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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/580,254	08/21/2012	Luke J. Aram	265280-222415	9622
23643	7590	05/16/2018	EXAMINER	
Barnes & Thornburg LLP (IN) 11 S. Meridian Street Indianapolis, IN 46204			MERENE, JAN CHRISTOP L	
			ART UNIT	PAPER NUMBER
			3733	
			NOTIFICATION DATE	DELIVERY MODE
			05/16/2018	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LUKE J. ARAM, WILLIAM BUGBEE,
CHARLES A. ENGH, JOSEPH MOSKAL, MARK PAGNANO,
MICHAEL SWANK, BRYAN ROSE, and JOSE F. GUZMAN¹

Appeal 2017-004459
Application 13/580,254
Technology Center 3700

Before RICHARD J. SMITH, JOHN E. SCHNEIDER, and
RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision under 35 U.S.C. § 134(a) involving claims on appeal directed to a method to create a customized patient-specific orthopaedic instrument. Claims 1–19 are on appeal as rejected under 35 U.S.C. § 101 and § 103. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.²

¹ Appellants identify the Real Party in Interest as “DePuy Synthes Products, Inc., a Johnson & Johnson Company.” Appeal Br. 2.

² We refer herein to the Specification filed Aug. 21, 2012 (“Spec.”); Non-Final Office Action mailed Mar. 24, 2016 (“Non-Final Action”); Appeal Brief filed Aug. 24, 2016 (“Appeal Br.”); Examiner’s Answer to Appellants’ Appeal Brief mailed Nov. 23, 2016 (“Answer”); and Reply Brief filed Jan. 23, 2017 (“Reply Br.”).

STATEMENT OF THE CASE

The Specification states that the invention, at least in part, relates to an algorithm 10 for fabricating a customized patient-specific orthopaedic surgical instrument is illustrated. What is meant herein by the term “customized patient-specific orthopaedic surgical instrument” is a surgical tool for use by a surgeon in performing an orthopaedic surgical procedure that is intended, and configured, for use on a particular patient.

Spec. ¶ 37. The claims recite that a “surgical design plan compris[es] a preoperatively planned size of at least one bone chip produced as a result of a surgical resection of [a] bone of the patient consistent with the surgical design plan,” and the Specification, in relation thereto, states “a part of the surgical design plan is to create a model that includes the individual sizes of the ‘bone scrap’ [i.e., bone chip(s)] created by proper execution of the surgical design plan.” Spec. ¶ 47.

Claims 1, 10, and 17 are the independent claims and are reproduced below:

1. A method for a vendor to create a customized patient-specific orthopaedic instrument for a patient of a healthcare facility that is external to the vendor, comprising:

receiving, from the healthcare facility external to the vendor, an instrument request that includes data relevant to a bone of the patient,

creating, in response to receiving the instrument request, a surgical design plan that has been customized for the patient per data of the instrument request, ***the surgical design plan comprising a preoperatively planned size of at least one bone chip produced as a result of a surgical resection of the bone of the patient consistent with the surgical design plan,*** and

sending the surgical design plan to the healthcare facility.

10. A method of performing an orthopaedic surgical procedure on a bone of a patient at a healthcare facility, comprising:

making a cut in the bone of the patient at a location indicated in a surgical design plan obtained from a vendor that is external to the healthcare facility that has been customized for the patient per data relevant to a bone of the patient, ***the surgical design plan comprising a preoperatively planned size of a bone chip produced as a result of the cut,***

measuring the actual size of the bone chip produced as a result of the cut, and

comparing the measured actual size of the bone chip to the preoperatively planned size of the bone chip of the surgical design plan.

17. A method of performing an orthopaedic surgical procedure on a bone of a patient, comprising:

preoperatively planning a size of a bone chip to be produced by resecting the bone of the patient at a predetermined location,

making a cut in the bone of the patient at the predetermined location thereby producing a bone chip,

measuring the actual size of the bone chip produced as a result of the cut, and

comparing the measured actual size of the bone chip to the preoperatively planned size of the bone chip.

Appeal Br. 33, 35, 38 (Claims App'x; emphasis added).

The following rejections are appealed:

Claims 1 and 3–9 stand rejected under 35 U.S.C. § 101 because the claimed invention is directed to a judicial exception (i.e., an abstract idea) without significantly more. Non-Final Action 3.

Claims 1–15, 17, and 18 stand rejected under 35 U.S.C. § 103(a) over Aker³ and Haddad.⁴ *Id.* at 4.

Claims 16 and 19 stand rejected under 35 U.S.C. § 103(a) over Aker, Haddad, and Klein.⁵ *Id.* at 9.

DISCUSSION

“[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).

PATENT-ELIGIBILITY

“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

³ US 8,425,524 B2 (issued Apr. 23, 2013) (“Aker”).

⁴ US 8,265,949 B2 (issued Sept. 11, 2012 (“Haddad”).

⁵ US 8,417,544 B2 (issued Apr. 9, 2013) (“Klein”).

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 79, 78).

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, analyzing, 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); *Electric Power Grp.*, 830 F.3d at 1350 (receiving specific data from a source, analyzing the data, displaying the data, and manipulating the data in some useful way, even if limited to a specific technological environment, is akin to an ordinary mental process excluded from § 101); *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).

Here, the Examiner determined, pursuant to *Alice* step one, the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more. Claim(s) 1 is/are directed to an abstract idea; the method is an idea standing alone, basically a mental process that can be accomplished as a mental process performed by the human mind or by a human using pencil and paper.

Non-Final Action 3; Answer 2, 9. Pursuant to *Alice* step two, the Examiner determined,

The claim(s) does/do not include additional elements that are sufficient to amount to significantly more than the judicial exception because the steps in claim 1 include receiving, creating, and sending which may be performed either in one's mind or simply with paper and pencil (sending). The information being acted upon are similar to abstract ideas such as comparing new information (instrument request) with stored information (bone chip/resection) and identifying options (creating and sending the design plan). While the claim does have additional elements beyond a purely abstract idea, the additional elements do not amount to significantly more than an abstract idea. That the instrument request is received at an external facility is not germane to the creation of the design plan and does not add a meaningful limit to the idea. That the creation of the plan is based on the size of a bone chip (resection) also does not add a significant detail to the creation [abstract idea], because the chip size is value or quantity of information [mere data] which can be mentally manipulated for the creation of the plan. Finally, the sending step include[d] does not present any additional inventive step or details to the method.

Non-Final Action 3–4. We discern no error in the Examiner's determinations.

Appellants argue the facts here are analogous to those of *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016), where the Federal Circuit held claims to an improvement in how computers use tabular data was patent-eligible. Appeal Br. 5.

This argument is not persuasive. The facts here are not analogous to those of *Enfish*. In *Enfish*, the Federal Circuit relied on the distinction made in *Alice* between computer-functionality improvements and uses of existing computers as mere tools in processes focused on abstract ideas (e.g., the creation and manipulation of data). See *Enfish*, 822 F.3d at 1335–36; see *Alice*, 134 S. Ct. at 2358–59; see also *Elec. Power Grp.*, 830 F.2d at 1354 (distinguishing *Enfish*). Here, unlike *Enfish*, we are not presented with claims directed to an improvement in computer technology, but with claims directed to, essentially, a process of making a (surgery) plan based on transmitted data. This, regardless of the specific data or technological environment of its use, is an abstract idea.

Although not cited by Appellants, as the case was too-recently decided, we further distinguish the facts (and claims) here from those of *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017). In *Thales*, the Federal Circuit analogized the claims, which it found not to be directed to an abstract idea, to those found patent-eligible in *Diehr*. The Federal Circuit reasoned that the claims in *Thales* were directed to using sensors and algorithms (the application of physics to create an improved technique) “in a non-conventional manner” to improve measuring and orienting moving objects, as in *Diehr* where an algorithm and sensor were used to improve a rubber-making process. *Thales*, 850 F.3d at 1348–49.

Here, on the other hand, claim 1 is directed to mere data transmission and analysis to create more data, which is also transmitted. Nothing other than data (a plan) results from the process of claim 1. *Compare* to claim 2 (not included in the § 101 rejection and reciting fabricating an instrument).

Appellants argue the Examiner's determination that the claims are directed to an abstract idea is overly generalized and not adequately tied to the claim language. Appeal Br. 5.

This argument is not persuasive. We conclude the Examiner's determination is not overly generalized; it is reasonably specific within the context of the generalized language of claim 1. Claim 1 recites receiving data, creating a plan based on that data, and sending that created plan back to the data sender. While the claim also recites that the data is sent from a healthcare facility, is received at a vendor outside that facility, and that the plan is a customized plan and includes bone chip information, the Examiner addresses these elements in determining they do not amount to significantly more than the mere abstract idea to which the claim is directed. *See* Non-Final Action 3–4.

Appellants argue the subject matter of claim 1 is not an abstract idea because it “requires determining ‘a preoperatively planned size of at least one bone chip that would be produced as a result of a surgical resection of the bone consistent with the surgical design plan’ as part of creating the surgical design plan.” Appeal Br. 6.

This argument is not persuasive. The specific type of data does not extricate the claimed subject matter from realm an abstract idea. As

discussed above, the bone chip size is mere data, the sending/receiving and analysis of which our reviewing court has held to be an abstract idea.

Appellants argue that, even if the claims are directed to an abstract idea, as a whole, they recite significantly more and, so, are patent-eligible. Appeal Br. 8. Appellants point to the claim element “the instrument request [] received at an external facility,” as being important to the *something more*. *Id.* (emphasis omitted). Appellants point to the claim element that the surgical design plan is customized for a patient as being important. *Id.* Appellants argue these are more than mere mental steps, but involve creation of computer models or simulations. *Id.*

This argument is not persuasive. As discussed above, who sends and who receives data, or that these parties are not in the same place, does not amount to significantly more than the abstract idea. The specific type of data, i.e., a bone chip measurement for a future-conducted surgery, also fails to amount to significantly more than the abstract idea. The claimed elements, individually or as a whole, do not provide an inventive concept to distinguish the abstract idea and confer patent eligibility here.

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

OBVIOUSNESS

Obviousness criteria includes: 1) scope and content of prior art; 2) differences between prior art and claims at issue; 3) level of ordinary skill in the art at the time invention was made; and 4) objective evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). “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). “In determining whether the subject matter of a patent claim is obvious, . . . [w]hat matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.” *Id.* at 419. When a prima facie case of obviousness has not been established, the rejection must be reversed. *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). “[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.” *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

The Examiner determined the Aker-Haddad combination taught or suggested the invention of the claims, relying on Aker for much of the claim elements and Haddad for preparing a surgical plan based on a preoperatively planned size of a bone chip to be produced by following the surgical plan. *See Non-Final Action 5*. The Examiner determined that, because Haddad disclosed estimating amounts of bone to be resected to leave a bone ready for an implant, that Haddad also taught or suggested planning a preoperative size for a bone chip to be removed by such resection and basing a surgical plan, at least in part, on that information. *Id.* (citing Haddad 11:5–28).

Regarding all claims, Appellants argue the Aker-Haddad combination “fails to disclose preoperatively defining the size any bone chips produced during the surgical procedure, the proposed combination fails to arrive at the claimed invention.” *See, e.g., Appeal Br. 10*. Appellants contend that Aker and Haddad merely disclose preoperatively planning the shape of the surgically prepared bone surface, but not the size/shape of a bone piece to be removed (i.e., a bone chip). *Id.* at 10–11.

Appellants argue that considering a bone chip is not inherent in view of Aker's disclosure. *Id.* at 13. Appellants also argue Haddad does not disclose using bone chip size information for designing a surgical plan. *Id.* at 13–14. Appellants contend that Haddad teaches “a surgical plan based on ‘an estimated ***amount of a resection*** of the patient[']s[] bone,’ which is the total amount of bone that needs to be removed from the patient's bone,” but that this only equates to “preoperatively plann[ing the] size of the patient's remaining bone and does not disclose preoperatively planning the size and shape of [a] bone chip removed from the patient's bone.” *Id.* at 14–15.

Appellants argue there is no articulated reasoning to modify the references to arrive at the claimed invention. Appeal Br. 16. Appellants argue there is an important difference between a surgeon planning for a final shape of a bone to receive an implant and a surgeon planning for the size or shape of a bone chip to cut away from the bone to leave such a final shape. *Id.* Appellants contend Aker and Haddad teach only the former and the Examiner has done no more than conclude that the latter would be obvious. *Id.* at 17.

We are persuaded by Appellants' arguments, as identified above. While the disclosed subject matter of Aker and Haddad is undeniably similar to that of Appellants' Specification and claims, the distinction identified by Appellants is an important one. Neither Aker nor Haddad suggest planning to create a specific sized bone chip during surgery and planning a surgery and surgical instrument to be fabricated based upon such bone chip information. Deciding how a bone should ultimately be shaped to be paired with an orthopedic implant is not the same as deciding what sized piece of

scrap to cut from that bone. The Examiner presents no persuasive rationale why a skilled artisan would have read Haddad (or Aker) to suggest planning for or keeping track of the bone scraps removed during resection of a bone during orthopedic surgery.

For the reasons above, we reverse the obviousness rejections, which rely on the Aker-Haddad combination (Klein is not cited by the Examiner as providing the teachings identified as missing from the other prior art, as discussed above).

SUMMARY

The rejection of claims 1 and 3–9 as directed to patent-ineligible subject matter is affirmed.

The obviousness rejections are each reversed.

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-IN-PART