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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KIRSI ILONA NURMILAUKAS, MIKA PETRI YLIHAUTALA,
REKO TAPIO VUORINEN, JULIA KRISTINA ENHOLM,
and JAAKKO JUHANI TÖLÖ¹

Appeal 2018-002003
Application 14/440,167
Technology Center 3700

Before FRANCISCO C. PRATS, ULRIKE W. JENKS, and
RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) involving claims to a medical apparatus, computer program product for controlling a medical apparatus, and a method of operating a medical apparatus. Claims 1–19 are on appeal as rejected under 35 U.S.C. § 101, § 112, first paragraph, and § 103. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

¹ Appellants identify the Real Party in Interest as “Koninklijke Philips, N.V.” Appeal Br. 3.

STATEMENT OF THE CASE

Claims 1, 14, and 15 are the independent claims. Claim 1 is representative and is reproduced below:

1. A medical apparatus comprising:
 - a high intensity focused ultrasound system for sonicating a subject,
 - a processor for controlling the medical apparatus,
 - a memory for storing machine executable instructions for execution by the processor, wherein:
 - execution of the instructions causes the processor to:
 - receive previous sonication data descriptive of a previous sonication of the subject by the high intensity focused ultrasound system;
 - construct a thermal property map of the subject using the previous sonication data and a thermoacoustic model, wherein the thermal property map is descriptive of a thermal property, wherein the thermal property map is spatially dependent and temporally dependent;
 - determine a maximum energy map using the thermoacoustic model and the thermal property map, wherein the maximum energy is time dependent;
 - display the maximum energy map on a display; and
 - receive a selection of at least one sonication volume from a user interface.

Response to Notice of Non-Compliant Appeal Brief 3 (submitted June 25, 2017) (Claims App'x).

The following rejections are appealed:

Claims 1–19 stand rejected under 35 U.S.C. § 101 as drawn to patent-ineligible subject matter. Final Action 2.

Claims 1–19 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. *Id.* at 5.

Claims 1–19 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. *Id.* at 6.

Claims 1–3, 6–16, and 18 stand rejected under 35 U.S.C. § 103(a) over Kohler.² *Id.*

Claims 4, 5, 17, and 19 stand rejected under 35 U.S.C. § 103(a) over Kohler and Vortman.³ *Id.* at 10.

DISCUSSION

Relating to each outstanding rejection, we adopt the Examiner’s findings of fact, reasoning on scope and content of the claims and prior art, and conclusions set out in the Final Action and Answer. Final Action 2–13; Answer 2–18. Specific findings of fact set forth below highlight certain evidence of record.

Only those arguments made by Appellants in the Appeal Brief and properly presented in the Reply Brief have been considered in this Decision. Arguments not so presented in the Briefs are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015); *see also Ex parte Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) (informative) (“Any bases for asserting error, whether factual or legal, that are not raised in the principal brief are waived.”).

“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

² US 2011/0313329 A1 (pub. Dec. 22, 2011) (“Kohler”).

³ US 2004/0236253 A1 (pub. Nov. 25, 2004) (“Vortman”).

PATENT ELIGIBILITY

1. *Findings of Fact*

FF1. The Specification describes a generic high-intensity focused ultrasound (HIFU) system. *See* Spec. 15:25–16:14, Figure 5.

FF2. The Specification describes a generic processor device and states, “[a] ‘processor’ as used herein encompasses an electronic component which is able to execute a program or machine executable instruction or computer executable code.” Spec. 3:22–23.

FF3. The Specification describes a generic computer memory and states, “[c]omputer memory’ or ‘memory’ is an example of a computer-readable storage medium. Computer memory is any memory which is directly accessible to a processor.” Spec. 3:17–19.

2. *Analysis*

“Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.” *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). Claims directed to *nothing more* than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible for patent protection. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *accord* MPEP § 2106 (II) (discussing *Diehr*).

In analyzing patent-eligibility questions under 35 U.S.C. § 101, the Supreme Court instructs us to “first determine whether the claims at issue are directed to a patent-ineligible concept.” *Alice Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014). If the initial threshold is met, we then move to a second step and “consider the elements of each claim both

individually and ‘as an ordered combination’ to determine whether the additional elements ‘transform the nature of the claim’ into a patent-eligible application.” *Id.* (quoting *Mayo*, 566 U.S. at 97).

The Federal Circuit has “recognize[d] that defining the precise abstract idea of patent claims in many cases is far from a ‘straightforward’ exercise.” *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1150 (Fed. Cir. 2016) (quoting *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1257 (Fed. Cir. 2014)). However, “we continue to ‘treat[] analyzing information by steps people [could] go through in their minds, or by ***mathematical algorithms, without more, as essentially mental processes within the abstract-idea category.***”” *Synopsys*, 839 F.3d at 1146–47 (emphasis added) (quoting *Electric Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016) (citations omitted)); *see also Electric Power Grp.*, 830 F.3d at 1353 (“collecting information, analyzing it, and displaying certain results of the collection and analysis” “fall[s] into a familiar class of claims ‘directed to’ a patent-ineligible concept,” that of the abstract idea). The Federal Circuit has recognized that “a claim for a *new* abstract idea is still an abstract idea.” *Synopsys*, 839 F.3d at 1151.

The Federal Circuit, in *Intellectual Ventures I LLC v. Capital One Financial Corp.*, 850 F.3d 1332 (Fed. Cir. 2017), where the claims were held to be directed to a computer programmed to edit XML documents, “conclude[d] [the claims were] . . . at their core, directed to the abstract idea of collecting, displaying, and manipulating data.” *Id.* at 1339–40. Even though the patent at issue in *Intellectual Ventures I* indicated its invention provided a concrete solution to a particular problem in computer programming, it “at best, . . . limit[ed] the invention to a technological

environment for which to apply the underlying abstract concept,” which does “not render an otherwise abstract concept any less abstract.” *Id.* at 1340 (citing *Affinity Labs of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1259 (Fed. Cir. 2016)). Under step two of the *Alice* analysis, the court in *Intellectual Ventures I* held that claims reciting generic computer components or elements and their functions, e.g., organizing, mapping, identifying, defining, detecting, and modifying, “merely describe the functions of the abstract idea itself” and are not sufficient to supply significantly more than the abstract idea so as to confer patent-eligibility. *Id.* at 1341.

The Federal Circuit has established in several other cases that collecting, classifying, storing, and organizing data, regardless of whether such data manipulations are limited to a particular environment, is an abstract idea and, without more, is not patent eligible. *See, e.g., In re TLI Communications LLC Patent Litigation*, 823 F.3d 607 (Fed. Cir. 2016) (collecting and organizing data in the form of digital images is abstract and patent ineligible and using computer systems in their generic ways do not add an inventive concept); *Content Extraction and Transmission LLC v. Wells Fargo Bank, Nat’l Ass’n*, 776 F.3d 1343 (Fed. Cir. 2014) (extracting data from documents, recognizing information therefrom, and storing the information is abstract).

The Examiner determined, pursuant to *Alice* step one, “[c]laim(s) 1-15 [rejected claims 1–19] are directed to the abstract idea of removing signal component.” Final Action 2. The Examiner further explained that

[t]he device and method involve mathematical concepts such as mathematical relationships, mathematical formulas, and calculation (an algorithm/model for determining maximum

energy map and thermal property map) which correspond to concepts identified as abstract ideas by the courts. The claims involve mathematical relationship but do not claim the significan[ce] of this mathematical relationship and reason for creating and display maps.

Id. at 3. We discern no error in the Examiner’s determinations.

Pursuant to *Alice* step two, the Examiner determined, “[t]he claim(s) does/do not include additional elements that are sufficient to amount to significantly more than the judicial exception because the additional device elements, which are recited at a high level of generality, provide conventional device functions that do not add meaningful limits to practicing the abstract idea.” *Id.* at 2. The Examiner determined further that the claim(s)

recites the additional limitations of a “hifu [high intensity focused ultrasound] system” for transmitting hifu, a “processor” for processing data, a “memory” for storing data. These additional elements are recited at a high level of generality and are recited as performing generic computer functions routinely used in computer applications. Generic computer components recited as performing generic computer functions that are well-understood, routine and conventional activities amount to no more than implementing the abstract idea with a computerized system. Thus, taken alone [and as an ordered combination], these additional elements do not amount to significantly more than the above-identified judicial exception (the abstract idea).

Id. at 3–4. We discern no error in the Examiner’s determinations. *See* FF1–FF3.

Appellants argue the claims do “not reveal the disclosure of [claim or recite] any mathematical relationships, or mathematical formulae,” and “the absence of mathematical relationships, or mathematical formulae in the claims render their relegation to an abstraction due to the inclusion of math

therein improper.” Appeal Br. 8. Further, Appellants contend, without conceding, that even if the claims are directed to mathematical algorithms they cannot be directed to an abstract idea if the math is used for a practical application. *Id.* (citing *Parker v. Flook*, 437 U.S. 584 (1978) and *Diamond v. Diehr*, 450 U.S. 175 (1981)).

The Examiner’s response to this argument is that the claim language requiring a thermoacoustic model implicitly invokes a mathematical relationship or formula because one cannot create or determine a model without such. Answer 12. We conclude the Examiner has the better position. The claims are directed to manipulating sonication data based on understood thermodynamics and organizing it into maps (spatial representations of the data). Such a process necessarily relies upon mathematical calculations and algorithms, whether they are explicitly claimed or not. Further, unlike the facts of *Diehr* (where math was used to improve rubber production), the claims here do not require that the data collected and analyzed is then used to do anything, even if it is associated with a specific machine.

Appellants subsequently agree that the claimed subject matter of constructing a thermal map using sonication data, a thermoacoustic model, and determining a maximum energy map based on that model can be considered algorithmic and mathematical and, so, is considered an abstract idea under Supreme Court precedent. *Id.* at 9. Appellants identify that such mathematics, as invoked by the claims, can have practical applications, for example, forming a treatment plan, which Appellants analogize to the facts of *Diehr*. *Id.* at 9–10. Appellants also cite the Federal Circuit decision in *Amdocs* as somehow supportive of patent eligibility here. *Id.* at 10 (citing

generally *Amdocs (Israel) Limited v. Openet Telecom, Inc.*, 841 F.3d 1288 (2016)). Appellants go on to generally argue that the claims' mathematics is tied to a particular machine (the HIFU) and that the invention is clearly an advance in the technical field of sonographic treatment. Appeal Br. 10–11, 16.

The Examiner dismisses Appellants' concession as it relates to unclaimed subject matter (e.g., "the limitation of sonication duration determined through instructions such as a treatment plan that stems from the determination of the maximum energy map is not in the claim"), but responds that the claim limitations relating to mathematical calculations, such as determining a maximum energy map, do not tie the mathematics to improving treatment or preventing injury, which are not claimed (as mentioned above, we conclude the Examiner is correct). Answer 14. The Examiner also determined that the HIFU system is merely a well-known machine used in a conventional way and the claims do not require that it have any special structure different (or be used differently) from a generic HIFU system. *Id.* at 12–13; *see also* FF3. Thus, the Examiner's determination is that the claimed HIFU system (or processor or memory; *see* FF1, FF2) does not add the something more to the claims so as to provide an inventive concept for the claimed invention.

We have considered the above and also Appellants' subsequent arguments that the facts here are like those of *SiRF Tech. Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319 (Fed. Cir. 2010), where invoked mathematics could not be performed without a GPS receiver, which saved the claims from patent-ineligibility, like those of *O'Reilly v. Morse*, 56 U.S. 62 (1853), where claims directed to a system of signs/marks with machinery (remote

printing similar to Morse code) were patent eligible while claims directed to electromagnetism without associated machinery were not. We are unpersuaded by Appellants' arguments and conclude the balance of evidence supports the Examiner's determinations.

SiRF was decided before *Mayo* and *Alice* (and the plethora of subsequent Federal Circuit cases directed to the patent-eligibility of algorithmic inventions) and, thus, did not have the guidance provided by those cases (*O'Reilly* was decided over 160 years before *Alice* and *Mayo*). It is therefore not clear that *SiRF* (and certainly not *O'Reilly*) was decided under the current test. *See SiRF*, 601 F.3d at 1332. In *SiRF*, a GPS receiver was considered to place a meaningful limitation on the claim because “without a GPS receiver it would be impossible to generate pseudoranges or to determine the position of the GPS receiver whose position is the precise goal of the claims.” *Id.* The algorithm in *SiRF* was used to determine the position of the GPS receiver.

The claims in this case are distinguishable because the algorithm, while receiving data from a HIFU system, has no claimed application to the operation or structure of the HIFU system. Rather, the algorithm is used to deduce information about how the HIFU system has heated the body upon which it was used; such historical data is not claimed to be used to affect how the HIFU system is thereafter used, even if it conceivably *might* be so-used. In *O'Reilly's* indirect decision on patent-eligibility, the Court found that the invention was the application of electro-magnetism to print and record intelligible characters remotely, an application which revolutionized both printing and communications. *O'Reilly*, 56 U.S. at 60–61. Thus, in *O'Reilly*, actual improvements were made to a printing machine to function

in this new way, which is not the case with the presently appealed claims, which do not claim to change the HIFU system in any way other than having an associated processor collect and analyze data for a map.

We find the facts here more analogous to those of *Affinity Labs of Texas, LLC v. DIRECTV, LLC*, where the Federal Circuit held that the claims, “stripped of excess verbiage,” were

directed to a broadcast system in which a cellular telephone located outside the range of a regional broadcaster (1) requests and receives network-based content from the broadcaster via a streaming signal, (2) is configured to wirelessly download an application for performing those functions, and (3) contains a display that allows the user to select particular content, which, while certainly reciting significant, concrete, physical components (a broadcast system, a network, a cellular telephone), were nonetheless directed to a mere abstract idea because there was “nothing in [the claims] that is directed to *how* to implement out-of-region broadcasting on a cellular phone”; the claims were “drawn to the idea itself.” *Affinity Labs*, 838 F.3d at 1256, 1258. The court held “that merely limiting the field of use of the abstract idea to a particular existing technological environment does not render the claims any less abstract.” *Id.* at 1259.

This is the scenario presented here because, while claim 1 certainly limits data manipulation and display to the field of sonication therapy, the claimed invention is still directed to the abstract idea of data manipulation. Further, as determined by the Examiner, the claimed structural elements are generic devices that are not improved by the otherwise-claimed abstract idea; they are a platform for its use or a generator for data.

Appellants also urge the Board to compare the facts here to those of *Secured Mail Solutions LLC v. Universal Wilde, Inc.*, 873 F.3d 905 (Fed.

Cir. 2017). Reply Br. 5. We are not persuaded. In *Secured Mail*, the Federal Circuit affirmed a district court’s holding that claims to a method of providing electronic data (a unique identifier) for mail objects were *not* patent-eligible as directed to an abstract idea, without more, finding that Secured Mail’s claims were not directed to an improvement in the functionality of the computer, or anything, associated with the invention, but were directed to the abstract idea of communicating information about mail objects using personalized markings. Here, the claims are directed to collecting temporal-spatial-thermal data after ultrasonic energy is applied to a body and organizing that data into a map (or maps), which, like applying a unique identifier to a mail object, consists of no more than an abstract idea.

As discussed, the steps and concepts identified in this case are merely the manipulation and organization of data via mathematical algorithms, using well-known, routine, conventional computer/data related means. As the case law makes clear, the use of computers to perform well-known data organization and analytics cannot supply the *something more* to confer patent-eligibility to an otherwise ineligible claim. Simply put, “[i]nformation as such is an intangible,” and collecting it and analyzing it by mathematical algorithms without more is abstract, and storing, searching, or presenting that information with routine tools “is abstract as an ancillary part of such collection and analysis.” *Electric Power Grp.*, 830 F.3d at 1353–54. The claims merely require selection of information, manipulation of that data for analytical purposes, using a conventional computer system programmed to do so; such steps do not transform the abstract ideas of the claims into a patent-eligible invention.

For the reasons set forth above, we affirm the § 101 rejection.

WRITTEN DESCRIPTION AND ENABLEMENT

3. *Findings of Fact*

FF4. The Specification states “[e]xecution of the instructions further cause the processor to construct a thermal property map of the subject using the previous sonication data and a thermoacoustic model” and “[e]xecution of the instructions further cause the processor to determine a maximum energy map using the thermoacoustic model and the thermal property map” and “[t]his maximum energy may be determined by performing the calculation with the thermoacoustic model and modeling effects of performing another sonication at spatially different positions. Spec. 6:19–30.

FF5. The Specification states:

The thermoacoustic model is operable for determining the thermal property map in a sonication region of a subject. The sonication region as used herein encompasses the region of the subject through which a measurable or significant quantity of ultrasound passes through the subject. This would include not just the sonication volume but also the near field region and the far field region. The thermoacoustic model is operable for determining a predicted thermal property map in a sonication region using the thermal property map and a predicted ultrasound beam geometry.

Spec. 7:15–21.

FF6. The Specification states:

The thermoacoustic model is operable for determining the maximum power for each sonication volume by limiting a maximum thermal property in the predicted thermal property map to a predetermined maximum value. For instance the thermoacoustic model may model the near field region and ensure that it is not overheated by multiple sonications.

Spec. 7:28–31.

FF7. The Specification states, “[i]n another embodiment execution of the instructions further cause the processor to calculate an energy intensity map using the beam geometry, the maximum power and a thermoacoustic model.” Spec. 8:3–5.

FF8. The Specification states, “[t]he thermoacoustic model is further operable for determining the predicted thermal property map by calculating adjustments to the ultrasound beam geometry using a beam path ultrasound transducer model.” Spec. 8:17–19.

FF9. The Specification states:

In another embodiment execution of the instructions further causes the processor to modify the thermoacoustic model using the temperature change rate map. For instance the thermoacoustic model may assume that energy or temperature is dissipated at a particular location at a determined rate. By actually measuring the rate at which temperature changes the thermoacoustic model may be updated or corrected for the specific subject.

Spec. 10:17–21.

FF10. The Specification states:

The computer memory 550 is also shown as containing a thermoacoustic model 562. The thermoacoustic model 562 contains computer-executable code 544 which enables the processor to calculate the thermal property map from the previous sonication data 552 and the maximum energy map 556 from the thermal property map 554.

Spec. 15:29–33.

FF11. The Specification states:

The overlapping region 602 would be heated when both sonication volumes 522, 522' are sonicated. The overlapping region 602 would be heated more than the ultrasound in the regions which are not overlapping. This Fig. illustrates that it is

beneficial to use the thermoacoustic model to construct a thermal property map which is descriptive of the change in the thermal properties of the subject 502 after the points 522 and 522' have been sonicated.

Spec. 16:33–17:3.

4. *Analysis*

“In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.” *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. *See id.*

The Examiner determined that the Specification does not comply with the written description requirement because it fails to disclose how a thermoacoustic model (or a beam path ultrasound transducer model, a translation ultrasound transducer model, and beam geometry) is (are) used to determine a maximum energy/power map or thermal property map (or cool down map and energy intensity map). Final Action 5. The Examiner asks, “[w]hat are these models?” and determined that the “specification does not explain.” *Id.* We discern no error in the Examiner’s determination.

Appellants argue “the claims do not recite a particular method in which the thermoacoustic model, beam path ultrasound transducer model, translation ultrasound transducer model and beam geometry are used to determine the maximum energy/power map, thermal property map, cool down map and energy intensity map.” Appeal Br. 17. Therefore, Appellants argue, the Specification’s disclosure is commensurate with the claims. *Id.* Appellants also state, “Applicant’s claims do not explain the

models or recite how to determine the models,” seemingly arguing that the lack of claiming what the claimed models are, specifically, or how they work, specifically, means the Specification can be similarly ambiguous *Id.* at 18.

Reviewing the Specification, we conclude the Examiner is correct that the Specification does not explain what the claimed model (thermoacoustic model) actually is, but merely describes how it might generally fit into the invention’s algorithm. FF4–FF11 (these facts are illustrative of the Specification’s disclosure on the claimed model). The Specification does not support that Appellants were in possession of the models recited by the claims; merely stating, e.g., the words “thermoacoustic model” somewhere in the Specification, does not inform the ordinary artisan what that model is. Indeed, the Examiner’s question, “what are these models?” goes unexplained by either the Specification or the briefing by Appellants on appeal.

Hypothetically, a claim could recite “a widget,” and an associated specification might mention “a widget,” or that “a widget can be used to open a door,” but unless the skilled artisan can discern what a widget is, the mere duplication of a claim’s words or the mere indication of a potential use for a claim element in a specification cannot provide a disclosure of the claimed subject matter so as to “convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention.”

For the reasons above, we affirm the written description rejection.

Turning to enablement, “[s]ection 112 requires that the patent specification enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation [S]ee also *In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993) (“[T]he specification must

teach those of skill in the art how to make and how to use the invention as broadly as it is claimed.’.” *Invitrogen Corp. v. Clontech Labs. Inc.*, 429 F.3d 1052, 1070–71 (Fed. Cir. 2005) (internal quotes omitted).

Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). *Wands* factors are factual inquiries underlying the enablement conclusion. *Enzo Biochem Inc. v. Calgene Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999).

The Examiner determined that, “[w]ithout understanding the processing and calculating steps of the [claimed] models,” “one of ordinary skill in the art could not use[] the [claimed] models to calculate maps,” as claimed. Final Action 6. Thus, the Examiner determined that the claims recite subject matter not enabled by the Specification. *Id.*

Appellants argue, “the Final Rejection merely asserts that Applicants’ specification does not provide a description (i.e., ‘the processing and calculating steps’) of a specific model that could be used by the skilled artisan.” Appeal Br. 20–21. Appellants argue “the specification need not enable a skilled artisan to make or use a specific thing that is not recited in the claims. As such, at least because the claims do not recite a specific model, Applicants’ specification need not describe ‘the processing and calculating steps of the [specific] model’.” *Id.* at 21. Appellants further argue, “[a] patent need not teach, and preferably omits, what is well known in the art,” and “[t]he Final Rejection provides no finding of fact to support

an inference that a skilled artisan would be unable to construct a map using a model based upon Applicants' disclosure.” *Id.*

The Examiner has determined that the model(s) recited by the claims are not explained or sufficiently defined by the Specification for a skilled artisan to know what they are or how to use them within the context of the claims. Appellants provide no explanation adequately responding to the Examiner’s confusion over the claimed subject matter; no definition of the models is provided by Appellants, nor a citation to a source explaining what the claimed models are or how they are to be specifically used, nor anything beyond an insinuation that somehow the claimed models are well-known and, therefore, need no explanation.

Considering the *Wands* factors, in this case: (1) there is no direct evidence on the quantity of experimentation necessary to practice the invention; (2) there is very little, if any, direction or guidance presented in the Specification on the claimed models identity or use; (3) there are no working examples identified in the Specification; (4) there is no evidence as to how the nature of the invention impacts enablement; (5) there is no evidence as to the state of the prior art; (6) there is no evidence as to how the relative skill of those in the art impacts enablement; (7) there is no evidence as to how the predictability or unpredictability of the art impacts enablement; and (8) the claims are broad in scope as to the component parts of the medical apparatus, computer program, or method of operating a medical apparatus, which are claimed generically. *See, e.g.*, FF4–FF11. On balance, these factors favor the Examiner’s position.

For the reasons above, we affirm the rejection of the claims as not enabled.

OBVIOUSNESS

5. *Findings of Fact*

FF12. Kohler discloses:

A therapy system comprises a therapy module to perform successive deposits of energy in a target zone, the therapy system being provided with a control module [which] is configured to prior [to] the deposits of energy produce an a priori estimate of the induced heating. For example a thermometry module is provided to measure temperature in a measurement field. The induced heating may be derived on the basis of a tissue model from the settings of the therapy module. In particular the therapy module is a high-intensity focuse[d] ultrasound transmitter. A magnetic resonance examination system configured for thermometry is employed as the thermometry module.

Kohler Abstract; *see also* Final Action 6–11 and Answer 7–11, 16–18 (discussing Kohler).

FF13. Kohler discloses:

Notably, the safety of each energy deposit is estimated a priori when the amount of energy to be deposited and position have been determined. The induced heating can be estimated on the basis of the parameter settings of the therapy module and a tissue model or the induced heating can be estimated from temperature measurements of the target area.

Kohler ¶ 11; *see also* Final Action 6–11 and Answer 7–11, 16–18 (discussing Kohler).

FF14. Kohler discloses estimating a “cool down period” needed after induced heating by an HIFU system and before further inducing heating with the system, based on measuring induced heat and based on calculations based on a “multilayer tissue model” used to simulate thermal perfusion and diffusion, “i.e., the transport of heat through tissue,” taking three dimensional geometry of tissue and thermal

properties into account. Kohler ¶¶ 13–16, 20; *see also* Final Action 6–11 and Answer 7–11, 16–18 (discussing Kohler).

FF15. Further to the preceding finding of fact, Kohler discloses a computer program, i.e., a “control module [which] compares the estimated induced heating to a safety limit,” and determines safe heating, which is represented “by the estimated maximum temperature and/or thermal dose” for induced heating. Kohler ¶¶ 17–18, 24; *see also* Final Action 6–11 and Answer 7–11, 16–18 (discussing Kohler).

FF16. Kohler discloses its induced heating measurements and calculation are spatially and temporally dependent, for example, the system determines the time factor involved in necessary cooling before further induced heating based on 3D geometry and spatially encoded temperature measurements. Kohler ¶¶ 30, 32; *see also* Final Action 6–11 and Answer 7–11, 16–18 (discussing Kohler).

FF17. Kohler discloses, “[t]he therapy system of the invention is provided with a delay module 6 which delays the activation of the therapy module 1. The delay leads to the cool-down period. The delay is set by the control unit on the basis of the measured temperature.” Kohler ¶ 34; *see also* Final Action 6–11 and Answer 7–11, 16–18 (discussing Kohler).

FF18. Kohler discloses, “the temperature was filtered with a 5x5 voxel median filter (voxel size 2.5x2.5 mm²).”⁴ Kohler ¶ 35; *see also* Final Action 6–11 and Answer 7–11, 16–18 (discussing Kohler).

⁴ A “voxel” is, “(in computer-based modelling or graphic simulation) each of an array of elements of volume that constitute a notional three-dimensional space, especially each of an array of discrete elements into

FF19. Kohler discloses:

1. A therapy system comprising

a therapy module to perform successive deposits of energy in a target zone, the therapy system being provided with a thermometry module to measure temperature in a measurement field and

a control module to regulate the therapy module and

wherein the control module is configured to prior the deposits of energy produce an a priori estimate of the induced heating.

2. A therapy system, in particular as claimed in claim 1, the successive deposits being separated by a cool down period, wherein the control module is configured to regulate the cool down period and prior [to] the deposits of energy produce an a priori estimate of the cool down period, on the basis of the estimated induced heating.

3. A therapy system as claimed in claim 1 further comprising a thermometry module to measure temperature in a measurement field and the control module being arranged to estimate induced heating on the basis of the measured temperature.

4. A therapy system as claimed in claim 1, wherein the control module is configured to estimate the induced heating on the basis of a thermo-acoustic layered tissue model.

5. A therapy system as claimed in claim 2, wherein the thermo-acoustic layered thermal tissue model accounts for heat distribution both along and transverse to the direction of the energy deposition.

Kohler at 3–4 (claims 1–5); *see also* Final Action 6–11 and Answer 7–11, 16–18 (discussing Kohler).

which a representation of a three-dimensional object is divided.” OXFORD DICTIONARY, *voxel*, <https://en.oxforddictionaries.com/definition/voxel>, visited Apr. 9, 2018.

6. *Analysis*

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “[T]he analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. “[I]f a technique has been used to improve one device [or process], and a person of ordinary skill in the art would recognize that it would improve similar devices [or processes] in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *Id.* at 417. “In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.” *Id.* at 419.

The Examiner determined that Kohler disclosed, taught, and suggested each element of the medical apparatus of claim 1 and, likewise, the similar computer program of claim 14 and method of claim 15. Final Action 7 (citing Kohler Abstract, ¶¶ 5, 11–18, 20, 24, 29, 30, 34, 35, Figures 1 and 2, claims 4 and 5). We discern no error in the Examiner’s determinations.

Appellants argue “*Kohler, et al.* does not disclose that the thermal tissue model, representing thermal perfusion and diffusion, is established using data descriptive of an ultrasound sonication of a subject,” a feature required by claim 1. Appeal Br. 24. This argument is not persuasive. Kohler is directed to an HIFU therapy system that measures how a complex,

three-dimensional mass of tissue is heated by ultrasonic sonication to calculate the maximum temperature reached and how long is needed to allow that mass of tissue to cool before a next application of ultrasonic energy. FF12–FF15. Because Kohler uses temperature measurements in its calculations, it teaches using data descriptive of an ultrasound sonication of a subject.

Appellants argue “*Kohler, et al.* does not disclose that the thermal tissue model, representing thermal perfusion and diffusion, is established using a thermoacoustic model, whereas Appellants’ claim 1 recites ‘construct[ing] a thermal property map of the subject using . . . a thermoacoustic model.’” Appeal Br. 25. Appellants argue “*Kohler, et al.* does not disclose that the thermal tissue model, representing thermal perfusion and diffusion, is a map, whereas Appellants’ claim 1 recites ‘construct[ing] a thermal property map.’” Appeal Br. 26. These arguments are not persuasive. Kohler discloses that, in addition to actual temperature measurements, a “tissue model” and a “multilayer tissue model” are used to estimate induced heating variables and simulate thermal perfusion and diffusion in three dimensions. FF13–FF14, FF16, FF18. Determining induced heating via sonication in tissue in three dimensions using a complex tissue model teaches or suggests the claimed thermoacoustic model and constructing a thermal property map using a thermoacoustic model.

Appellants argue:

Claim 1 further recites: “determin[ing] a maximum energy map using the thermoacoustic model and the thermal property map.” The Final Rejection acknowledges that Kohler, et al. does not disclose this subject matter (see Final Rejection page 7, lines 15 and 16). To overcome this deficiency, the Final

Rejection relegates this feature of claim 1 as “only require[ing] routine skill in the art to determine. . .” (*see* page 8, lines 2-4).

However, a statement that modifying the prior art to meet the claimed invention would have been within the ordinary skill of an artisan at the time the claimed invention was made is not sufficient to establish a *prima facie* case of obviousness without some objective reason to modify the prior art to achieve the claimed subject matter.

Appeal Br. 26. This argument is not persuasive. We understand the Examiner to have determined that Kohler, while not disclosing the claimed subject matter verbatim (for example, Kohler does not use the terminology “a maximum energy map”), nonetheless taught and suggested the claimed subject matter. We conclude Kohler teaches and suggests determining a maximum energy map, as claimed, in that Kohler teaches measuring how a three-dimensional mass of tissue has been heated by sonication and determines how long that tissue must cool before again applying sonication energy and estimates “maximum temperature and/or thermal dose” of such sonication heating in relation to a safety limit. FF14, FF15, FF19.

For the reasons set forth above we affirm the obviousness rejection over Kohler.

Regarding the rejection of claims 4 and 5 (and, though not specified in the brief, presumably also 17 and 19, which are also rejected with claims 4 and 5) as obvious over Kohler and Vortman, Appellants contend “Claims 4 and 5 depend from claim 1, which is patentable over the applied art for at least the reasons set forth above. Accordingly, claims 4 and 5 are also in condition for allowance.” Appeal Br. 30.

Vortman, as determined by the Examiner, teaches and suggests using a sonication therapy similar to that of Kohler and discloses a focused

ultrasound transducer array controller to steer or move a location of a focal zone of sonication. Final Action 10–11 (citing Vortman Abstract and Figures). Because Appellants do not contest the Examiner’s determination with respect to Vortman or its combination with Kohler and do not otherwise argue these claims or this rejection separately from the rejection over Kohler, we affirm the rejection for the reasons discussed above.

SUMMARY

The rejection of the claims as directed to patent-ineligible subject matter is affirmed.

The written description rejection is affirmed.

The enablement rejection is affirmed.

The obviousness rejections are each affirmed.

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)(1)(iv).

AFFIRMED