UNITED STATES PATENT AND TRADEMARK OFFICE

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UNITED STATES PATENT AND TRADEMARK OFFICE
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BEFORE THE PATENT TRIAL AND APPEAL BOARD
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Ex parte YASSER ALSAFADI
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Appeal 2019-000810
Application 12/441,184
Technology Center 3600
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Before KARL D. EASTHOM, AMBER L. HAGY, and
KARA L. SZPONDOWSKI, *Administrative Patent Judges.*

EASTHOM, *Administrative Patent Judge.*

DECISION ON APPEAL

I. STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision finally rejecting claims 1–13 in a Final Office Action. Final Act. 1. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

II. DISCLOSED AND CLAIMED SUBJECT MATTER

The Specification describes a molecular diagnostics decision support system. Spec. 1:1–5.[2] The support system interconnects databases and software components in order to create information, namely, patient related information (PRI). *See* Spec., Fig. 1, 8:10–12. According to the Specification, "the present invention *does not provide a diagnosis as part of the patient related information PRI*. Rather, the invention provides information PRI that can assist a physician, a clinician, and/or a technician in reaching a diagnosis." Spec. 8:10–12 (emphasis added).

Claim 1, reproduced below, illustrates the claimed subject matter:

> 1. A molecular diagnostics decision support system (MD-DSS) for providing patient related information (PRI), the system comprising:
> a molecular diagnostic measurement device that generates a gene expression of a biopsy sample of a patient,
> a patient information database (EMJ) storing patient data about the patient,

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[1] "Appellant" here constitutes an "applicant" as defined in 37 C.F.R. 1.42(a). Appellant identifies the real party in interest as Koninklijke Philips, N.V. Appeal Br. 3.

[2] The record USPTO filing system includes three copies of Specifications. We refer to the Specification having the following nomenclature: PH00578US1 bearing the following date: "28.08.2006." The three Specifications appear to be materially the same.

a data input section (DAT) that receives the gene expression, as input data (MDx), from the molecular diagnostic measurement device,

a clinical guideline database (CL),

a knowledge database (KB),

a first decision support mechanism (1DSM),

a second decision support mechanism (2DSM),

an inference engine (IE), and

a middleware (MW) section interconnecting the patient information database (EMJ), the data input section (DAT), the clinical guideline database (CL), the knowledge database (KB), the first decision support mechanism (1DSM), and the second decision support mechanism (2DSM),

wherein the inference engine (IE) is configured to classify asserted facts in the knowledge base (KB) to determine a correct position of a class of classes in a hierarchy using logical definitions of the classes,

wherein the first (1DSM) and the second (2DSM) decision support mechanisms process input data (MDx) into patient related information (PRI) using the patient information database (EMJ), the clinical guideline database (CL) and the knowledge database (KB), and

wherein the first (1DSM) and the second (2DSM) decision support mechanism are operably coupled through the middleware (MW) so as to interact during the processing of the input data (MDx).

III. REFERENCES

The Examiner relies upon the following prior art:

Name	Reference	Date
Avinash	US 2004/0122787 A1	June 24, 2004
Lu	WO 03/017038 A2	Feb. 27, 2003

IV. REJECTIONS

Claims Rejected	35 U.S.C. §	Reference(s)/Basis
1–12	112 2nd	Indefiniteness
1–13	112 1st	Written Description

Claims Rejected	35 U.S.C. §	Reference(s)/Basis
1–13	101	Nonstatutory Subject Matter
13	102	Anticipation, Avinash
1–12	103	Obviousness, Avinash and Lu

V. OPINION

As set forth in the table above, the Examiner rejects claims 1–13 for reciting nonstatutory subject matter and lack of written description, claims 1–12 for indefiniteness and obviousness, and claim 13 for anticipation. We primarily cite the Final Action and Appeal Brief in support of this Decision. Nonetheless, we considered all the briefing in reaching the Decision, including the Examiner's Answer and Appellant's Reply Brief, which largely emphasizes certain points in the Appeal Brief.

A. Claim Construction, 35 U.S.C. § 112, Sixth Paragraph

The Examiner construes three claim 1 limitations, "decision support mechanism," "interference engine," and "middleware section," as falling under 35 U.S.C. § 112, sixth paragraph, because "they use a generic placeholder 'engine,' 'mechanism' and 'section' coupled with functional language 'process' and 'for' without reciting sufficient structure to achieve the function." Final Act. 3. The Examiner explains "the generic placeholder is not preceded by a structural modifier." *Id.*

Under 35 U.S.C. § 112, sixth paragraph:

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

Appellant initially notes that "because the term 'means for . . .' is not recited with respect to any of these limitations in claim 1, a rebuttable presumption arises that 35 U.S.C 112, sixth paragraph, does not apply." Appeal Br. 6 (emphasis omitted). Appellant "submit[s] that the Office Action has not successfully rebutted this presumption, i.e., that the terms do provide sufficient structure for performing the corresponding functions, when considered in light of the [S]pecification and commonly accepted meanings in the technological art." *Id.* (emphasis omitted).

Contrary to Appellant's argument, nothing in the Specification or record indicates that the terms "decision support *mechanism*," "interference *engine*," and "middleware *section*," invoke a commonly accepted meaning in the art. As the Examiner reasons, "[t]he problem is that the Appellant's [S]pecification does not particularly point out what the invention comprises." Ans. 3. The Examiner directs attention to the Specification at page 9, lines 1–13. *See* Final Act. 3. That section describes a first and second "decision support mechanism" as implementing a "Genetic Algorithm" (GA), or as using a "Bayesian" or "a Fuzzy logic based network to resolve a criterion in a decision step," with the two support mechanisms including "tight couplings." *See* Spec. 9:1–13.

Page 9 of the Specification also describes an "inference engine IE [that] will classify the asserted facts in the knowledge base KB to find the correct position of a class in a hierarchy using the logical definition of the classes." *Id.* at 9:25–27.[3] It further describes the "inference engine IE" as a "generic component[] of a decision support system" with "no specific

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[3] In some instances, the Specification refers to the same component as an "interference engine IE." *See, e.g.*, Spec. 9:18. Claim 9 also recites an

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requirements for a molecular diagnosis application." *Id.* at 9:19–23. It states "Racer is an example inference engine" and "[i]t should be consider[ed] to use available off the shelf components for these engines IE and CL-EE." *Id.* at 9:28–29.

Page 8 of the Specification states "[t]he middleware section MW interconnecting the elements of the DSS *can include any kind of connection including, but not limited to, electrical connections and wireless connections.*" *Id.* at 8:21–23 (emphasis added). Page 7 of the Specification describes the middleware section as follows:

> The middleware MW section 110 interconnects the patient information database EMJ, the data input section DAT, the clinical guideline database CL, the knowledge database KB, the first decision support mechanism 1DSM, and the second decision support mechanism 2DSM. As such the other components depicted in Fig. 1 may be considered to be embedded in the middleware MW, but for practical considerations the middleware section MW enables the communication by electric/wireless connections and control this communication.

Id. at 7:20–26.

These Specification passages support the Examiner's findings. They show that the terms "decision support mechanism," "inference engine," and "middleware section" fall under 35 U.S.C. § 112, sixth paragraph. Contrary to Appellant's arguments, nothing in the Specification shows that an artisan of ordinary skill would have recognized the terms as connoting well-known

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"interference engine (IE)." The term "interference engine" appears to be a typographical mistake that Appellant should address in any subsequent prosecution. Accordingly, throughout this Decision, we treat the disclosed and claimed "interference engine" and "inference engine" as the same, and with the exception of quoting the briefs or the Specification, we refer only to the latter for discussion purposes.

or sufficient structure. *See* Appeal Br. 6–8. Even though the Specification indicates an inference engine may employ "off the shelf components" and describes "Racer" as an example, the Specification does identify what structure "Racer" connotes and does not describe the algorithmic or other structure of the "off the shelf components" as specific structure or class of structures. *See* Spec. 9:29–30. Rather, the Specification describes the "inference engine IE" as a "generic component[ ] of a decision support system." *Id.* at 9:19–20. Accordingly, the Specification does not sufficiently "connote a specific structure or a class of structures" for the term "inference engine." *See MTD Prods. Inc. v. Iancu*, 933 F.3d 1336 (Fed. Cir. 2019) ("That the specification discloses a structure corresponding to an asserted means-plus-function claim term does not necessarily mean that the claim term is understood by persons of ordinary skill in the art to connote a specific structure or a class of structures.").

The surrounding language in claim 1 further supports this determination. The limitation at issue, "the inference engine (IE) is configured to classify asserted facts in the knowledge base (KB) to determine a correct position of a class of classes in a hierarchy using logical definitions of the classes," recites an "inference" that appears to include a function of classifying facts "to determine a correct position of a class of classes in a hierarchy using logical definitions of the classes." But neither the phrase nor the Specification connotes specific algorithmic or hardware structure or such structure as a class.

Appellant does not address the Examiner's contention regarding the "interference engine." *See* Appeal Br. 6 (addressing "decision support mechanism" and "middleware section"). Appellant's arguments regarding

the "decision support mechanism" and "middleware section" support, rather than rebut, the Examiner's contention. Specifically, Appellant's arguments show that the Specification describes the terms "decision support mechanism" and "middleware section" in generic terms that cover a wide variety of structures, including respectively "hardware and/or software" and "hardware, firmware, or software, or a combination thereof":

> For example, the term "decision support mechanism (DSM)" alone connotes the *hardware and/or software* used to obtain a decision support system with a more comprehensive approach with respect to the patient because patient data are combined with input data (MDx) delivered from one or more molecular diagnostics measurement devices, as would be apparent to one of ordinary skill in the art. Appellants also note that illustrative DSMs [sic] a Bayesian network, an artificial neural network, a support vector machines mechanism, a K nearest neighbor mechanism, a genetic algorithm mechanism, a decision tree mechanism, a rule based system, a case based reasoning mechanism, and a fuzzy logic based mechanism. These mechanisms clearly can be instantiated in hardware and/or software, as would be readily appreciated by one of ordinary skill in the art, who had the benefit of the filed application. Similarly, the term "a middleware section" alone connotes the hardware, firmware, or software, or a combination thereof that interconnects portions of the system of various embodiments. For example, and as disclosed initially in paragraph [0015] of the filed application, in a representative embodiment, the middleware section interconnects the patient information database (EMJ), the data input section (DAT), the clinical guideline database (CL), the knowledge database (KB), the first decision support mechanism (1DSM), and the second decision support mechanism (2DSM).

Appeal Br. 6–7.[4]

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[4] We do not see, in this record, the Specification that Appellant references in its citation to "paragraph [0015] of the filed application." None of the three

Appellant correctly points out the terms need not "denote a specific structure or a precise physical structure to avoid the application of . . . 35 U.S.C. 112, paragraph 6." Appeal Br. 7. Also, "paragraph 6 will not apply if persons of ordinary skill in the art reading the specification understand the term to be the name for the structure that performs the function, even when the term covers a broad class of structures or identifies the structures by their function (e.g., 'filters,' 'brakes,' 'clamp,' 'screwdriver,' and 'locks')." *Id.* (citing *inter alia*, MPEP § 2181(I)(A)).

Nevertheless, nothing in the functions recited or descriptions in the Specification identify the structure or connote a broad class of structures. As the Examiner reasons, "Appellant continues with generic descriptions of functional items without describing how the functional items are created." Ans. 5.

Similarly, regarding the "middleware (MW) section interconnecting the patient information database (EMJ), the data input section (DAT), the clinical guideline database (CL), the knowledge database (KB), the first decision support mechanism (1DSM), and the second decision support mechanism (2DSM)," nothing in the recited interconnecting function specifies how the devices will be interconnected. Moreover, the Specification and Appellant's arguments indicate the term connotes several classes of structures, namely, hardware, software, a combination of the two, wireless structure, electrical structure, and/or, in addition, something that

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Specifications in the record include paragraph numbers. *See supra* note 2. In any event, we agree with Appellant that the Specification describes a wide variety of software and/or hardware as corresponding to "a middleware section" and "decision support mechanism."

"embeds" other components, and something that may or may not "control" the communication. *See* Spec. 7:20–26 ("As such the other components depicted in Fig. 1 may be considered to be *embedded* in the middleware MW, but for practical considerations the middleware section 25 MW enables the communication by electric/wireless connections *and control this communication*.") (emphasis added); Appeal Br. 6–7.

Similarly, regarding the "decision support mechanisms [for] process[ing] input data (MDx) into patient related information (PRI) using the patient information database (EMJ), the clinical guideline database (CL) and the knowledge database (KB)," nothing in the recited process function specifies how the "mechanisms" will "process" the input data (MDx) data using the three other databases recited in claim 1 (and similarly recited in claim 13). Nothing in the claim or the Specification indicates what the "process" entails, or what form the resulting PRI data takes. Nothing shows how the "hardware and/or software" implementing the various algorithms or mechanisms that Appellant describes represents a class of "mechanisms" that "process" data into PRI. *See* Appeal Br. 6–7 ("Appellant[] also note[s] that illustrative DSMs [sic] a Bayesian network, an artificial neural network, a support vector machines mechanism, a K nearest neighbor mechanism, a genetic algorithm mechanism, a decision tree mechanism, a rule based system, a case based reasoning mechanism, and a fuzzy logic based mechanism.").

As Appellant recognizes, "MPEP § 2181(I) . . . provide[s] some examples of 'nonce words' or 'generic placeholders' for the term 'means,' including 'mechanism for,' 'module for,' 'device for,' 'unit for,' 'component for,' 'element for,' 'member for,' 'apparatus for,' 'machine for,' or 'system

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for.'" Appeal Br. 8. Although Appellant contends these words are not "similar to 'interface'," none of the terms at issue here involve the term "interface." *See id.* Rather, the terms involve the generic terms "inference engine," "decision support mechanism," and "middleware (MW) section," as the Examiner recognizes.

Under *MTD Products*, 933 F.3d at 1338, the Board commits "err[or] by conflating corresponding structure in the specification with a structural definition for the term." *Id.* (holding "'mechanical control assembly' is a nonce term that is not used in common parlance and does not bring to mind any specific structure to a person of ordinary skill in the art"). Here, as discussed above, and as Appellant argues, the Specification discloses myriad generic structures that embrace all manner of structures capable of performing the functions of the terms "inference engine," "decision support mechanism," and "middleware (MW) section," as recited in claim 1. *See MTD Prods.*, 933 F.3d at 1342 ("Instead, the extrinsic evidence demonstrated only that 'a skilled artisan would understand the functional term cheque standby unit *to be any structure capable of performing the claimed function.*'" (quoting *Diebold Nixdorf, Inc. v. Int'l Trade Comm'n*, 899 F.3d 1291, 1300 (Fed. Cir. 2018) (internal quotation marks omitted) (emphasis added)).

MTD Products reiterates that "[g]eneric terms like 'module,' 'mechanism,' 'element,' and 'device' are commonly used as verbal constructs that operate, like 'means,' to claim a particular function rather than describe a 'sufficiently definite structure.'" *Id.* at 1341 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015) (en banc)). Directly contrary to Appellant's argument that "the presumption *is a*

strong one that is not readily overcome," Appeal Br. 6 (emphasis added), *Williamson* holds "*such a heightened burden is unjustified and that we should abandon characterizing as 'strong' the presumption* that a limitation lacking the word 'means' is not subject to § 112, para. 6." *Williamson*, 792 F.3d at 1349 (emphasis added).

As *MTD Products* directs, "we apply a rebuttable presumption that the term conveys sufficiently definite structure and is not subject to § 112, ¶ 6." *MTD Prods.,* 933 F.3d at 1342 (citing *Williamson*, 792 F.3d at 1348). "A challenger can rebut the presumption by demonstrating 'that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function.'" *Id.* (quoting *Williamson*, 792 F.3d at 1348 (internal quotations omitted)). Based on the foregoing discussion, the Examiner rebuts the *Williamson* presumption and shows the claim terms recite generic (nonce) words that do not connote sufficiently definite structure.

Accordingly, Appellant does not show error in the Examiner's construction of the three claim 1 limitations, "decision support mechanism," "interference engine," and "middleware section," as nonce words substituting for "means for" terms that fall under 35 U.S.C. § 112, sixth paragraph.

B. Indefiniteness

The Examiner rejects claims 1–12 under 35 U.S.C. § 112, second paragraph, as being indefinite, because the Specification does not disclose the algorithmic structure for the means plus function terms noted above in Section V.A, namely the "middleware (MW) section," the "inference

engine," and the "decision support mechanisms." Final Act. 9. The three

claim 1 terms at issue follow:

> a *middleware (MW) section interconnecting* the patient information database (EMJ), the data input section (DAT), the clinical guideline database (CL), the knowledge database (KB), the first decision support mechanism (1DSM), and the second decision support mechanism (2DSM),
> wherein *the inference engine (IE) is configured to classify asserted facts* in the knowledge base (KB) to determine a correct position of a class of classes in a hierarchy using logical definitions of the classes,
> wherein the first (1DSM) and the second (2DSM) *decision support mechanisms process input data (MDx) into patient related information (PRI) using the patient information database (EMJ), the clinical guideline database (CL) and the knowledge database (KB).*

As the Examiner determines, the Specification does not describe the

structure corresponding to the three means-plus-function terms at issue here.

See Final Act. 9.

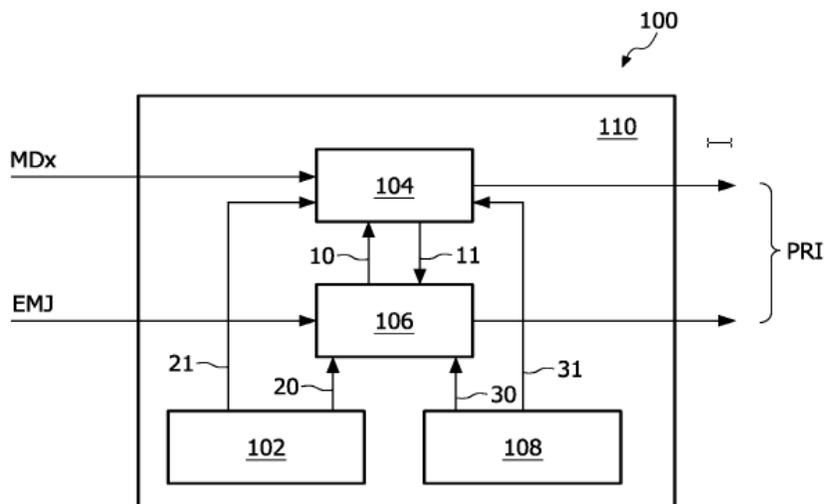Figure 1 of the Specification follows:

FIG. 1

Figure 1 above depicts first and second decision support mechanisms 104 and 106 for processing input data MDx, with clinical guideline database CL 102 and knowledge database KB 108, all included with or interconnected via middleware section 110. Spec. 7:1–26, 8:1–6.

Appellant argues claims 1–13 as a group, notwithstanding that the Examiner did not reject claim 13 for indefiniteness. Appeal Br. 9–10. Accordingly, claim 1 represents the claims rejected for indefiniteness.

Appellant argues that the Specification describes a wide variety of structure for the "decision support mechanism" and "middleware section." Appeal Br. 9. For example, Appellant describes at least nine generic algorithms that connote structure for the "decision support mechanism," maintaining "[t]hese mechanisms clearly can be instantiated *in hardware and/or software*":

> illustrative DSMs include a Bayesian network, an artificial neural network, a support vector machines mechanism, a K nearest neighbor mechanism, a genetic algorithm mechanism, a decision tree mechanism, a rule based system, a case based reasoning mechanism, and a fuzzy logic based mechanism. These mechanisms clearly can be instantiated in hardware and/or software, as would be readily appreciated by one of ordinary skill in the art, who had the benefit of the filed application.

Id. at 9–10. These arguments that describe generic algorithms, without more, support the Examiner's determination, because they essentially serve to capture every possible type of structure for the "decision support mechanisms," contrary to the requirements of 35 U.S.C. § 112, sixth paragraph.

The "decision support mechanisms" in claim 1 "process[es] input data (MDx) into patient related information (PRI) using the patient information

database (EMJ), the clinical guideline database (CL) and the knowledge database (KB)." According to the Specification, "[t]he elements and components of an embodiment of the invention may be physically, functionally and logically implemented in any suitable way." *Id.* at 8:16–18. According further to the Specification, "[t]he decision support system may then have several applications (e.g. diseases or users), each with different rules/procedures defining the operation of the middleware. The decision support system can thereby be very adaptive." *Id.* at 4:7–10. The Specification does not specify the "rules/procedures," or sufficient algorithmic or other structure for how "decision support mechanisms process input data . . . into patient related information (PRI) using" the recited databases, as claim 1 recites. The Specification does not describe what the "process" entails, including how the process creates the PRI, and how it uses the databases to create the PRI. As the Examiner finds, the Specification does not sufficiently disclose the algorithmic structure to achieve the claimed process involved in the decision support mechanisms. Final Act. 8–9.

Regarding "middleware section" 110, Appellant argues "in a representative embodiment, the middleware section interconnects the patient information database (EMJ), the data input section (DAT), the clinical guideline database (CL), the knowledge database (KB), the first decision support mechanism (1DSM), and the second decision support mechanism (2DSM)." Appeal Br. 10. However, Appellant contends "that the term 'a middleware section' alone connotes the hardware, firmware, or software, or a combination thereof that interconnects portions of the system of various

embodiments." *Id.* These arguments fail to show how the Specification discloses the corresponding algorithmic or hardware structure.

The Specification states "[t]he middleware MW section 110 interconnects the patient information database EMJ, the data input section DAT, the clinical guideline database CL, the knowledge database KB, the first decision support mechanism 1DSM, and the second decision support mechanism 2DSM." Spec. 7:20–23. It also states "other components depicted in Fig. 1 may be considered to be *embedded in the middleware* MW, but for practical considerations the middleware section MW enables the communication by electric/wireless connections and control this communication." *Id.* at 7:23–26 (emphasis added). Nothing indicates how the middleware *embeds* components, or how it "enables the electric/wireless connections and *control[s]* this communication." Nothing shows how the middleware section interconnects the seven claimed components, including three databases, two decision support mechanisms, and a data input section.

Another section of the Specification describes the following: "In one embodiment, the middleware section (MW) may comprise an application sub-section (APP), wherein an application is selectable, each application having one or more corresponding rules related to that application of the system." Spec. 4:5–10. The Specification does not describe the rules or the application.

The Specification further describes generic functionality for the middleware section, as "computer software," or otherwise "physically, functionally and logically implemented in any suitable way," "including any kind of connection including, but not limited to, electrical connections and wireless connections":

The invention as illustrated in Fig. 1 can be implemented in any suitable form including hardware, software, firmware or any combination of these. The invention or some features of the invention can be implemented as computer software running on one or more data processors and/or digital signal processors. The elements and components of an embodiment of the invention may be physically, functionally and logically implemented in any suitable way. Indeed, the functionality may be implemented in a single unit, in a plurality of units or as part of other functional units. As such, the invention may be implemented in a single unit, or may be physically and functionally distributed between different units and processors. The middleware section MW interconnecting the elements of the DSS *can include any kind of connection including, but not limited to, electrical connections and wireless connections.*

Spec. 8:13–23 (emphases added). As the Examiner finds, the Specification does not sufficiently disclose the algorithmic or hardware structure to achieve the claimed function of interconnecting by the middleware section, because the interconnecting function embraces every conceivable type of interconnection scheme, including some that may or may not control the data flow, and may or may not embed various interconnected components.

Appellant does not present argument with respect to the inference engine. *See* Appeal Br. 9–10. In any event, similar remarks apply to "wherein the inference engine (IE) is configured to classify asserted facts in the knowledge base (KB) to determine a correct position of a class of classes in a hierarchy using logical definitions of the classes," as claim 1 recites. Nothing in the Specification reveals how the inference engine classifies facts, what facts it classifies, how it uses "a hierarchy using logical definitions of the classes," and what "logical definitions" or "classes" it uses. As noted above, "[t]he guideline execution engine CL-EE and inference engine IE are generic components of a decision support system and have no

specific requirements for a molecular diagnosis application." Spec. 9:19–21.
They may include "available off the shelf components." *Id.* at 9:28–29.

Nevertheless, the Specification indicates this classification scheme does not involve basic functions of a microprocessor, and it does not clarify whether or not the off the shelf components require further special programming, or whether they connote a class of structure. In other words, as the Examiner finds, the Specification does not specify an algorithm or a sufficiently clear algorithm clearly linked to the functions of the inference engine. "A microprocessor or general purpose computer lends sufficient structure only to basic functions of a microprocessor. All other computer implemented functions require disclosure of an algorithm." *EON Corp. IP Holdings LLC v. AT&T Mobility LLC*, 785 F.3d 616 (Fed. Cir. 2015). ("As we stated in *Katz*, a microprocessor can serve as a structure for a computer-implemented function only where the claimed function is 'coextensive' with a microprocessor itself. . . . Examples of such coextensive functions are 'receiving' data, 'storing' data, and 'processing' data.") (citing *In re Katz,* 639 F.3d 1303, 1316 (Fed. Cir. 2015)); *Noah Sys., Inc., v. Intuit Inc.*, 675 F.3d 1302, 1316–17 & n.9 (Fed. Cir. 2012) (indicating "off-the-shelf accounting software" cannot fill the gaps for algorithmic structure required in processor claims).[5] As the Examiner finds, the Specification does not

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[5] *EON* and *Noah* do not foreclose or address squarely the situation in which a patent discloses and identifies corresponding structure as known, or "off the shelf," hardware and/or software clearly linked to a claimed function at issue. In *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1381 (Fed. Cir. 1999), the patentee claimed an apparatus that included a "high voltage generating means" limitation, thereby invoking 35 U.S.C. § 112 ¶ 6. The specification incorporated by reference a non-patent document from a technical journal, which described a particular high voltage

sufficiently disclose the algorithmic structure to achieve the claimed function of classifying asserted facts by the inference engine.

Based on the foregoing discussion, Appellant does not show error in the Examiner's rejection of claims 1–12 for indefiniteness under 35 U.S.C. § 112, second paragraph.

C. Written Description

The Examiner rejects claims 1–13 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. Final Act. 7–8. According to the Examiner, "the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor . . . had possession of the" "process" and "processing" features of the decision support mechanisms as respectfully recited in claims 1 and 13. *See* Final Act. 7–8.

The Examiner quotes the Specification, *inter alia*, as stating "[a] formal definition of what constitutes a decision support mechanism (DSM) can be very difficult to formulate." Final Act. 8 (quoting Spec. 9:1–2). The Examiner quotes portions of the Specification that describe several examples of such mechanisms, including

> a Bayesian network, an artificial neural network, a support vector
> machines mechanism, a K nearest neighbor mechanism, a

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generating circuit. The Federal Circuit concluded that the title of the article in the specification may, by itself, be sufficient to indicate to one skilled in the art the precise structure of the means for performing the recited function, and it remanded the case to the district court "to consider the knowledge of one skilled in the art that indicated, based on unrefuted testimony, that the specification disclosed sufficient structure corresponding to the high-voltage means limitation." *Id.* at 1382.

genetic algorithm mechanism, a decision tree mechanism, a rule
based system, a case based reasoning mechanism, and a fuzzy
logic based mechanism. Thus, the first (IDSM) and/or the
second (2DSM) decision support mechanism may be chosen
from such a group of decision support mechanisms.

Id. (quoting Spec. 3:25–32).

The Examiner also points to a portion of the Specification that refers
to "open boxes" for the two support mechanisms, describing the two as
"interact[ing] tightly from within the mechanism."

The Examiner quotes the following related coupling teachings and
generic algorithms/logic involved with the two support mechanisms:

One example is to use inferences from the Knowledge
Base KB to drive the crossover and mutations in a Genetic
Algorithm (GA). This tight coupling will introduce biological
knowledge to guide the purely statistical process in the Genetic
Algorithm GA. Thus, the genes in the GA are not treated as
anonymous independent entities, but rather as ones with
significance and interrelationships. Another example is to use a
Bayesian - or a Fuzzy logic based network to resolve a criterion
in a decision step in a clinical guideline CL. This requires the
Bayesian/Fuzzy network to access the patient state in the
guideline.

Final Act. 9 (quoting Spec. 9:1–13).

Appellant groups claims 1 and 13 together, and does not present
separate arguments for the dependent claims. *See* Appeal Br. 19–21.
Accordingly, claim 1 represents the claims rejected for written description.
Appellant contends "the claims do not recite an algorithm for
processing input data. Thus, [the S]pecification needs not provide a written
description of an algorithm for processing input data." Appeal Br. 20.

Appellant's argument does not squarely address the Examiner's point.
The Specification describes a wide variety of decision making processes in

functional and generic terms, but does not describe what the "process" and "processing" features of the decision support mechanisms entail, including the extent of the claimed "operably coupled" and "interacting" features involved in the "processing," in light of the "tight coupling" disclosed.

The Examiner recognizes that a lack of disclosure of algorithmic structure that otherwise would serve to provide written descriptive support and circumscribe the "process" and "processing" of claims 1 and 13, shows that the inventors did not have possession of the invention. In particular claim 1, similar to claim 13, specifies that the first and second support mechanisms "process" the input data "using" three databases and "are operably coupled so as to interact during the processing of" the input data:

> wherein the first (1DSM) and the second (2DSM) decision support mechanisms *process* input data (MDx) into patient related information (PRI) *using the patient information database (EMJ), the clinical guideline database (CL) and the knowledge database (KB)*, and
> wherein the first (1DSM) and the second (2DSM) decision support mechanism *are operably coupled* through the middleware (MW) *so as to interact during the processing* of the input data (MDx).

Appeal Br. 28 (App'x (emphasis added to claim 1 limitations)).

The absence of clearly linked algorithmic structure leaves an artisan of ordinary skill wondering as to the amount and type of processing and interacting that occurs to create the PRI, including the type of data the process "use[es]" from the three databases, and the type of process the support mechanisms perform on the input data and any data within the three recited databases the support mechanisms "us[e]." The Specification also does not describe sufficiently the amount and type of "coupling" and "interact[ing]" between the two decision support mechanisms "during the

processing" of the input data to create the PRI, and it mentions highly generic algorithms without any specificity, for example using "a Bayesian - or a Fuzzy logic based network," and/or a "Genetic Algorithm (GA)." *See* Spec. 9:1–13.[6]

This lack of description of the process involved in creating the PRI shows the inventors lacked possession of the process of the decision support mechanisms as recited in claims 1 and 13 that create the PRI. Essentially, the inventors seek to claim every possible manner in functional and generic terms, including any type of decision process and interaction between the two support mechanisms, to process data creating the PRI, without describing structural features common to all the types of processes disclosed, as necessary to show possession of the whole breadth of the "process" or "processing." In other words, the Specification fails to disclose "a representative number of species falling within the scope of the genus or structural features *common to the members of the genus* so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en

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[6] The Specification introduces other levels of speculation in the decision support mechanisms, further indicating a lack of possession of the claimed process involved in the decision support mechanisms:

> *It has to be decided what recommendations the decision support system MD DSS needs to produce*, and work backwards to establish what data must be collected in order to support the production of these recommendations, and further backwards to identify where the relevant data come from and how they will be captured and normalized, see S. Coady, Influencing physician practice variation, in Health Management Technology, 2002.

Spec. 11:20–25 (emphasis added).

banc) (quoting *Regents of the Univ. of California v. Eli Lilly & Co.*, 119

F.3d 1559, 1568–69 (Fed. Cir. 1997) (emphasis added).

Ariad explains further,

> [a]s this court has repeatedly stated, the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Rochester*, 358 F.3d at 920 (quoting *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed.Cir.2000)). It is part of the *quid pro quo* of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time. *Enzo*, 323 F.3d at 970.

Id. at 1353–54 (citing *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 375

F.3d 1303 (Fed. Cir. 2004); *Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d

956, 970 (Fed. Cir. 2002)).

Appellant's arguments show a lack of a meaningful contribution

disclosed relative to claim scope in violation of the *quid pro quo* enunciated

by *Ariad*. For example, Appellant agrees that the breadth of the claims

encompasses all manner of structure, reciting, *inter alia*, the following

portion of the Specification in an effort to rebut the Examiner's written

description rejection:

> FIG. 1 can be implemented *in any suitable form including hardware, software, firmware or any combination of these*. The invention or some features of the invention can be implemented as computer software running on one or more data processors and/or digital signal processors. The elements and components of an embodiment of the invention *may be physically, functionally and 1ogically implemented in any suitable way*. Indeed, the functionality may be implemented in a single unit, in a plurality of units or as part of other functional units. As such, the invention may be implemented in a single unit, or may be

> physically and functionally distributed between different units
> and processors.

Appeal Br. 21 (quoting Spec. 8:13–21) (emphases added).

This quotation of the Specification by Appellant shows a lack of commonality as to structure, because it refers to "hardware, software, firmware or any combination of these" and describes the invention as capable of being "physically, functionally and logically implemented in any suitable way." *See* Spec. 8:13–21. Appellant provides quotations of similar bearing from the Specification describing operations illustrated with respect to Figures 2 and 3, some of which we discuss above. *See* Appeal Br. 22–23. These Specification portions show the inventors seek to capture all manner of processing data to create the PRI. None of the citations show the inventors had possession of the full scope of the claimed process of the decision support mechanisms in claims 1 and 13 that create the PRI. *See* Appeal Br. 21–23. The Specification does not describe the amount and type of interaction between, or the amount and type of process implemented by, the recited decision support mechanisms, to create the PRI, and accordingly, what the PRI entails. In short, the Specification attempts to embrace, in generic terms, any type of process existing at the time of the invention to create any type of PRI, failing to provide adequate disclosure to show the inventors had possession of the full scope of claims 1 and 13. Lacking "a meaningful disclosure," *Ariad Pharm., Inc.*, 598 F.3d at 1354, claims 1 and 13 "overreach the scope of the inventor's contribution to the field of art as described in the patent specification," *id.* at 1354 (quoting *Rochester*, 358 F.3d at 920).[7]

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[7] The written description problem stems from a lack of a disclosure of the

Accordingly, Appellant does not show that the Examiner erred in rejecting claims 1–13 under 35 U.S.C. § 112, first paragraph, for lack of a written description.

D. Non-Statutory Subject Matter

A patent-eligible invention must claim a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. However, the Supreme Court, in a long line of precedent, interprets 35 U.S.C. § 101 to include implicit exceptions to statutory subject matter: "[l]aws of nature, natural phenomena, and abstract ideas." *See, e.g., Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014).

In determining whether a claim falls within an excluded category, the Supreme Court's two-step framework, described in *Mayo* and *Alice*, frames the analysis. *Id.* at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). In accordance with that framework, a tribunal first determines what concept the claim is "directed to." *See Alice*, 573 U.S. at 219 ("On their face, the claims before us are drawn to the

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algorithmic structure corresponding to the decision support mechanisms' process functionality, as the Examiner recognizes and as indicated above. *See* Final Act. 7–8. "Sufficient structure must simply 'permit one of ordinary skill in the art to know and understand what structure corresponds to the means limitation' so that he may 'perceive the bounds of the invention.'" *See In re Aoyama*, 656 F.3d 1293, 1298 (Fed. Cir. 2011); *cf. EnOcean, GmbH v. Face Int'l Corp.*, 742 F.3d 955, 959 (Fed. Cir. 2014) (quoting *Aoyama,* 656 F.3d at 1298, in determining if a priority document provided written description support for the term "receiver," concluding "receiver" is not a means plus function limitation, so "[i]n requiring that the German and PCT applications 'expressly describe the structure of the receiver,' the Board applied an incorrect standard" (quoting the underlying Board decision)).

concept of intermediated settlement, *i.e.,* the use of a third party to mitigate settlement risk."); *see also Bilski v. Kappos*, 561 U.S. 593, 611 (2010) ("Claims 1 and 4 in petitioners' application explain the basic concept of hedging, or protecting against risk.").

Concepts determined to be abstract ideas, and thus patent ineligible, include certain systems for, or methods of, organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219–20; *Bilski*, 561 U.S. at 611); mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)); and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 69 (1972)).

If the claim is "directed to" an abstract idea, the second step of the *Alice* and *Mayo* framework requires "examin[ing] the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." *Alice*, 573 U.S. at 221 (quotation marks omitted). "A claim that recites an abstract idea must include 'additional features' to ensure 'that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].'" *Id.* (quoting *Mayo*, 566 U.S. at 77). "[M]erely requir[ing] generic computer implementation[] fail[s] to transform that abstract idea into a patent-eligible invention." *Id.*

The PTO recently published revised guidance on the application of § 101. USPTO's January 7, 2019 Memorandum, *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 ("*Guidance*"). Under Step 2A of the *Guidance*, PTO judges and examiners must determine if the claims recite any judicial exceptions, i.e., a law of nature, a natural phenomenon, or an abstract idea (mathematical concepts, certain methods of

organizing human activity such as a fundamental economic practice, or

mental processes) (Prong 1); and additional elements in the claim as a whole

that integrate the judicial exception into a practical application (*see* MPEP

§ 2106.05(a)–(c), (e)–(h)) (Prong 2). *Id.* at 52–54.

Furthermore, under Prong 1, the *Guidance* "extracts and synthesizes

key concepts identified by the courts as abstract ideas to explain that the

abstract idea exception includes the following groupings of subject matter,

when recited as such in a claim limitation(s) (that is, when recited on their

own or per se)":

> (a) Mathematical concepts—mathematical relationships,
> mathematical formulas or equations, mathematical calculations;
> (b) Certain methods of organizing human activity—
> fundamental economic principles or practices (including
> hedging, insurance, mitigating risk); commercial or legal
> interactions (including agreements in the form of contracts; legal
> obligations; advertising, marketing or sales activities or
> behaviors; business relations); managing personal behavior or
> relationships or interactions between people (including social
> activities, teaching, and following rules or instructions); and
> (c) Mental processes—concepts performed in the human
> mind (including an observation, evaluation, judgment, opinion).

Id. at 52 (footnotes omitted).

Under Step 2B, only if the claim recites a judicial exception and does

not recite additional elements that integrate the judicial exception into a

practical idea, then PTO examiners and judges investigate whether the

claim

> [a]dds a specific limitation or combination of limitations
> that are not well-understood, routine, conventional activity in the
> field, which is indicative that an inventive concept may be
> present; or
> simply appends well-understood routine, conventional
> activities previously known to the industry, specified at a high

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level of generality, to the judicial exception, which is indicative
that an inventive concept may not be present.

Id. at 56 (bullet points omitted).

Guidance, Step 2A, Prong 1

The Examiner refers to the "interconnecting," "classify," and
"process" steps in claim 1 as gathering and processing different types of
data, namely, the following steps of claim 1: "a middleware (MW) section
interconnecting the patient information database (EMJ), the data input
section (DAT), the clinical guideline database (CL), the knowledge database
(KB), the first decision support mechanism (1DSM), and the second
decision support mechanism (2DSM)," "wherein the inference engine (IE)
is configured *to classify asserted facts in the knowledge base (KB) to
determine a correct position of a class of classes in a hierarchy using logical
definitions of the classes*," and "wherein the first (1DSM) and the second
(2DSM) decision support mechanisms *process* input data (MDx) into patient
related information (PRI) using the patient information database (EMJ), the
clinical guideline database (CL) and the knowledge database (KB)." *See*
Final Act. 5–6 (emphasis added).

According to the Examiner,

[t]hese steps describe the concept of receiving data, processing
data, and outputting the results, which corresponds to concepts
identified as abstract ideas by the courts, such as collecting,
displaying, and manipulating data in *Int. Ventures v. Cap One
Financial*, and collecting information, analyzing it, and
displaying certain results of the collection and analysis in *Elect*[.]
Power. . . . All of these concepts relate to abstract ideas in and
of themselves. The concept described in claim 1 is not
meaningfully different than those concepts found by the courts
to be abstract ideas. As such, the description in claims 1 and 13

of assisting clinician, a technician or a patient during the various
phases of molecular diagnostics is an abstract idea.

Id. at 5–6 (citing *Elec. Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350
(Fed. Cir. 2016) ("*Electric Power*"); *Intellectual Ventures I LLC v. Capital
One Financial Corp.*, 850 F.3d 1332 (Fed. Cir. 2017) ("*Capital One*")).

By applying the above-noted claim recitations as analogous to the
claims involved in *Electric Power* and *Capital One*, and characterizing the
claims as a whole as involving "various phases of molecular diagnosis," the
Examiner shows the claims recite system limitations that include certain
methods for organizing human activity, namely following rules or
instructions for the collection and creation of the PRI data for teaching, and
the mental processes of assisting in the "molecular diagnostics," both of
which constitute abstract ideas per the *Guidance*. *See Guidance*, 84 Fed.
Reg. at 52.

Specifically, although the "*interconnecting*" of different types of data
amounts to a physical connection of hardware or software components,
underlying that connection includes the mental evaluation by a human to
determine the types of data to "interconnect" in order to provide "patient
related information" ("PRI"), according to claim 1. Similarly, the step to
"classify" "facts" and "to *determine* a correct position of a class of classes in
a hierarchy using logical definitions of the classes," as recited in claim 1,
involves using a "logical" human evaluation mental process "to determine a
correct position" in a classification hierarchy and involves following rules or
instructions, namely "a hierarchy using logical definitions." Similarly, the
step "to *process* input data (MDx) into *patient related information* (PRI)
using" different types of data, including data in "the patient information
database (EMJ), the clinical guideline database (CL) and the knowledge

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database (KB)," recites a human mental evaluation and judgment process a clinician performs on relevant medical data.

In addition, by reciting "for providing patient related information (PRI)" in the preamble of claim 1, the system includes organizing human activity, following certain rules or instructions of the claimed system to process the data discussed above into PRI, and then "providing" the PRI to teach the patient how to manage her behavior following instructions implicit in the PRI. In other words, in addition to reciting mental processes, the claims recite another abstract idea under the *Guidelines*, namely certain methods of organizing human activity. Although claim 1 does not recite or require explicitly an output, a prognosis, or a diagnosis, in addition to reciting a step of organizing human activity, "providing" "PRI" also amounts to a mental process of announcing or presenting the PRI to teach a clinician about the data.[8] *See* Spec. 8:7–8 ("A user interface, e.g. a screen or a similar device, for presenting the patient related information PRI should be used."). Nevertheless, the above-noted claim limitations as a group recite a system of organizing human activity, managing behavior by following rules or instructions to process the data to create the PRI, and then presenting the teachings in the PRI to a patient, so that the patient can alter her regimen or behavior in order to overcome her illness according to teachings in the PRI.

Appellant groups independent claim 1 together with independent claim 13, and does not argue any of the dependent claims separately. *See* Appeal Br. 10–19. Accordingly, claim 1 represents the claims on appeal

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[8] *See FairWarning IP, LLC v. Iatric Systems, Inc.*, 839 F.3d 1089 (Fed. Cir. 2016) ("[announcement] does nothing significant to differentiate a process from ordinary mental processes") (full quotation provided below).

under this § 101 rejection. Appellant initially contends the Examiner merely

sets forth "a conclusion regarding the alleged non-statutory subject matter of

claims 1 and 13." *Id.* at 11. Contrary to this argument, however, as

discussed above, the Examiner analogizes claims held by *Electric Power* and

Capital One to recite non-statutory subject matter to claim 1 at issue here by

referring to specific steps recited therein. Moreover, Appellant recognizes

the Examiner's analogy to *Electric Power* as alleging a "human mental

process," *id.* at 14, but "disagree[s]" with that analogy, as follows:

> Appellant[] disagree[s] with the Final Office Action's
> assertion that claims 1–13 are analogous to *Electric Power
> Group, LLC v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016). In
> that case, the Federal Circuit finds that the subject patents
> describe and claim systems and methods for real-time
> performance monitoring of an electric power grid by collecting
> data from multiple data sources, analyzing the data, and
> displaying the results, or stated differently, collecting, analyzing
> and displaying available information in a particular field.

Id. at 13.

According to Appellant, "the claims of the present Application do not

merely collect and analyze data, and display the results. Nor is the

information available in the field, but rather provides a molecular

diagnostics decision support system (MD-DSS) for providing patient related

information as information is acquired." *Id.*

Rather, according to Appellant,

> unlike the data of the present claims, the data in *Electric Power*
> . . . were stored data that could be *collected and analyzed by
> human mental process*. Plainly, the generation, by the IE by the
> classification of asserted facts in the knowledge base KB to find
> the correct position of a class in a hierarchy using the logical
> definition of the classes certainly *cannot be effected mentally*.

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Id. at 14 (emphases added). Appellant also contends the claims are not directed to "conventional handling of conventional information." *Id.* Appellant explains "conventional handling of preexisting data has been held problematic, whereas introduction of 'new' data not known until the claim processing is embraced as not being abstract." *Id.*

Appellant's arguments do not show error in the Examiner's determination that claim 1 recites an abstract idea. Appellant merely provides a conclusion without explaining why the data recited in claim 1 normally processed and used by a clinician could not be processed mentally by a clinician.

Specifically, Appellant fails to explain the basis for its assertion that "the classification of asserted facts in the knowledge base KB to find the correct position of a class in a hierarchy using the logical definition of the classes certainly *cannot be effected mentally*." *See* Appeal Br. 14 (emphasis added). Humans have been classifying data in a hierarchy through observation, evaluation, and judgment for a long time. Appellant admits that "a **limited number of trained technicians** . . . are capable of performing complex assays." *Id.* at 16.[9] As noted above, in general, the Specification,

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[9] We recognize "the gene expression, as input data (MDx), from the molecular diagnostic measurement device," as recited in claim 1, involves machine created data, but Appellant appears to acknowledge trained technicians can analyze even that data. *See also* Spec. 1:11–12 ("Decision support systems for aiding with molecular diagnostics (MD) are currently applied for analyzing the values found in a molecular diagnostic assay. . . . Such decision support systems are quite helpful for the clinician's interpretation of values found in the molecular diagnostics when considering the amount and/or complexity of such MD data.").

tracking claim 1, reveals that "the *invention provides information* PRI that can assist a physician, a clinician, and/or a technician in reaching a diagnosis." Spec. 8:10–12 (emphasis added). Humans have provided general information to create specific information, to assist in mentally understanding the information, or to make decisions, including medical decisions, for a long time.

As Appellant recognizes, recent precedent, including *Electric Power* cited by the Examiner, shows that under certain circumstances, processing and manipulating data may be abstract as a mental process, notwithstanding that a computer also processes the data. As an example, *FairWarning IP, LLC v. Iatric Systems, Inc.*, 839 F.3d 1089 (Fed. Cir. 2016), citing *Electric Power*, characterizes certain data gathering recitations as involving an abstract mental process:

> As we have explained, "merely selecting information, by content or source, for collection, analysis, and [announcement] does nothing significant to differentiate a process from ordinary *mental processes*, whose implicit exclusion from § 101 undergirds the information-based category of abstract ideas."

FairWarning, 839 F.3d at 1097 (quoting *Elec. Power*, 830 F.3d at 1355) (emphasis added) (information added by *FairWarning*).

As another example, according to *Data Engine Technologies LLC v. Google LLC*, 906 F.3d 999, 1010 (Fed. Cir. 2018), "[t]he invention [involved in *Capital One*] allowed users to make changes to data in a 'dynamic document,' which could then be dynamically propagated back into an original XML document." *Id.* (quoting *Capital One*, 850 F.3d at 1339). The *Data Engine* court characterized the *Capital One* holding as follows: "We held those claims were 'directed to the abstract idea of collecting, displaying, and manipulating data.'" *Id.* (quoting *Capital One*, 850 F.3d at

1339). Appellant recognizes, without providing a meaningful distinction
over the recitations relied upon in claim 1 here, that *Electric Power* involves
claims directed to "real-time performance monitoring" of data—claims the
court in that case held recited a mental process, and hence an abstract idea.
See Appeal Br. 13–14.

Essentially, the invention seeks to automate a mental process of
classifying certain facts, and processing and combining different types of
informational data to create other information, namely, PRI, without
requiring a diagnosis. The record shows that claim 1 recites limitations
directed to, and claim 1 focuses on, a mental process to create and present
PRI, and also, organizing human activity including managing personal
behavior by following rules to obtain PRI and teaching a patient or a
clinician via PRI.

As noted above, Appellant groups claims 1–13 together. Based on the
foregoing discussion, the Examiner shows that claims 1–13, individually and
as a whole, recite the abstract ideas of mental processes and a system of
organizing human activity.

Guidance, Step 2A, Prong 2

In determining whether the claims are "directed to" the identified
abstract idea, we consider here whether the claims recite "additional
elements" that integrate the judicial exception into a practical application.
See Guidance, 84 Fed. Reg. at 54–55.[10] The Examiner finds that the

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[10] Some of the considerations at Step 2A, second prong, properly may be
evaluated under Step 2 of *Alice* (Step 2B of the Office guidance). *See*
Memorandum, 84 Fed. Reg. at 55 n.25, 27–32.

"generic components" recited in the claims, "considered both individually and as an ordered combination," fail to integrate the judicial exception into a practical application. *See* Final Act. 7.

Appellant argues "various elements in the claims are sufficient to ensure that the claims amount to significantly more than the abstract idea itself, particularly in that the claim as a whole is for a particular application of the asserted abstract idea." Appeal Br. 15. Appellant relies on recited software components that claim 1 does not require or that merely implement mental processes or limitations involved in organizing human activity, by using generic computer components, as follows:

> For example, claim 1 introduces the concept of a guideline execution engine CL-EE. The *guideline execution engine* CL-EE is a software component that can step through the executable guideline and suggest one or more steps in the guideline based on patient status. The GUF3 Guideline Execution Engine (GLEE) is an example of such engine. Claim 1 also introduces the concept of an *inference engine* (IE) that is configured to classify asserted facts in the knowledge base (KB) to determine a correct position of a class of classes in a hierarchy using logical definitions of the classes. The inference engine IE will classify the asserted facts in the knowledge base KB to find the correct position of a class in a hierarchy using the logical definition of the classes. This will enable an application section to learn about the inferred relationships among the facts. *With respect to guidelines CL, it can be said that some guidelines aim to overcome the problem of having a limited number of trained technicians who are capable of performing complex assays.* Other guidelines aim to identify the necessary education and counseling that must be made available to patients. For example the Huntington's disease Society of America provides a series of guides aimed at educating and counseling patients and their families. (See pp. 9–10 of the filed application.) As such, by the present teachings *the system overcomes at least a shortage in train technicians*.

Appeal Br. 15–16 (emphases omitted and added).

First, no claim recites a guideline execution engine. Second, as argued above, Appellant fails even to assert that the inference engine software does anything more than what a human performs mentally. Third, even if the claims require both the guideline and inference engines, Appellant admits that "a limited number of trained technicians . . . are capable of performing complex assays." *See id.* at 16. Appellant also admits "by the present teachings[,] the system overcomes at least a shortage in train technicians," *id.*, thereby showing the system merely automates mental processes or organizes human activity using a computer as a tool. Nothing in the Specification cited by Appellant and required by the claims rebuts the Examiner's showing that the invention as recited in claim 1 recites anything more than generic components and functionality, employing a process a human can perform, and a system of organizing human activity, managing behavior by following rules or instructions, and teaching, by presenting PRI that a clinician can relay to a patient.[11]

As noted in the *Guidance*, courts have found that "[a]n additional element [that] merely recites the words 'apply it'' (or an equivalent) with the judicial exception, or merely includes instructions to implement an abstract idea on a computer, or merely uses a computer as a tool to perform an abstract idea," may not integrate the judicial exception into a practical application. *Guidance*, 84 Fed. Reg. at 55. Here, the Examiner shows that claim 1 involves applying generic computer components and functionality as tool to create information, namely PRI.

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[11] Under the *Guidance*, 84 Fed. Reg. at 55, even "conventional elements may still integrate an exception into a practical application."

Specifically, claim 1 requires the "decision support mechanisms" to "process input data" into "PRI" using several databases each containing different types of data. Claim 1 does not specify anything more than "using" the databases in a generic configuration. The "inference engine" "is configured to classify asserted facts in the knowledge base," but the "decision support mechanism" merely "us[es]" the "knowledge base" and other databases, and does not necessarily even use the "asserted facts" that the "inference engine . . . is configured to classify." Claim 1 also requires the decision support mechanism to be "operably coupled . . . so as to interact" during the "processing" of the input data into PRI. Appellant does not rely on the "operably coupled . . . so as to interact" during processing feature. Nevertheless, computer system components generally and typically interact during processing, and claim 1 specifies no special interaction or processing.

The Specification states "the present invention does not provide a diagnosis as part of the patient related information PRI." Spec. 8:10–11. It also states "the present invention is intended for application on a single patient at a time." *Id.* at 6:31. As the Examiner recognizes, claim 1 operates at a high degree of generality simply to gather and process data. *See* Final Act. 6 ("The molecular diagnostic support system, the patient database, and the middleware section are recited at a high level of generality and are recited as performing generic computer functions routinely used in computer applications."). Appellant does not provide persuasive argument rebutting this finding.

In other words, the claims combine a mental process and organizing human activity to create PRI information that a doctor or counselor would

have used manually to assist a patient, by implementing the execution of mental steps or rules performed by generic computer software or hardware components. *See Credit Acceptance Corp. v. Westlake Svcs.*, 859 F.3d 1044, 1055 (Fed. Cir. 2017) ("Our prior cases have made clear that mere automation of manual processes using generic computers does not constitute a patentable improvement in computer technology."). Moreover, "relying on a computer to perform routine tasks more quickly or more accurately is insufficient to render a claim patent eligible." *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363 (Fed. Cir. 2015) (citing *Alice*, 573 U.S. at 224 ("use of a computer to create electronic records, track multiple transactions, and issue simultaneous instructions" is not an inventive concept)); *Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Can. (U.S.)*, 687 F.3d 1266, 1278 (Fed. Cir. 2012) (a computer "employed only for its most basic function . . . does not impose meaningful limits on the scope of those claims").

The Specification supports the Examiner's contention that the claimed invention involves generic components combined in a highly generic manner. As one example, the Specification states "[t]he elements and components of an embodiment of the invention *may be physically, functionally and logically implemented in any suitable way*. Indeed, the functionality may be implemented in a single unit, in a plurality of units or as part of other functional units." Spec. 8:16–19 (emphasis added). As another example, the Specification states "[t]he guideline execution engine CL-EE and inference engine IE are *generic components* of a decision support system *and have no specific requirements for a molecular diagnosis application*." *Id.* at 9:19–21 (emphasis added). Also, according to the

Specification, the two decision support mechanisms recited in the claims "are treated as 'black boxes'" and "do not interfere with the internal working of the other mechanism[s]." *Id.* at 8:30–33. Nothing in the Specification indicates that any other components, including the several types of databases recited in the claims and the "molecular diagnostics measurement device," do anything more than their generic functions.

The Specification also describes the knowledge data base in generic terms: "The knowledge database KB 108 *comprises what is necessarily or prototypically true about a domain.*" *Id.* at 7:8–9 (emphasis added). Furthermore, the Specification states it uses "available off the shelf components" for the "inference engine," including "as an *example*," "Racer," to "*classify the asserted facts in the knowledge base KB to find the correct position of a class in a hierarchy using the logical definition of the classes.*" *Id.* at 9:25–29 (emphases added). Employing "off the shelf" generic components for the generic processes described here, namely classifying asserted facts using logic, indicates the classification involves steps humans performed long ago by following certain rules to arrive at medical information to aid in a diagnosis, namely PRI as recited by claim 1.

As the Examiner recognizes, the mere mention of certain generic computer components in claim 1 (e.g., "molecular diagnostic measurement device," "patient information database (EMJ)," "data input section (DAT)," "clinical guideline database (CL)," "knowledge database (KB)," "first decision support mechanism (1 DSM)," "second decision support mechanism (2DSM)," "inference engine (IE)," "middleware (MW) section interconnecting the patient information database (EMJ), the data input section (DAT), the clinical guideline database (CL), the knowledge database

(KB), the first decision support mechanism (1DSM), and the second decision support mechanism (2DSM)") does not impose sufficiently meaningful limitations on claim scope beyond these mental steps and human activity. *See* Final Act. 6–7; *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375 (Fed. Cir. 2011) ("[W]e have never suggested that simply reciting the use of a computer to execute an algorithm that can be performed entirely in the human mind" renders a claim patent eligible).

As noted above, Appellant groups claims 1–13 together. Based on the foregoing discussion, Appellant does not show error in the Examiner's determination that claims 1–13 recite nonstatutory subject matter.

Guidance, Step 2B and *Alice/Mayo* Step 2

Step 2B of the *Guidance* tracks Step 2 of the *Alice/Mayo* framework, and requires determining whether the claims (a) add a specific limitation or combination of limitations that are not well-understood, routine, conventional activity in the field, or (b) simply append well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception. *See Guidance*, 84 Fed. Reg. at 56. The Examiner finds that the claims do not include additional elements that amount to significantly more than the abstract idea. Final Act. 6. Rather, the Examiner finds the additional elements beyond the abstract idea are merely "[g]eneric computer components" that perform "generic computer functions that are well-understood, routine and conventional activities." *Id.* In addition, as described in the previous section, claim 1 embraces generic components and functionality, and here, these generic components and functionality include within their scope well-understood, routine, and conventional components and activities.

Based on the software components listed by Appellant as quoted above with respect to prong 2, Step 2A, Appellant contends "the present teachings the system overcomes at least a shortage in trained technicians." Appeal Br. 16. Nothing in Appellant's arguments or the Specification reveal how the claimed system overcomes the shortage, other than using a computer as a tool to implement the basic abstract idea. Appellant cites Federal Circuit precedent involving claims reciting an inventive concept, but Appellant fails to rebut the Examiner's showing that the claims here do anything more than append well-understood, routine, conventional activities previously known to the industry, at a high level of generality, to the judicial exception. *See* Appeal Br. 15–16 (citing, *e.g., BASCOM Global Internet Svcs. Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016)).

As discussed above, the claims are directed to gathering and manipulating information to create other information, namely PRI data. Viewed individually and as a whole, nothing in claim 1 adds significantly more (i.e., an inventive concept) to the abstract idea. As set forth above, the additional elements in claim 1 amount to no more than mere instructions to apply the judicial exception using generic computer components and functionality, an insufficient application to provide an inventive concept. Appellants do not direct attention to anything in the Specification that indicates the claimed computer components and functionality involves anything more than receiving and outputting data, as the Examiner determines. *See Elec. Power*, 830 F.3d at 1355 ("Nothing in the claims, understood in light of the specification, requires anything other than off-the-shelf, conventional computer, network, and display technology for gathering, sending, and presenting the desired information."); *buySAFE, Inc.*

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v. Google, Inc., 765 F.3d 1350, 1355 (Fed. Cir. 2015) ("That a computer receives and sends information over a network—with no further specification—is not even arguably inventive."); *Alice*, 573 U.S. at 224–26 (receiving, storing, sending information over networks insufficient to add an inventive concept).

BASCOM involved claims generally directed to filtering content. 827 F.3d at 1348. Although the Federal Circuit determined the claims recited generic computer, network, and Internet components, deemed not inventive individually, the Federal Circuit found the ordered combination of the components and other limitations provided the requisite inventive concept. *Id.* at 1349–1350 ("[A]n inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces"). There, the patent claimed and explained how a particular arrangement of elements creates "a technical improvement over prior art ways of filtering such content." *Id.* at 1350 ("According to BASCOM, the inventive concept harnesses this technical feature of network technology in a filtering system by associating individual accounts with their own filtering scheme and elements while locating the filtering system on an ISP server.").

Unlike in *BASCOM*, Appellant does not explain adequately how the Examiner erred in determining that the claims perform nothing more than routine, conventional functions of generic software or hardware computer components to gather and create information that manually could have been gathered and created, namely PRI. In contrast to *BASCOM*, claim 1 does not require any non-conventional computer components, or a "non-conventional and non-generic arrangement of known, conventional pieces," *cf. id.* at 1350, but merely calls for performance of the claimed information of receiving,

processing, and producing PRI "on a set of generic computer components." *See id.*

As noted above, Appellant groups claims 1–13 together. Based on the foregoing discussion, Appellant does not show error in the Examiner's determination that claims 1–13 recite nonstatutory subject matter in violation of 35 U.S.C. § 101.

E. Claim 13, Anticipation

The Examiner rejects claim 13 as anticipated by Avinash. In the rejection, the Examiner reads all the claim elements onto Avinash's medical diagnostic system. *See* Final Act. 17–19. Regarding the step of classifying by the inference engine, the Examiner finds Avinash discloses it as follows:

> classifying by the interference engine (IE) asserted facts in the knowledge base (KB) (paragraph 288, use experts to categorize the data) to determine a correct position of a class of classes in a hierarchy using logical definitions of classes (paragraph 288, example provided -This is the intended result of the classification as such the Examiner does not make a relative rejection regarding how the "hierarchy" is determined. This could also simply being sorting data as the specification provides zero guidance),

Final Act. 18–19.

The Examiner also finds paragraphs 285–288 of Avinash disclose an inference engine as part of an integrated knowledge base. *Id.* at 18.

In response, Appellant directs attention and argument to the classifying step employing the inference engine (IE) as recited in claim 13. Appeal Br. 24–25. In particular, Appellant argues Avinash "fails to disclose an IE, or the classifying thereby of asserted facts in the knowledge base to determine a correct position of a class of classes in a hierarchy." *Id.* at 25. Appellant does not explain why Avinash does not disclose providing the IE or the classifying step. Appellant does not point to any particular error in the

Examiner's findings, as quoted above. Appellant's argument, therefore, amounts to a mere denial without explanation, thereby waiving any argument directed to claim 13.

Even if Appellant does not waive the argument, the Examiner shows persuasively that claim 13 reads on Avinash, including the recited IE and classifying step. The disputed steps follows: "providing an inference engine (IE) . . . and classifying by the inference engine (IE) asserted facts in the knowledge base (KB) to determine a correct position of a class of classes in a hierarchy using logical definitions of the classes." *See* Appeal Br. 24–25 (quoting the disputed step, comma omitted).

At the paragraph cited by the Examiner, Avinash discloses an "automated" "classification process" employing, *inter alia*, the following initial steps: "collect representative data for a particular clinical event, set up a domain-expert panel to review the data, use experts to categorize the data into different valid groupings, and corroborate the expert findings with some reference standard technique. Avinash ¶ 288; Final Act. 17–19. In addition, the paragraphs cited by the Examiner describe an "INTEGRATED KNOWLEDGE BASE," created by filtering and processing data (i.e., an inference engine), using various algorithmic programs, integrating of all types of health and other data, including expert opinion data, using rules and predictive models. *See* Avinash ¶¶ 285–288. Appellant does not explain why placing and categorizing data from Avinash's integrated knowledge base into different valid groupings using an automated algorithmic process fails to satisfy "classifying asserted facts in the knowledge base . . . to determine a correct position of a class of classes in a hierarchy using logical

definitions of the classes" with an inference engine. We adopt and incorporate the Examiner's findings as persuasive. *See* Final Act. 17–19.

Moreover, claim 13 does not specify how the claimed "computer readable medium," "configured to enable a method" that includes "providing an inference engine," *provides* the inference engine, implying at most, that the inference engine constitutes part of an intended use for the claimed "computer readable medium." Claim 13 also does not specify how the inference engine interacts with the remaining claim steps. The "processing" step implemented by the "decision support mechanism" includes "using . . . the knowledge database (KB)," and the inference engine classifies "asserted facts in the knowledge base," but claim 13 does not require using the "asserted facts" of the KB in the processing step or otherwise. *See* Spec. 9:17–18 ("[T]he knowledge database KB 406 is operably connected to communicate with an interference engine IE 408."). Given the breadth of claim 13 and the lack of interconnection with other components and steps recited in clam 13, the Examiner shows persuasively that claim 13's inference engine and classifying step read on the processing functionality and structure involved in Avinash's integrated knowledge database. *See* Final Act. 17–19.

Based on the foregoing discussion, Appellant does not show error in the Examiner's anticipation rejection of claim 13.

F. Claims 1–12, Obviousness

The Examiner rejects claims 1–12 for obviousness over Avinash and Lu. *See* Final Act. 10–17. The obviousness rejection involves the same material issue as the anticipation rejection, because Appellant advances the same argument regarding the inference engine and classifying step.

Appellant does not present arguments for any other claim element, and relies on its arguments for claim 1. Appeal Br. 23–24. Therefore, claim 1 represents the claims on appeal for this obviousness rejection.

For the same reasons explained above in connection with the anticipation rejection of claim 13, Appellant waives the argument with respect to claim 1. In short, Appellant presents a mere denial and fails to present a clear argument as to how the Examiner erred in the obviousness determination. *See* Appeal Br. 23–24. Also, for similar reasons set forth above in the anticipation discussion, even if Appellant does not waive the argument, Appellant does not show error in the Examiner's determination of obviousness, because Avinash discloses the inference engine and its function of classifying asserted facts, as the Examiner determines and as explained above. *See id.*; Final Act. 10; *supra* Section V.E.

Unlike claim 13, claim 1 does not involve an intended use of an inference engine, as it positively recites an inference engine and knowledge base, as follows:

> wherein the inference engine (IE) is configured to classify asserted facts in the knowledge base (KB) to determine a correct position of a class of classes in a hierarchy using logical definitions of the classes,
> wherein the first (1DSM) and the second (2DSM) decision support mechanisms process input data (MDx) into patient related information (PRI) using the patient information database (EMJ), the clinical guideline database (CL) and the knowledge database (KB).

Similar to claim 13, however, claim 1 does not specify how the inference engine interacts with the remaining claim components. The "process" function of the decision support mechanisms include "using . . . the knowledge database (KB)," and the inference engine classifies "asserted

facts in the knowledge base," but nothing in claim 1 requires using the "asserted facts" during the "process" function of the support mechanisms, or otherwise. Accordingly, the Examiner shows that Avinash discloses the claimed inference engine and classifying function as part of the processing involved in Avinash's knowledge database, as discussed above in connection with claim 13. *See* Final Act. 10 (citing Avinash ¶¶ 285–288). We adopt and incorporate the Examiner's findings and determination of obviousness as persuasive. *See id.* at 10–17.

Based on the foregoing discussion, Appellant does not show error in the Examiner's obviousness rejection of claims 1–12.

VI. CONCLUSION

We affirm the Examiner's Decision finally rejecting the claims, as follows: The rejection of claims 1–13 under 35 U.S.C. § 101 as directed to non-statutory subject matter; the rejection of claims 1–13 under 35 U.S.C. § 112, ¶ 1 for lack of written description; the rejection of claims 1–12 under 35 U.S.C. § 112, ¶ 2 for indefiniteness; the rejection of claim 13 under 35 U.S.C. § 102 for anticipation; and, the rejection of claims 1–12 under 35 U.S.C. § 103 for obviousness over Avinash and Lu.

VII. DECISION SUMMARY

Claims Rejected	35 U.S.C. §	Basis/References	Affirmed	Reversed
1–12	112 2nd	Indefiniteness	1–12	
1–13	112 1st	Written Description	1–13	
1–13	101	Nonstatutory Subject Matter	1–13	
13	102	Anticipation, Avinash	13	
1–12	103	Obviousness, Avinash, Lu	1–12	

Claims Rejected	35 U.S.C. §	Basis/References	Affirmed	Reversed
Overall Outcome			1–13	

VIII. TIME PERIOD FOR RESPONSE

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

AFFIRMED