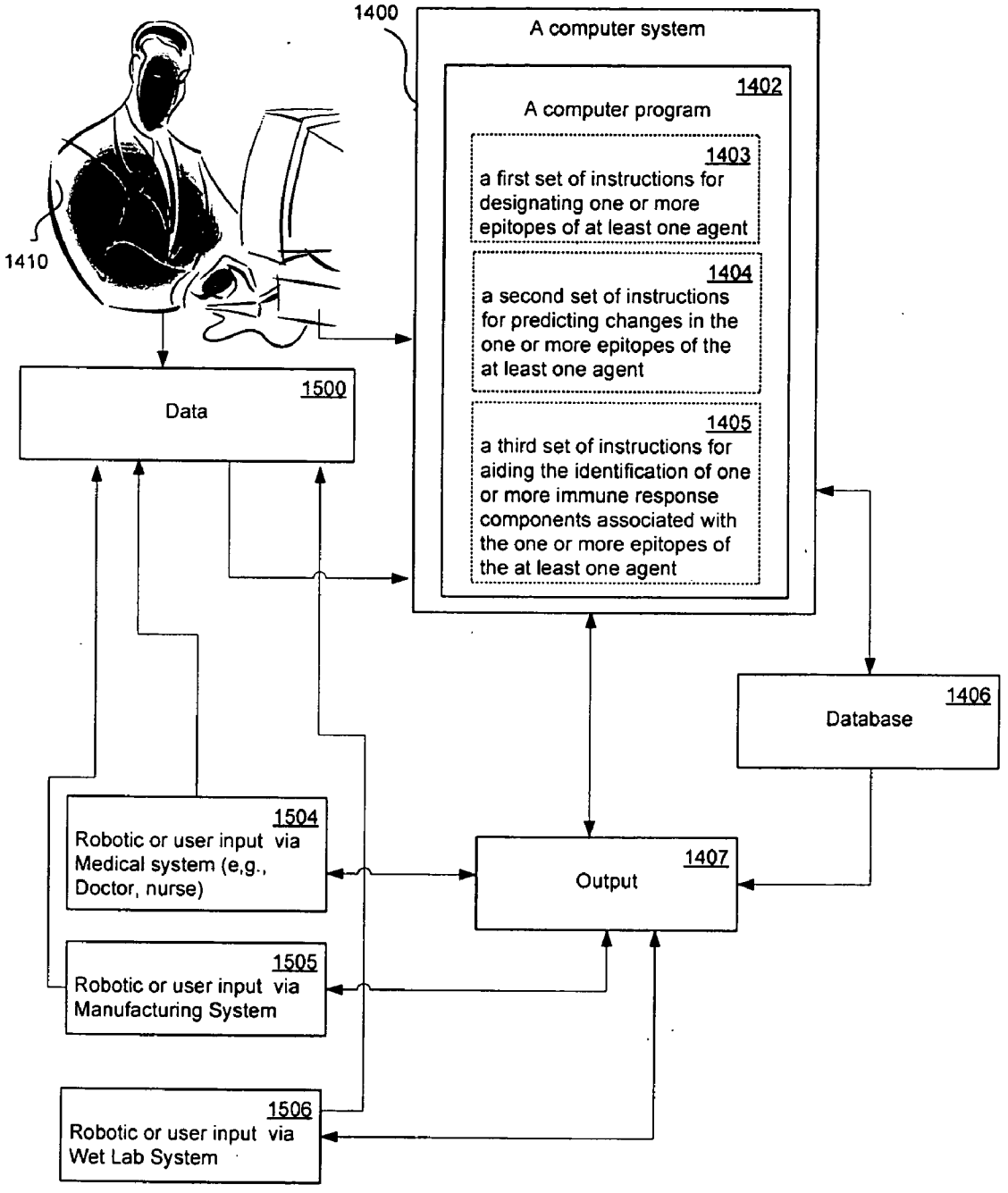

1400
A computer system
1402
A computer program
1403
a first set of instructions for designating one or more epitopes of at least one agent
1404
a second set of instructions for predicting changes in the one or more epitopes of the at least one agent
1405
a third set of instructions for aiding the identification of one or more immune response components associated with the one or more epitopes of the at least one agent
1406
Database
1407
Output
1410

FIG. 15


1400
A computer system
1402
A computer program
1403
a first set of instructions for designating one or more epitopes of at least one agent
1404
a second set of instructions for predicting changes in the one or more epitopes of the at least one agent
1405
a third set of instructions for aiding the identification of one or more immune response components associated with the one or more epitopes of the at least one agent
1410
1500
Data
1406
Database
1504
Robotic or user input via Medical system (e,g., Doctor, nurse)
1407
Output
1505
Robotic or user input via Manufacturing System
1506
Robotic or user input via Wet Lab System

SYSTEM AND METHOD RELATED TO AUGMENTING AN IMMUNE SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is related to, claims the earliest available effective filing date(s) from (e.g., claims earliest available priority dates for other than provisional patent applications; claims benefits under 35 USC § 119(e) for provisional patent applications), and incorporates by reference in its entirety all subject matter of the following listed applications; the present application also claims the earliest available effective filing date(s) from, and also incorporates by reference in its entirety all subject matter of any and all parent, grandparent, great-grandparent, etc. applications of the following listed applications:

[0002] 1. United States patent application entitled A SYSTEM AND METHOD RELATED TO IMPROVING AN IMMUNE SYSTEM naming Muriel Y. Ishikawa, Edward K. Y. Jung, Nathan P. Myhrvold, Richa Wilson, and Lowell L. Wood, Jr. as inventors, filed contemporaneously herewith.

[0003] 2. United States patent application entitled A SYSTEM AND METHOD RELATED TO ENHANCING AN IMMUNE SYSTEM naming Muriel Y. Ishikawa, Edward K. Y. Jung, Nathan P. Myhrvold, Richa Wilson, and Lowell L. Wood, Jr. as inventors, filed contemporaneously herewith.

TECHNICAL FIELD

[0004] The present application relates, in general, to detection and/or treatment.

SUMMARY

[0005] In one aspect, a method includes but is not limited to: identifying an association of at least a portion of one or more agents with at least a part of an immune response; projecting a pattern of changes relating to the at least a portion of the one or more agents; and selecting one or more immune response components in response to the projecting. In addition to the foregoing, other method aspects are described in the claims, drawings, and text forming a part of the present application.

[0006] In another aspect, a method includes but is not limited to: accepting an input of one or more agents; and identifying an association of at least a portion of one or more agents with at least a part of an immune response related to eradicating the one or more agents. In addition to the foregoing, other method aspects are described in the claims, drawings, and text forming a part of the present application.

[0007] In another aspect, a method includes but is not limited to: projecting a pattern of changes relating to the at least a portion of one or more agents; and selecting one or more immune response components in response to said projecting. In addition to the foregoing, other method aspects are described in the claims, drawings, and text forming a part of the present application.

[0008] 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.

[0009] In addition to the foregoing, various other method and or system aspects are set forth and described in the text (e.g., claims and/or detailed description) and/or drawings of the present application.

[0010] The foregoing is a summary and thus contains, by necessity; simplifications, generalizations and omissions of detail; consequently, those skilled in the art will appreciate that the summary is illustrative only and is NOT intended to be in any way limiting. Other aspects, inventive features, and advantages of the devices and/or processes described herein, as defined solely by the claims, will become apparent in the non-limiting detailed description set forth herein.

BRIEF DESCRIPTION OF THE FIGURES

[0011] **FIG. 1** is a diagrammatic view of one aspect of an exemplary interaction of an immune response component, for example, an antibody interacting with an epitope displayed by an agent.

[0012] **FIG. 2** is a diagrammatic view of one aspect of a method of enhancing an immune system.

[0013] **FIG. 3** depicts one aspect of an antigen antibody interaction showing the occurrence of mutational changes in a selected epitope and corresponding changes in a complementary antibody.

[0014] **FIG. 4** is an illustration of one aspect of mutational changes in an epitope displayed by an agent and the corresponding changes in an immune response component, for example, an antibody.

[0015] **FIG. 5** depicts a high-level logic flow chart of a process.

[0016] **FIG. 6** depicts a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**.

[0017] **FIG. 7** depicts a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**.

[0018] **FIG. 8** depicts a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**.

[0019] **FIG. 9** depicts a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**.

[0020] **FIG. 10** depicts a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**.

[0021] **FIG. 11** depicts a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**.

[0022] **FIG. 12** depicts a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**.

[0023] **FIG. 13** depicts a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**.

[0024] **FIG. 14** depicts a partial view of a system that may serve as an illustrative environment of and/or for subject matter technologies.

[0025] **FIG. 15** depicts a partial view of a system that may serve as an illustrative environment of and/or for subject matter technologies.

[0026] The use of the same symbols in different drawings typically indicates similar or identical items.

DETAILED DESCRIPTION

[0027] The present application uses formal outline headings for clarity of presentation. However, it is to be understood that the outline headings are for presentation purposes, and that different types of subject matter may be discussed throughout the application (e.g., device(s)/structure(s) may be described under the process(es)/operations heading(s) and/or process(es)/operations may be discussed under structure(s)/process(es) headings). Hence, the use of the formal outline headings is not intended to be in any way limiting.

[0028] With reference now to **FIG. 1**, depicted is a diagrammatic view of one aspect of an exemplary interaction of an immune response component, for example, an antibody interacting with an epitope displayed by an agent. Accordingly, the present application first describes certain specific exemplary methods of **FIG. 1**; thereafter, the present application illustrates certain specific exemplary structures. Those having skill in the art will appreciate that the specific structures and processes described herein are intended as merely illustrative of their more general counterparts. It will also be appreciated by those of skill in the art that an antigen-antibody interaction is an exemplary interaction of the interaction of an immune response component with an antigen. Therefore, although, the exact nature of the interaction may vary the overall picture as described herein and in other related applications relates to the interaction of an immune response component interacting with the antigen.

[0029] A. Structure(s) and or System(s)

[0030] With reference to the figures, and with reference now to **FIG. 1**, depicted is a diagrammatic view of one aspect of an exemplary interaction of an immune response component, for example, an antibody **104** interacting with an epitope **102** displayed by an agent **100**.

[0031] The term "agent"**100** may include, for example, but is not limited to, an organism, a virus, a bacterium, a yeast, a mold, a fungus, a mycoplasma, an *ureaplasma*, a *Chlamydia*, a *rickettsia*, a nanobacterium, a prion, an agent responsible for a transmissible spongiform encephalopathy (TSE), a multicellular parasite, a protein, an infectious protein, a nucleic acid, a metabolic by product, a cellular by product, and/or a toxin. The term "agent"**100** may include, but is not limited to, a putative causative agent of a disease or disorder, a cell that is deemed, for example, a target for therapy, a target for neutralization, and/or or a cell whose removal may prove beneficial to the host. The term "agent"**100** may also include, but is not limited to, a byproduct of a cell that may be neutralized and/or whose removal may prove beneficial to the host. Furthermore, the term "agent"**100** may include an agent belonging to the same family or a group, or an agent exhibiting a common and/or a biological function.

[0032] The term "antibody"**104** as used herein, is used in the broadest possible sense and may include but is not limited to 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, and/or an antibody fragment. The term "antibody" may also include but is not limited to types of antibodies such as IgA, IgD, IgE, IgG and/or IgM, and/or the subtypes IgG1, IgG2, IgG3, IgG4, IgA1 and/or IgA2. The term antibody may also include but is not limited to an antibody fragments such as at least a portion of an intact antibody **104**, for instance, the antigen binding variable region. Examples of antibody fragments include Fv, Fab, Fab', F(ab'), F(ab').sub.2, Fv fragments, diabodies, linear antibodies single-chain antibody molecules, multispecific antibodies, or other antigen binding sequences of antibodies. Additional information may be found in U.S. Pat. No. 5,641,870, U.S. Pat. No. 4,816,567, WO 93/11161, Holliger Et Al., Diabodies: Small Bivalent And Bispecific Antibody Fragments, PNAS (Proc. Natl. Acad. Sci. USA), 90: 6444-6448 (1993), Zapata et al., Engineering Linear F(Ab')2 Fragments For Efficient Production In *Escherichia Coli* And Enhanced Antiproliferative Activity, Protein Eng. 8(10): 1057-1062 (1995), which are incorporated herein by reference. Antibodies may be generated for therapeutic purposes by a variety of known techniques, such as, for example, phage display, and/or transgenic animals.

[0033] The term "heteroantibodies", as used herein, may include but is not limited to, two or more antibodies, antibody fragments, antibody derivatives, and/or antibodies with at least one specificity linked together. Additional information may be found in U.S. Pat. No. 6,071,517, which is incorporated herein by reference.

[0034] The term "chimeric antibodies", as used herein, may include but is not limited to antibodies having mouse variable regions joined to human constant regions. In one aspect, "chimeric antibodies" includes antibodies with human framework regions combined with complementarity determining regions (CDR's) obtained from a mouse and/or rat; those skilled in the art will appreciate that CDR's may be obtained from other sources. Additional information may be found in EPO Publication No 0239400, which is incorporated herein by reference. Although the foregoing has referred to the plural term "chimeric antibodies," those having skill in the art will appreciate that the singular term "chimeric antibody" may include but is not limited to singular instances of examples given for the plural term, as appropriate to context (see, e.g., the as-filed claims). The same is generally true for the use of substantially any plural and/or singular terms as used herein; that is, those having skill in the art can translate from the plural to the singular and/or from the singular to the plural as is appropriate to the context or application, and hence the various singular/plural permutations are not expressly set forth herein for sake of clarity.

[0035] The term "humanized antibody", as used herein, may include but is not limited to an antibody having one or more human regions, and/or a chimeric antibody with one or

more human regions, also considered the recipient antibody, combined with CDR's from a donor mouse and/or rat immunoglobulin. In one aspect, humanized antibodies may include residues not found in either donor or recipient sequences. Humanized antibodies may have single and/or multiple specificities. Additional information may be found in U.S. Pat. No. 5,530,101, and U.S. Pat. No. 4,816,567, which are incorporated herein by reference. Information may also be found in, Jones et al., Replacing The Complementarity-Determining Regions In A Human Antibody With Those From A Mouse, Nature, 321:522-525(1986); Riechmann et al., Reshaping Human Antibodies For Therapy, Nature, 332:323-327 (1988); and Verhoeyen et al., Reshaping Human Antibodies: Grafting An Antilysozyme Activity, Science, 239:1534 (1988), which are all incorporated herein by reference.

[**0036**] The term "human antibodies", as used herein, may include but is not limited to antibodies with variable and constant regions derived from human germline immunoglobulin sequences. The term human antibodies may include is not limited to amino acid residues of non-human origin, encoded by non-human germline, such as, for example, residues introduced by site directed mutations, random mutations, and/or insertions. Methods for producing human antibodies are known in the art and incorporated herein by reference. Additional information may be found in U.S. Pat. No. 4,634,666, which is incorporated herein by reference.

[**0037**] The term "recombinant antibody", as used herein, may include antibodies formed and/or created by recombinant technology, including, but not limited to, chimeric, human, humanized, hetero antibodies and the like.

[**0038**] The term "immune response component", as used herein, may include, but is not limited to, at least a part of a macrophage, 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 cytotoxic T-lymphocyte, a T-8 lymphocyte, 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, an antibody fragment, and/or synthetic antibody.

[**0039**] Continuing to refer to **FIG. 1**, the epitope **102** or parts thereof may be displayed by the agent **100**, may be displayed on the surface of the agent **100**, extend from the surface of the agent **100**, and/or may only be partially accessible by the immune response component. The term "epitope"**102**, as used herein, may include, but is not limited to, a sequence of at least 3 amino acids, a sequence of at least nine nucleotides, an amino acid residue, a nucleotide, a carbohydrate, a protein, a lipid, a capsid protein, a polysaccharide, a lipopolysaccharide, a glycolipid, a glycoprotein, and/or or at least a part of a cell. As used herein, the term "epitope"**102** may be used interchangeably with antigen, paratope binding site, antigenic determinant, and/or determinant. As used herein, the term determinant can include an influencing or determining element or factor, unless context indicates otherwise. In one aspect the term "epitope"**102** includes, but is not limited to, a peptide binding site. As used herein, the term "epitope"**102** may include structural and/or functionally similar sequences found in the agent **100**. The term "epitope"**102** 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 **100**.

[**0040**] In one aspect, the epitope **102** may be a linear determinant. For example, the sequences may be adjacent to each other. In another aspect, the epitope **102** is a non-linear determinant, for example, including juxtaposed groups which are non-adjacent but become adjacent to each other on protein folding. Furthermore, the sequence of the non-linear determinant may be derived by proteasomal processing and/or other mechanisms and the sequence synthetically made for presentation to the immune response component.

[**0041**] Continuing to refer to **FIG. 1**, in one aspect, the immune system launches a humoral response producing antibodies capable of recognizing and/or binding to the epitope **102** followed by the subsequent lysis of the agent **100**. Mechanisms by which the antigen **102** elicits an immune response are known in the art and such mechanisms are incorporated herein by reference. In one aspect, the binding of the antibody **104** to the epitope **102** to form an antigen-antibody complex **105** is characterized as a lock and key fit.

[**0042**] The epitope **102** may include any portion of the agent. In one aspect, the epitope **102** may include at least a portion of a gene. In another aspect the epitope may include at least a part of a non-coding region.

[**0043**] In one aspect, the epitope **102** is capable of evoking an immune response. The strength and/or type of the immune response may vary, for example, the epitope **102** may invoke a weak response and/or a medium response as measured by the strength of the immune response. It is contemplated that in one instance the epitope **102** selected for targeting may be one that invokes a weak response in the host, however, it may be selective to the agent **100**. In another example, the epitope **102** selected may invoke a weak response in the host, however it may be selected for targeting as it is common to agents deemed as targets. The herein described implementations are merely exemplary and should be considered illustrative of like and/or more general implementations within the ambit of those having skill in the art in light of the teachings herein.

[**0044**] With reference to the figures, and with reference now to **FIG. 2** depicted is a diagrammatic view of one aspect of a method of enhancing an immune system. In one aspect, an effective treatment therapy towards a disease and/or a disorder may utilize one or more immune response components designed to recognize one or more antigens common to one or more agents. Such common antigens may represent an effective target group of antigens. The immune response components designed to seek out and neutralize the common antigens may be effective against one or more agents.

[**0045**] With reference now to **FIGS. 1 and 2**, in one aspect, a shared epitope **200** is depicted as common to three agents **206**, **210** and **220**. In another aspect, a second shared epitope **212** is common to two agents **206** and **210**. In yet another aspect, a third shared epitope **218** is common to two agents **210** and **220**. Finding a subset of common epitopes shared amongst one or more agents may be done by statistical analysis, for example, by metaprofiling. One variation

of this aspect is identification of at least one common epitope shared with one or more agents also referred to as an antigenic profile, and/or an antigenic signature. Additional information may be found in a publication by Rhodes et al., Large Scale Meta-Analysis Of Cancer Micorarray Data Identifies Common Transcriptional Profiles Of Neoplastic Transformation And Progression, PNAS Jun. 22, 2004, 101:(25) 9309-9314, and is incorporated herein by reference.

[**0046**] Continuing to refer to **FIGS. 1 and 2**, in one aspect, one or more agents **206**, **210**, and **220** depicted may share a subset of common epitopes. The selection of epitopes may depend on a number of criteria. For example, the initial selection may be based on, including, but not limited to, the number of instances of occurrences of the epitope **102** by one or more agents, the number of instances of occurrence of the epitope **102** by the agent **100**, the location of the epitope **102**, the size of the epitope **102**, the nature of the epitope **102**, the sequence identity and/or homology of the epitope **102** with host sequences, the composition of the epitope **102**, and/or putative known or predicted changes in the epitope **102** sequence. The selection of epitopes may also depend on, for example, the type of immune response component desired for treating and/or managing the disease, disorder, and/or condition.

[**0047**] In one aspect, the epitope **102** selected has a probable sequence match with an entity. The term "entity", as used herein, may include the agent **100** and/or a host depending on context. For example, whether the term entity includes the agent **100**, the host, or both will sometimes depend, for example, on the nature of a described interaction. The term "host", as used herein, may include but is not limited to an individual, a person, a patient, and/or virtually anyone requiring management of a disease, disorder, and/or condition. For example, the epitope **102** selected may have a 0-70% sequence match at the amino acid level with the entity, for example, the host, or a 0-100% sequence match with the entity, for example, the host or the agent **100**. Those having skill in the art will recognize that part of that context in relation to the term "entity" is that generally what is desired is a practicably close sequence match to the agent (e.g., HIV), so that the one or more immune system components in use can attack it and a practicably distant sequence match to the host (e.g., a patient), in order to decrease or render less aggressive any attack by the immune system components in use on the host. However, it is also to be understood that in some contexts the agent will in fact constitute a part of the host (e.g., when the agent to be eradicated is actually a malfunctioning part of the host, such as in an auto-immune disease), in which case that part of the host to be eradicated will be treated as the "agent", and that part of the host to be left relatively undisturbed will be treated as the "host." In another aspect, the epitope **102** selected has a sequence match with the entity, for example, a high sequence match, a relatively higher sequence match with other agents compared to the host, or a 0-100% sequence match with the agent **100**. The term "sequence match", as used herein, includes both sequence matching at the nucleic acid level and/or at the protein level. In an embodiment, the epitope **102** selected has a low probable sequence match with the host. In another embodiment, the epitope **102** selected has a high sequence match with other agents.

[**0048**] In another aspect the epitope **102** selected has a likely and/or a probable sequence match with other epitopes, for example, including, but not limited to, the epitope **102** having a structural sequence match, a functional sequence match, a similar functional effect, a similar result in an assay and/or a combination. Structural comparison algorithms and/or 3-dimensional protein structure data may be used to determine whether two proteins may have a structural sequence match. In another example the epitope **102** may have a functional match and/or share a similar functional effect with epitopes of interest. In this example, the epitope **102** may have a lower probable sequence match but may still exert the same functional effect. In another example, the epitope **102** and/or other epitopes of interest may have a lower probable sequence match but may share similar activities, for example, enzymatic activity and/or receptor binding activity, as determined by using an assay.

[**0049**] In another aspect the epitope **102** selected may be an immunological effective determinant, for example, the epitope **102** may be weakly antigenic, however it may invoke an effective immune response relating to, for example, the nature and/or the type of the immune response component it invokes. In another aspect the epitope **102** may exert a similar effect on the immune response, for example, the epitope **102** selected may be part of the antigenic structure of an agent unrelated to the disease or disorder in question, however, it may exert a substantially similar effect on the immune system as measured by, for example, the type, the nature, or the period of the immune response.

[**0050**] In one aspect, a sequence match with an entity may be determined by, for example, calculating the percent identity and/or percent similarity between epitopes and/or between the epitope **100** and the host. In one aspect, the percent identity between two sequences may be calculated by determining a number of substantially similar positions obtained after aligning the sequences and introducing gaps. For example, in one implementation the percent identity between two sequences is treated as equal to (=) a number of substantially similar positions/total number of positions× 100. In this example, the number and length of gaps introduced to obtain optimal alignment of the sequences is considered. In another aspect, the percent identity between two sequences at the nucleic acid level may be determined by using a publicly available software tool such as BLAST, BLAST-2, ALIGN and/or DNASTAR software. Similarly, the percent identity between two sequences at the amino acid level may be calculating by using publicly available software tools such as, for example, Peptidecutter, AACompSim, Find Mod, GlycoMod, InterProtScan, DALI and/or tools listed on the ExPasy (Expert Protein Analysis System) Proteomics Server at http://www.expasy.org/. In one embodiment, the percent identity at the nucleic acid level and at the amino acid level are determined.

[**0051**] It will be appreciated by those skilled in the art that the epitope **102** selected need not be limited to a matching sequence displayed by the agent **100**. In one aspect, a meta signature and/or a consensus sequence may be derived based on any number of criteria. In one aspect, the meta signature may be derived by analysis of data from sources such as, for example, antigenic evolution, genetic evolution, antigenic shift, antigenic drift, data from crystal structure, probable match with a host, probable match with other strains, and/or strength of the immunogenic response desired. The meta

signature may include new sequences and/or may exclude some sequences. For example, it may include silent mutations, mismatches, a spacer to bypass a hotspot or a highly mutagenic site, predicted changes in the sequence, and/or may include epitopes from multiple agents thus providing protection from multiple agents. As another example, the meta signature may exclude sequences, such as, for example, including, but not limited to, mutagenic sequences and/or sequences with a match to the host.

[0052] In one aspect, the predicted changes in the epitope **102** may be determined by analysis of past variations observed and/or predicted in the agent **100** (e.g., **FIG. 1**). Computational analysis can be used to determine regions showing sequence variations and/or hot spots. In one aspect, high speed serial passaging may be performed computationally mimicking the serial passaging that occurs naturally with a production of a new strain of the agent **100**. It will be appreciated by those of skill in the art that the hot spots need not be identified by examining the epitope **102**, and/or by examining the epitope **102** in context with the agent **100**. Information pertaining to hot spots can also be extrapolated by performing sequence analysis of other agents and/or domain analysis of the other agents. For example, in one implementation the epitope **102** may be part of a domain shared between multiple agents which may lack the epitope **102** of interest. Information pertaining to hotspots identified in the domain of the other agents may be of practical use in determining the metasignature.

[0053] In one aspect, one or more sets and/or subsets of epitopes may be formed. The nature and type of criteria used to form the sets and/or subsets will depend, for example, on the nature and type of the agent **100**, the duration of the immune response desired (e.g., short-term immunity, or long-term immunity), the nature of the immune response desired (e.g., weak, moderate, or strong), the population seeking protection (e.g., presence of prior exposure) and the like. The sets and subsets so formed may accept input either robotically or from a user (e.g., a manufacturer of immune response components, wet lab, or medical personnel).

[0054] The pattern changes predicted in the epitope **102** may be supplemented, for example, by other methodology, statistical analysis, historical data, and other extrapolations of the type utilized by those having skill in the art. The knowledge of these predicted pattern changes represents an arsenal in the design and/or selection of the immune response components. The predicted pattern changes may be used to determine the progression of the changes in the immune response component required to manage such changes. Inferring the pattern changes in the epitope **102** and using the information to modulate the progressing response may help manage the response more effectively. For example, the pattern changes may be used to provide a timeline of when the therapy could be changed, what therapy should constitute the change, or the duration of the change. As a more specific example, one reason why Human Immunodeficiency Virus (HIV) is able to successfully kill its host is that the virus mutates faster than the immune system can track and respond to its mutations. In a specific implementation of the subject matter described herein, a sample of HIV is taken from a patient at a point in time and computational biological techniques are used to infer likely mutations of the virus at future times. Cloning techniques are then utilized to synthesize immune system activating aspects of the future HIV strains, and thereafter subsequent cloning techniques are utilized to rapidly generate copious amounts of one or more immune system components (e.g., antibodies) that are keyed to the likely future generation of the patient's HIV. Once cloned, the immune system components are then loaded back to the patient and thus are present and waiting for the HIV when it mutates. If the HIV mutates as anticipated, the preloaded immune response components attack the mutated HIV, thereby likely greatly reducing the presence of the HIV. In another implementation, the actual mutation of the HIV is manually tracked, and once the actual mutation has been determined, yet more cloning techniques are utilized to generate yet more immune system components appropriate to the mutated virus.

[0055] In one aspect, the epitope **102** selected for designating the immune response component may be synthetically made and/or derived from the agent **100**. In one embodiment the epitope **102** selected is derived from an agent **100** extracted from an individual desiring treatment and/or an individual found resistant to that agent. In one aspect the epitope **102** selected for designating the immune response component may include multiple copies of the exact same epitope and/or multiple copies of different epitopes.

[0056] In one aspect the metasignature includes sequences matching adjacent and/or contiguous sequences. In another aspect the metasignature includes non adjacent sequences. For example, it will be appreciated by those of skill in the art that peptide splicing and/or proteosomal processing of the epitope **102** that occurs naturally may result in the formation of a new epitope, for example, a non-linear epitope. In this example, proteosomal processing may result in the excision of sequences transposing non-contiguous sequences to form the non-linear epitope. Additional information may be found in Hanada et al., Immune Recognition Of A Human Renal Cancer Antigen Through Post-Translational Protein Splicing, Nature 427:252 (2004), and Vigneron et al., An Antigenic Peptide Produced By Peptide Splicing In The Proteosome, Science 304:587 (2004) hereby incorporated by reference herein in its entirety.

[0057] Additionally, it will also be appreciated by those of skill in the art that the metasignature may include sequences displayed on two different parts of the agent **100**. For example, non adjacent sequences may appear adjacent each other when the protein is folded. In this aspect, the metasignature may include the nonadjacent sequences for identifying the metasignature. Furthermore, the metasignature may include nonadjacent sequences corresponding to a specific conformational state of a protein. Immune response components designed to bind such sequences may be specific to the conformational state of the protein. 3-D and/or crystal structure information may also be used to designate the metasignature.

[0058] In one aspect, the metasignature may include multiple sets of epitopes targeting a predicted pattern change and/or an observed pattern change. For example, multiple sets of epitopes may be designed for vaccination and/or for production of immune response components.

[0059] Techniques for epitope mapping are known in the art and herein incorporated by reference. For example, FACS analysis and ELISA may be used to investigate the binding of antibodies to synthetic peptides including at least

a portion of the epitope. Epitope mapping analysis techniques, Scatchard analysis and the like may be used to predict the ability of the antibody **104** to bind to the epitope **102** presented on the agent **100**, to determine the binding affinity of the antibody **104** to the epitope **102**, and/or to discern a desirable configuration for the antibody **104**.

[**0060**] Continuing to refer to **FIG. 2**, in one aspect, for example, the sequences of selected epitopes **200**, **212**, and **218** may be used to design one or more complementary antibodies **224**, **222**, and **226**, respectively. Techniques for making antibodies are known in the art and are incorporated herein by reference. The purified complementary antibodies **230**, **228**, or **232** may then be made available for therapeutic and/or prophylactic treatment.

[**0061**] The term "an effective treatment therapy", as used herein, includes, but is not limited to, the use of immune response components in combination with other antibodies, antibody fragments, and/or in combination with other treatments, including, but not limited to, drugs, vitamins, hormones, medicinal agents, pharmaceutical compositions and/or other therapeutic and/or prophylactic combinations. In another aspect, the immune response component may be used in combination, for example, with a modulator of an immune response and/or a modulator of an antibody. In one aspect, cocktails of immune response components may be administered, for example, by injecting by a sub-cutaneous, nasal, intranasal, intramuscular, intravenous, intraarterial, intrathecal, intracapsular, intraorbital, intracardiac, transdermal, intradermal, intraperitoneal, transtracheal, subcuticular, intraarticular, subcapsular, subarachnoidal, intraspinal, epidural, intrasternal, infusion, topical, sublingual, and/or enteric route.

[**0062**] The therapeutic effect of the immune response component may be produced by one or more modes of action. For example, in one aspect, the immune response component may produce a therapeutic effect and/or alleviate the symptoms by targeting specific cells and neutralizing them. In another aspect, the immune response component may bind to and/or block receptors present on the agent **100** and/or may directly and/or indirectly block the binding of molecules, such as, for example, cytokines, and/or growth factors, to the agent **100**. In another aspect, the therapeutic effect of the immune response component is produced by functioning as signaling molecules. In this example, the immune response component may induce cross linking of receptors with subsequent induction of programmed cell death.

[**0063**] The immune response component may be engineered to include, for example, one or more effector molecules, such as, for example, drugs, small molecules, enzymes, toxins, radionuclides, cytokines, and/or DNA molecules. In this example, the immune response component may serve as a vehicle for targeting and binding the agent **100** and/or delivering the one or more effector molecules. In one aspect, the immune response component may be engineered to include the one or more effector molecules without the natural effector functions of the immune response component.

[**0064**] In another aspect, one or more immune response components may be coupled to molecules for promoting immune system cells to eliminate unwanted cells. This technique has been described for the treatment of tumors, viral infected cells, fingi, and bacteria using antibodies. Additional information may be found in U.S. Pat. No. 4,676,980 to Segal, which is incorporated herein by reference.

[**0065**] The criteria for selection of the one or more immune response components may vary, for example, one criterion may include the strength of the interaction or the binding affinity of the immune response component for the antigen **102**. Numerous techniques exist for enhancing the binding affinity of the antibody for the antigen **102**. In one aspect, the binding affinity of the antibody for the antigen **102** may be enhanced by constructing phage display libraries from an individual who has been immunized with the antigen **102** either by happenstance or by immunization. The generation and selection of higher affinity antibodies may also be improved, for example, by mimicking somatic hypermutagenesis, complementarity-determining region (CDR) walking mutagenesis, antibody chain shuffling, and/or technologies such as Xenomax technology (available from Abgenix, Inc. currently having corporate headquarters in Fremont, Calif. 94555). In one example, antibodies including introduced mutations may be displayed on the surface of filamentous bacteriophage. Processes mimicking the primary and/or secondary immune response may then be used to select the desired antibodies, for example, antibodies displaying a higher binding affinity for the antigen and/or by the evaluating the kinetics of dissociation. For additional information see, Low et al., Mimicking Somatic Hypermutation: Affinity Maturation Of Antibodies Displayed On Bacteriophage Using A Bacterial Mutator Strain, J. Mol. Biol. 260:359-368 (1996); Hawkins et al. Selection Of Phage Antibodies By Binding Affinity. Mimicking Affinity Maturation, J. Mol. Biol. 226:889-896 (1992), which are incorporated herein by reference.

[**0066**] In another example, the generation and/or selection of higher affinity antibodies may be carried out by CDR walking mutagenesis, which mimics the tertiary immune selection process. For example, saturation mutagenesis of the CDR's of the antibody **104** may be used to generate one or more libraries of antibody fragments which are displayed on the surface of filamentous bacteriophage followed by the subsequent selection of the relevant antibody using immobilized antigen. Sequential and parallel optimization strategies may be used to then select the higher affinity antibody. For additional information see Yang et al., CDR Walking Mutagenesis For The Affinity Maturation Of A Potent Human Anti-HIV-1 Antibody Into The Picomolar Range, J. Mol. Biol. 254(3):392-403 (1995), which is incorporated herein by reference in its entirety.

[**0067**] In yet another example, site directed mutagenesis may be used to generate and select higher affinity antibodies, for example, by parsimonious mutagenesis. In this example, a computer based method is used to identify and screen amino acids included in the one or more CDR's of a variable region of an antibody **104** involved in an antigen-antibody binding. Additionally, in some implementations, the number of codons introduced is such that about 50% of the codons in the degenerate position are wildtype. In another example, antibody chain shuffling may be used to generate and select higher affinity antibodies. These techniques are known in the art and are herein incorporated by reference.

[**0068**] The dosage of the immune response component may vary and in one aspect may depend, for example, on the

duration of the treatment, body mass, severity of the disease, and/or age. Compositions including immune response components may be delivered to an individual for prophylactic and/or therapeutic treatments. In one aspect, an individual having a disease and/or condition is administered a treatment dose to alleviate and/or at least partially cure the symptoms. In this example, a therapeutically effective dose is administered to the patient.

[0069] In another aspect, an individual's resistance may be enhanced by providing a prophylactically measured dose. For example, including, but not limited to, the individual may be genetically vulnerable to the disease and/or condition, the individual may visit a location where the agent **100** is prevalent, or the individual may fear exposure to the agents and/or related agents associated with the disease and/or condition.

[0070] Optimization of the physico-chemical properties of the immune response component may be improved, for example, by computer based screening methods. Properties affecting antibody therapeutics may be improved, such as, for example, stability, antigen binding affinity, and/or solubility. Additional information may be found in U.S. Patent Application number 20040110226 to Lazar, which is incorporated herein by reference.

[0071] With reference to the figures, and with reference now to **FIGS. 1, 2**, and **3**, depicted is one aspect of the antigen antibody interaction **105** showing the occurrence of mutational changes in the selected epitope **200** and corresponding changes in the complementary antibody **224**. Such mutational changes in the epitope **200**, for example, may be minor or major in nature. These minor and/or major antigenic variations may render an existing treatment less effective. Thus an effective treatment therapy towards a disease or disorder may include treating the disease or disorder with one or more antibodies designed to anticipate one or more antigenic variations common to one or more agents **100** or one or more related agents. Furthermore, predicting the course of the minor and/or major antigenic variations of the agent **100** and/or the related agents would also be beneficial in designing or selecting the one or more antibodies. Additionally, in some implementations the inclusion of information from SNP databases is helpful in designing antibodies for binding the selected epitope **200**.

[0072] Minor changes in the epitope **102** which do not always lead to the formation of a new subtype may be caused, for example, by point mutations in the selected epitope **200**. In one aspect, the occurrence of point mutations may be localized, for example, to hotspots of the selected epitope **200**. The frequency and/or occurrence of such hotspots may be provided by the computer based method. Additionally, the method provides for access to databases including, for example, historical lists of the antigenic variations of the agent **100** and/or of the selected epitope **200**, for example, from previous endemics and/or pandemics. Such information may be part of an epitope profile for charting the progression of the immune response. For example, including, but not limited to, a point mutation in the glutamic acid at position **92** of the NS1 protein of the influenza virus has been shown to dramatically downregulate activation of cytokines. Such information may be useful in designating the metasiganture.

[0073] Continuing to refer to **FIGS. 1, 2**, and **3**, depicted is that a mutation **310** in the selected epitope **200** results in a mutated epitope **302**. The term "the selected epitope **200**" as typically used herein, often constitutes a type of the more general term of presented epitope, unless context indicates otherwise. The generation of the mutated epitope **302** may reduce the binding of the immune response component, for example, the antibody **224**. In one aspect, effective binding could be enhanced by generating a new antibody **324** corresponding to the mutated epitope **302**. The frequency of minor antigenic variations may be predicted by examining known and/or predicted hotspots. For example, additional mutations **311** and/or **314** may be predicted by the computer based method and corresponding antibodies **328** and/or **326** respectively, designed to factor such antigenic variations in the mutated epitopes **306** and/or **304**, respectively. In one aspect, an effective treatment therapy, may incorporate this knowledge in providing an effective humoral response towards an agent **100**. For example, a cocktail of immune response components may include the antibodies **224**, **324**, **326**, **328** for binding to the selected epitope **200** and/or its predicted mutated versions. In one aspect, the cocktail of one or more antibodies may be supplemented by additional chemicals, growth factors, drugs, or growth factors. In another aspect, the effective treatment therapy may include varying doses of immune response components, for example, a substantially larger dosage of **326** relative to **324**, **328**, and/or **224**.

[0074] Referring now to **FIG. 4**, for example, one or more new epitopes **402**, **404**, **406**, and/or **408** may appear on the surface of the agent **100**. In one aspect, major changes may occur in the antigenic variants present on the surface of the agent **100** resulting in the formation of a new subtype. The appearance of new epitopes observed, for example, may occur as a result of antigenic shifts, reassortment, reshuffling, rearrangement of segments, and/or swapping of segments and generally marks the appearance of a new virulent strain of the agent **100**. In one instance the prediction of the new epitopes may mark the emergence of a new strain, a new subtype, and/or the reemergence of an older strain. In this instance, natural and/or artificial humoral protection in an individual does not provide adequate protection.

[0075] Generally, when major changes do occur a larger section of the population succumbs to the infection leading to a pandemic. The problem may be alleviated in part, for example, by predicting the appearance of new strains and/or subtypes as a result of the appearance of new epitopes and/or the disappearance of existing epitopes. In one aspect, for example, including, but not limited to, the prediction of the new epitopes may be directed towards a subset of genes, for example, important for virulence and/or replication of the agent **100**. For example, examining the appearance of new subtypes of influenza virus type A shows that the antigenic variations occur for the most part in the neuraminidase and/or hemagglutinin gene.

[0076] In another aspect, the selected epitope **200** may steer clear of highly variable regions and focus instead on areas of lower probability of mutations. Thus epitopes selected may circumvent hotspots of antigenic variations and target other specific regions of an agent **100**, such as, for example, the receptor binding site on the surface of the agent **100**. In another example, the selected epitope **200** may not be readily accessible to the immune response component, for example, the receptor binding site may be buried deep in a pocket and may be surrounded by readily accessible

sequences exhibiting a higher level of antigenic variations. In this example, one possibility may include providing small antibody fragments that penetrate the receptor binding site preventing the agent **100** from binding its target. In another example, a drug and/or chemical may be used to exaggerate the accessibility of the receptor binding site. In yet another example, a chemical with a tag may be used to bind to the residue and the tag used for biding the immune response component.

[**0077**] In another aspect, the immune response component may be so designed so as to circumvent the shape changes in the epitope **102** and provide minimally effective binding to the epitope **102**. In this example the antibody designed may include accommodations to its design by the prediction of hotspots and/or the mutational changes in the epitope **102**.

[**0078**] In one aspect the size of the immune response component may be manipulated. For example, an immune response component, for example, the antibody **104** may be designed to include the practicably minimal binding site required to bind the epitope **102**. In another example, the immune response component may be designed to the smallest effective determinant.

[**0079**] In one aspect, an effective treatment therapy towards a disease and/or disorder may include one or more immune response components designed to anticipate and/or treat an antigenic drift and/or an antigenic shift predicted for multiple agents. The agents need not be related to each other, for example, the therapy might be designed for an individual suffering from multiple diseases.

[**0080**] Following are a series of flowcharts depicting an illustrative environment for the implementation of processes. For ease of understanding, the flowcharts are organized such that the initial flowcharts present implementations via an overall "big picture" viewpoint and thereafter the following flowcharts present alternate illustrative environments and/or expansions of the "big picture" flowcharts as either sub-steps or additional steps building on one or more earlier-presented flowcharts. Those having skill in the art will appreciate that the style of presentation utilized herein (e.g., beginning with a presentation of a flowchart(s) presenting an overall view and thereafter providing additions to and/or further details in subsequent flowcharts) generally allows for a rapid and easy understanding of the various illustrative environments.

[**0081**] With reference now to **FIG. 14**, depicted is a partial view of a system that may serve as an illustrative environment of and/or for subject matter technologies. In one aspect the environment depicted includes a computer system **1400** including a computer program **1402**. Depicted is the computer program **1402** including instructions **1403**, **1404**, and/or **1405**. The computer program **1402** may include a first set of instructions for designating one or more epitopes of at least one agent **1403**. The computer program **1402** may include a second set of instructions for predicting changes in the one or more epitopes of the at least one agent **1403**. The computer program **1402** may include a third set of instructions for aiding the identification of one or more immune response components associated with the one or more epitopes of the at least one agent **1404**. In one exemplary implementation of the system, depicted is a user **1410** (e.g., a medical professional, a researcher, a scientist, a patient, a technician, a manufacturer, a drug maker or the like) employing the system. In another exemplary implementation of the system, the computer program **1402** has access to a database **1406**. In one exemplary implementation a feedback loop is set up between the computer program and the database **1406**. The output **1407** may be fed back into the computer program **1402** and/or displayed on the computer system **1400**. The system may be used as a research tool, as a tool for furthering treatment or the like.

[**0082**] With reference now to **FIG. 15**, depicted is a partial view of a system that may serve as an illustrative environment of and/or for subject matter technologies. The user **1410** may input data **1500**, for example, to affect the output **1407**. Robotic or user input of data may also be provided via a medical system **1504**, a manufacturing system **1505**, or a wet lab system **1506** and the output **1407** fed back into the computer program **1402** and/or displayed on the computer system **1400**.

[**0083**] B. Operation(s) and/or Process(es)

[**0084**] Following are a series of flowcharts depicting implementations of processes. For ease of understanding, the flowcharts are organized such that the initial flowcharts present implementations via an overall "big picture" viewpoint and thereafter the following flowcharts present alternate implementations and/or expansions of the "big picture" flowcharts as either sub-steps or additional steps building on one or more earlier-presented flowcharts. Those having skill in the art will appreciate that the style of presentation utilized herein (e.g., beginning with a presentation of a flowchart(s) presenting an overall view and thereafter providing additions to and/or further details in subsequent flowcharts) generally allows for a rapid and easy understanding of the various process implementations.

[**0085**] Several of the alternate process implementations are set forth herein by context. For example, as set forth herein in relation to **FIG. 5**, what is described as method step **504** is illustrated as a list of exemplary qualifications of an agent. Those skilled in the art will appreciate that when what is described as method step **504** is read in the context of what are described as method step **503** and method step **502**, it is apparent that the list of exemplary qualifications of the agent, in context, is actually illustrative of an alternate implementation of method step **502** of presenting at least a portion of at least one of a virus, a bacterium, a yeast, a mold, a fungus, a mycoplasma, a *ureaplasma*, a *Chlamydia*, a *rickettsia*, a nanobacterium, a prion, an agent responsible for TSE, a multicellular parasite, a protein, an infectious protein, a nucleic acid, a metabolic by-product, a cellular by-product, or a toxin. Likewise, when what is described as method step **505** is read in the context of what are described as method step **503** and method step **502**, it is apparent that, in context, method step **505** is actually illustrative of an alternate implementation of method step **502** of presenting at least a portion of a living agent. Likewise again, when what is described as method step **505** is read in the context of what are described as method step **503** and method step **502**, it is apparent that, in context, method step **505** is actually illustrative of an alternate implementation of method step **502** of presenting at least a portion of a non-living agent. Contextual readings such as those just set forth in relation to method steps **504**, **505**, and **506** are within the ambit of one having skill in the art in light of the teaching herein, and hence are not set forth verbatim elsewhere herein for sake of clarity.

[0086] With reference now to **FIG. 5**, depicted are high level logic flow charts of various alternate process implementations. Method step **500** shows the start of the process. Method step **502** shows the presentation of one or more determinants. Depicted is that in various alternate implementations, method step **502** includes steps **503** and/or **510**. Illustrated is that in various alternate implementations, method step **503** includes substeps **504**, **505**, and/or **506**. Method step **503** depicts some exemplary qualifications of an agent. As depicted method step **504** may include at least a portion of at least one of a virus, a bacterium, a yeast, a mold, a fungus, a mycoplasma, a *ureaplasma*, a *Chlamydia*, a *rickettsia*, a nanobacterium, a prion, an agent responsible for TSE, a multicellular parasite, a protein, an infectious protein, a nucleic acid, a metabolic by-product, a cellular by-product, and/or a toxin. The agent may include a living agent method step **504** and/or a non-living agent **506** of an agent. Method step **510** depicts the one or more determinants and includes additional steps **511**, **512**, and/or **513**. Method step **511** depicts including the one or more determinants wherein the one or more determinants include at least a part of at least one of an amino acid residue, a nucleotide, a carbohydrate, a protein, a lipid, a capsid protein, a polysaccharide, a lipopolysaccharide, a glycolipid, or a glycoprotein. Method step **512** depicts wherein the one or more determinants may include substantially linear determinants. Method step **513** depicts wherein the one or more determinants may include non-linear determinants. It will also be appreciated by those skilled in the art that method step **500** may include accepting input related to, for example, the agent, the one or more determinants and/or other relevant criteria such as a size of the determinant, a type of the determinant, a nature of the disease, a disorder and/or a condition requiring management, and/or a sensitivity of a group requiring management. Method step **530** depicts providing a predicted pattern for the progression related to the one or more determinants of the agent. For example, previous pattern changes known and/or predicted may be used to extrapolate future progressions of the pattern changes that may be observed in the one or more determinants of the agent. Method step **560** depicts designating the selection of at least one immune response component corresponding to the one or more determinants of the agent. The immune response components so designated may include those for managing a disease, a condition or for managing a response, for example. Method step **590** shows the end of the process.

[0087] With reference now to **FIG. 6**, depicted is a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**. Depicted is that method step **560** includes method step **603**, **604**, **605**, and/or **606**. Method step **603** depicts designating at least one immune response component, such as, for example, including but not limited to, of at least a part of one or more of a macrophage, 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 cytotoxic T-lymphocyte, a T-8 lymphocyte, or a cluster differentiation molecule such as a CD3 and/or a CD1 molecule. Method step **604** shows designating at least one immune response component, such as, for example, including but not limited to, at least one modulator of at least a part of at least one of a macrophage, lymphocyte, a T-lymphocyte, a killer T-lymphocyte, an immune response modulator, a helper T-lymphocyte, an antigen receptor, an antigen presenting cell, a cytotoxic T-lymphocyte, a T-8 lymphocyte, a cluster differentiation molecule, a CD3 molecule and/or a CD1 molecule. Method step **605** shows designating at least one immune response component, such as, for example, at least a part of at least one of a B-lymphocyte. Method step **606** shows designating at least one immune response component, for example, at least one of a modulator of at least a part of a B-lymphocyte.

[0088] Referring now to **FIG. 7**, depicted is a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**. Depicted is that in various alternate implementations method step **560** includes method step **703**, **704**, and/or **705**. Method step **703** shows designating at least one immune response component, for example, at least a part of at least one of 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, and/or an antibody fragment. Method step **704** depicts designating at least one immune response component, for example, at least one modulator of at least a part of at least one of 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, polyclonal antibody, and/or an antibody fragment. Method step **705** illustrates designating at least one immune response component e.g., at least a part of at least one of a synthetic antibody or a modulator of a synthetic antibody.

[0089] Referring now to **FIG. 8**, depicted is a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**. In one alternate implementation, as depicted in **FIG. 8**, method step **502** includes method steps **800**, **810**, **811**, and/or **812**. Method step **800** depicts including data from databases for influencing the selection of the one or more determinants of the agent. Method step **800** also includes additional steps **803**, **804** and/or **805**. Method step **803** depicts including at least one of a plant database, an animal database, a bacterium database, a viral database, a biological database, a genetic database, a genomic database, a structural database, a SNP database, or an immunological database. Method step **804** and **805** depicts including a human database or a pathogen database, respectively, for influencing the selection of the one or more determinants.

[0090] Continuing to refer to **FIG. 8**, method step **810** shows influencing the presentation of the one or more determinants of the agent by including information from one or more databases having information related to a restriction fragment length polymorphism, a microsatellite marker, a short tandem repeat, a random amplified polymorphic DNA, an amplified fragment length polymorphism, or a sequence repeat. Method step **811** depicts presenting one or more determinants of an agent associating with a response and wherein the response requires management (e.g., a biological response). Method step **811** depicts presenting one or more determinants of an agent associated with eliciting at least a part of at least one of an immune response or a progression of an immune response.

[0091] With reference now to **FIG. 9**, depicted is a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**. In one alternate implementation, as depicted in **FIG. 9**, method step **530** includes method steps **900**. Method step **900** depicts forming a set or a subset (e.g., a group of one or more determinants). The set or subset may be formed in response to an input method step **902** (e.g., biological criteria, geographical criteria or other substantive criteria), in response to a robotic input method step **903** and/or in response to a user input method step **904**.

[0092] With reference now to **FIG. 10**, depicted is a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**. Shown is one alternate implementation, method step **530** includes method steps **1000-1018**. The criteria used to form sets or subsets may include at least one determinant with up to about 80% amino acid sequence match with an entity method step **1001**. Method step **1002** depicts forming set or subsets by including at least one determinant with up to about 60% amino acid sequence match with an entity. Method step **1003** depicts forming set or subsets by including at least one determinant having at least 88% sequence match with an entity and/or at least a 75% sequence match with an entity. Method step **1004** depicts forming set or subsets by including at least one determinant having a likely sequence match with an entity. Method step **1005** depicts forming set or subsets by including at least one determinant with up to about 70% amino acid sequence match with an entity. Method step **1006** depicts forming set or subsets by including at least one determinant with up to about 0-80% amino acid sequence match with an entity. Method step **1007** depicts forming set or subsets by including at least one determinant having between 0 to 100% sequence match with an entity. Method step **1008** depicts forming set or subsets by including at least one determinant having a substantially similar structural match with an entity. Method step **10019** depicts forming set or subsets by including at least one determinant having a copy number of at least two and that is recognized (e.g., by the occurrence of an immune response directed towards the one or more determinants).

[0093] Continuing to refer to **FIG. 10**, method step **1010** depicts forming set or subsets by including at least one determinant having a substantially similar functional effect. Method step **1011** depicts forming set or subsets by including at least one substantially antigenic determinant. Method step **1012** depicts forming set or subsets by including at least one determinant displayed by the agent (e.g., on the surface of the agent). Method step **1013** depicts forming set or subsets by including at least one determinant having a substantially similar functional sequence match with an entity. Method step **1014** depicts forming set or subsets by including at least one determinant having a substantially similar effect on the immune response. Method step **1015** depicts forming set or subsets by including at least one determinant having a substantially similar result in an assay. Method step **1016** depicts forming set or subsets by including at least one immunologically effective determinant. Method step **1017** depicts forming set or subsets by including at least one determinant having a copy number of at least two and displayed by the agent. Method step **1018** depicts forming set or subsets by including at least one determinant bound by the agent (e.g., a cofactor, or an ectopic determinant that may be part of the agent or not part of the agent).

[0094] With reference now to **FIG. 11**, depicted is a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**. Depicted is that method step **530** includes method step **1102** and/or **1103**. Method step **1102** shows associating the one or more determinants of the agent with a predicted pattern for a progression of at least a part of an immune response in a host. Method step **1103** shows predicting one or more pattern changes in the one or more determinants of the agent. Method step **1103** includes method step **1104** which depicts correlating the one or more pattern changes in the one or more determinants of the agent to one or more progressions of an elicited immune response.

[0095] Referring now to **FIG. 12**, depicted is a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**. Depicted is that method step **560** includes method step **1202-1210**. Method step **1202** shows including data from at least one of a plant database, an animal database, a bacterium database, a viral database, a biological database, a genetic database, a genomic database, a structural database, a SNP database, or an immunological database. Method step **1203** shows including data from databases for influencing the identification of the one or more determinants of the agent. Method step **1204** shows including data from a human database. Method step **1205** shows including data from a pathogen database. Method step **1206** shows including designating the selection of at least one immune response component corresponding to the one or more determinants of the agent associated with the at least one determinant of the agent operable for modulating at least a part of the immune response. Method step **1207** shows including directing the formation of one or more human or humanized antibodies associated with the one or more determinants of the agent operable for modulating at least a part of the immune response. Method step **1208** shows including directing the formation of one or more chimeric antibodies associated with the one or more determinants of the agent operable for modulating at least a part of the immune response. Method step **1209** shows including directing the formation of one or more recombinant antibodies associated with the one or more determinants of the agent operable for modulating at least a part of the immune response. Method step **1210** shows including directing the formation of one or more recombinant antibodies associated with the one or more determinants of the agent operable for modulating at least a part of the immune response.

[0096] With reference now to **FIG. 13**, depicted is a high-level logic flowchart depicting alternate implementations of the high-level logic flowchart of **FIG. 5**. Depicted is that method step **560** includes method step **1302**. Method step **1302** includes aiding the selection of the at least one immune response component by providing a plan (e.g., a scheme, a list of options, or a course of action). What is shown is that method step **1302** includes additional method step **1303** and/or **1304**. Method step **1303** includes providing the plan for managing at least a part of the immune response. Method step **1304** includes wherein the plan is e.g., at least one of a dosage, a dosing pattern, an effective route, or duration of a dosage. Method step **1304** includes additional method step **1305** wherein the effective route is e.g., at least one of a sub-cutaneous route, a nasal route, an intranasal route, an intramuscular route, an intravenous route, an intraarterial route, an intrathecal route, an intracapsular

route, an intraorbital route, an intracardiac route, a transdermal route, an intradermal route, an intraperitoneal route, a transtracheal route, a subcuticular route, an intraarticular route, a subcapsular route, a subarachnoidal route, an intraspinal route, an epidural route, an intrasternal route, an infusion route, a topical route, a sublingual route, or an enteric route.

[0097] C. Variation(s), and/or Implementation(s)

[0098] Those having skill in the art will recognize that the present application teaches modifications of the devices, structures, and/or processes within the spirit of the teaching herein. For example, in one aspect, the immune response components may be formulated to cross the blood-brain barrier which is known to exclude mostly hydrophilic compounds. For example, an antibody fragment may be encased in a lipid vesicle. In another example, the antibody or a portion of the antibody may be tagged onto a carrier protein or molecule. In another example, an antibody may be split into one or more complementary fragments, each fragment encased by a lipid vesicle, and each fragment functional only on binding its complementary fragment. Once the blood-brain barrier has been crossed the lipid vesicle may be dissolved to release the antibody fragments which reunite with their complementary counterparts and form a fully functional antibody. Other modifications of the subject matter herein will be appreciated by one of skill in the art in light of the teachings herein.

[0099] Those having skill in the art will recognize that the present application teaches modifications of the devices, structures, and/or processes within the spirit of the teaching herein. For example, in one aspect the immune response components may be made in large format. The method lends itself to both small format or personalized care applications and large scale applications. Other modifications of the subject matter herein will be appreciated by one of skill in the art in light of the teachings herein.

[0100] Those having skill in the art will recognize that the present application teaches modifications of the devices, structures, and/or processes within the spirit of the teaching herein. For example, in one aspect, the method may be used to designate immune response components for any diseases or disorders. The application of this method is not limited to diseases where antigenic shift or drift keeps the immune system guessing making it slow to respond. Although, influenza or aids are likely candidates other diseases, disorders and/or conditions will likely benefit from this methodology. Other modifications of the subject matter herein will be appreciated by one of skill in the art in light of the teachings herein.

[0101] Those having skill in the art will recognize that the present application teaches modifications of the devices, structures, and/or processes within the spirit of the teaching herein. For example, in one aspect, real-time evaluation may be provided of the antigenic changes by including a portable PCR machine which samples the environment for strains locally present. The information may be sent remotely to another location or to a portable drip patch utilized by the person resulting in the activation of the necessary immune response components providing adequate protection. As the evaluation changes the portable drip patch may be triggered to change the dosage or type of immune response component delivered. Such a portable drip patch operably-coupled to a portable PCR machine has wide variety of application, for example, including, but not limited to, when medical personnel visit areas endemic to a disease, or when military personnel visit hostile territory. Other modifications of the subject matter herein will be appreciated by one of skill in the art in light of the teachings herein.

[0102] Those having skill in the art will recognize that the present application teaches modifications of the devices, structures, and/or processes within the spirit of the teaching herein. For example, in one aspect, an individual may use a drip-patch infused with the immune response components preprogrammed to provide the user the necessary protection over a period of time, and to anticipate pattern changes in the epitopes of the agent **100**. Other modifications of the subject matter herein will be appreciated by one of skill in the art in light of the teachings herein.

[0103] Those having skill in the art will recognize that the present application teaches modifications of the devices, structures, and/or processes within the spirit of the teaching herein. For example, in one aspect, RNA blockers, or single stranded RNAI technology may be used to downregulate genes or components of the immune system in conjunction with the method. Other modifications of the subject matter herein will be appreciated by one of skill in the art in light of the teachings herein.

[0104] Those skilled in the art will appreciate that the foregoing specific exemplary processes and/or devices and/or technologies are representative of more general processes and/or devices and/or technologies taught elsewhere herein, such as in the claims filed herewith and/or elsewhere in the present application.

[0105] Those having skill in the art will recognize that the state of the art has progressed to the point where there is little distinction left between hardware and software implementations of aspects of systems; the use of hardware or software is generally (but not always, in that in certain contexts the choice between hardware and software can become significant) a design choice representing cost vs. efficiency tradeoffs. Those having skill in the art will appreciate that there are various vehicles by which processes and/or systems and/or other technologies described herein can be effected (e.g., hardware, software, and/or firmware), and that the preferred vehicle will vary with the context in which the processes and/or systems and/or other technologies are deployed. For example, if an implementer determines that speed and accuracy are paramount, the implementer may opt for a mainly hardware and/or firmware vehicle; alternatively, if flexibility is paramount, the implementer may opt for a mainly software implementation; or, yet again alternatively, the implementer may opt for some combination of hardware, software, and/or firmware. Hence, there are several possible vehicles by which the processes and/or devices and/or other technologies described herein may be effected, none of which is inherently superior to the other in that any vehicle to be utilized is a choice dependent upon the context in which the vehicle will be deployed and the specific concerns (e.g., speed, flexibility, or predictability) of the implementer, any of which may vary.

[0106] 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), or other 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. 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 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, CD ROMs, digital tape, and computer memory; and transmission type media such as digital and analog communication links using TDM or IP based communication links (e.g., packet links).

[0107] 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).

[0108] 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 video display device, a memory such as volatile and non-volatile memory, processors such as microprocessors and digital signal processors, computational entities such as operating systems, drivers, graphical user interfaces, 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 (e.g., feedback for sensing position and/or velocity; control motors for moving and/or adjusting components and/or quantities). A typical data processing system may be implemented utilizing any suitable commercially available components, such as those typically found in data computing/communication and/or network computing/communication systems.

[0109] All of the referenced U.S. patents, U.S. patent application publications, U.S. patent applications, foreign patents, foreign patent applications, and/or non-patent publications referred to in this specification and/or listed in any Application Data Sheet, including but not limited to [insert list], are incorporated herein by reference, in their entireties.

[0110] 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. Specific examples of operably couplable include but are not limited to physically mateable and/or physically interacting components and/or wirelessly interactable and/or wirelessly interacting components.

[0111] While particular aspects of the present subject matter described herein have been shown and described, it will be apparent to those skilled in the art that, based upon the teachings herein, changes and modifications may be made without departing from this subject matter described herein and its broader aspects and, therefore, the appended claims are to encompass within their scope all such changes and modifications as are within the true spirit and scope of this subject matter described herein. Furthermore, it is to be understood that the invention is solely defined by the appended claims. It will be understood by those within the art that, in general, terms used herein, and especially in the appended claims (e.g., bodies of the appended claims) are generally intended as "open" terms (e.g., the term "including" should be interpreted as "including but not limited to," the term "having" should be interpreted as "having at least," the term "includes" should be interpreted as "includes but is not limited to," etc.). It will be further understood by those within the art that if a specific number of an introduced claim recitation is intended, such an intent will be explicitly recited in the claim, and in the absence of such recitation no such

intent is present. For example, as an aid to understanding, the following appended claims may contain usage of the introductory phrases "at least one" and "one or more" to introduce claim recitations. However, the use of such phrases should not be construed to imply that the introduction of a claim recitation by the indefinite articles "a" or "an" limits any particular claim containing such introduced claim recitation to inventions containing only one such recitation, even when the same claim includes the introductory phrases "one or more" or "at least one" and indefinite articles such as "a" or "an" (e.g., "a" and/or "an" should typically be interpreted to mean "at least one" or "one or more"); the same holds true for the use of definite articles used to introduce claim recitations. In addition, even if a specific number of an introduced claim recitation is explicitly recited, those skilled in the art will recognize that such recitation should typically be interpreted to mean at least the recited number (e.g., the bare recitation of "two recitations," without other modifiers, typically means at least two recitations, or two or more recitations). Furthermore, in those instances where a convention analogous to "at least one of A, B, and C, etc." is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., "a system having at least one of A, B, and C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.). In those instances where a convention analogous to "at least one of A, B, or C, etc." is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., "a system having at least one of A, B, or C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.).

1. A method, comprising:

identifying an association of at least a portion of one or more agents with at least a part of an immune response;

projecting a pattern of changes relating to the at least a portion of the one or more agents; and

selecting one or more immune response components in response to the projecting.

2. The method of claim 1, wherein the selecting one or more immune response components further comprises:

selecting at least a part of one or more of a macrophage, a lymphocyte, a T-lymphocyte, a killer T-lymphocyte, a immune response modulator, a helper T-lymphocyte, an antigen receptor, an antigen presenting cell, a cytotoxic T-lymphocyte, a T-8 lymphocyte, a cluster differentiation (CD) molecule, a CD3 molecule, or a CD1 molecule.

3. The method of claim 1, wherein the selecting one or more immune response components further comprises:

selecting one or more modulators of at least a part of at least one of a macrophage, 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 cytotoxic T-lymphocyte, a T-8 lymphocyte, a cluster differentiation (CD) molecule, a CD3 molecule, or a CD1 molecule.

4. The method of claim 1, wherein the selecting one or more immune response components further comprises:

selecting one or more of modulators of at least a part of a B lymphocyte.

5. The method of claim 1, wherein the selecting one or more immune response components further comprises:

selecting one or more of modulators of at least a part of a at least one of B-lymphocyte.

6. The method of claim 1, wherein the selecting one or more immune response components further comprises:

selecting at least a part of one or more of 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, or an antibody fragment.

7. The method of claim 1, wherein the selecting one or more immune response components further comprises:

selecting one or more of a modulator of at least a part of at least one of 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, or an antibody fragment.

8. The method of claim 1, wherein the identifying an association of at least a portion of one or more agents with a part of an immune response further comprises:

identifying an association of at least a portion of at least one of a virus, a bacterium, a yeast, a mold, a fungus, a mycoplasma, a *ureaplasma*, a *Chlamydia*, a *rickettsia*, a nanobacterium, a prion, an agent responsible for TSE, a multicellular parasite, a protein, an infectious protein, a nucleic acid, a metabolic by-product, a cellular by-product, or a toxin.

9. A system, comprising:

circuitry for associating at least a portion of one or more agents with at least a part of an immune response;

circuitry for projecting a pattern of changes relating to the at least a portion of the one or more agents; and

circuitry for selecting one or more immune response components responsive to said circuitry for projecting.

10. The system of claim 9, wherein the circuitry for selecting one or more immune response components further comprises:

circuitry for selecting at least a part of one or more of a macrophage, a lymphocyte, a T-lymphocyte, a killer T-lymphocyte, a immune response modulator, a helper T-lymphocyte, an antigen receptor, an antigen presenting cell, a cytotoxic T-lymphocyte, a T-8 lymphocyte, a cluster differentiation (CD) molecule, a CD3 molecule, or a CD1 molecule.

11. The system of claim 9, wherein the circuitry for selecting one or more immune response components further comprises:

circuitry for selecting one or more modulators of at least a part of at least one of a macrophage, 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 cytotoxic T-lymphocyte, a T-8 lymphocyte, a cluster differentiation (CD) molecule, a CD3 molecule, or a CD1 molecule.

12. The system of claim 9, wherein the selecting one or more immune response components further comprises:

circuitry for selecting one or more of modulators of at least a part of a B lymphocyte.

13. The system of claim 9, wherein the circuitry for selecting one or more immune response components further comprises:

circuitry for selecting one or more of modulators of at least a part of a at least one of B-lymphocyte.

14. The system of claim 9, wherein the circuitry for selecting one or more immune response components further comprises:

circuitry for selecting at least a part of one or more of 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, or an antibody fragment.

15. The system of claim 9, wherein the circuitry for selecting one or more immune response components further comprises:

circuitry for selecting one or more of a modulator of at least a part of at least one of 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, or an antibody fragment.

16. The system of claim 9, wherein the circuitry for identifying an association of at least a portion of one or more agents with a part of an immune response further comprises:

circuitry for identifying an association of at least a portion of at least one of a virus, a bacterium, a yeast, a mold, a fungus, a mycoplasma, a *ureaplasma*, a *Chlamydia*, a *rickettsia*, a nanobacterium, a prion, an agent responsible for TSE, a multicellular parasite, a protein, an infectious protein, a nucleic acid, a metabolic by-product, a cellular by-product, or a toxin.

17. A method, comprising:

accepting an input of one or more agents; and

identifying an association of at least a portion of one or more agents with at least a part of an immune response related to eradicating the one or more agents.

18. A system, comprising:

circuitry for accepting an input of one or more agents; and

circuitry identifying an association of at least a portion of one or more agents with at least a part of an immune response related to eradicating the one or more agents.

19. A method, comprising:

projecting a pattern of changes relating to the at least a portion of one or more agents; and

selecting one or more immune response components in response to said projecting.

20. A system, comprising:

circuitry for projecting a pattern of changes relating to the at least a portion of one or more agents; and

circuitry for selecting one or more immune response components in response to said projecting.

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