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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 CHLOE AUDIGIER, TOMMASO MANSI, VIOREL MIHALEF, ALI KAMEN, DORIN COMANICIU, PUNEET SHARMA, and SAIKIRAN RAPAKA[1]

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Appeal 2019-003371
Application 14/769,844
Technology Center 1600

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Before ERIC B. GRIMES, TIMOTHY G. MAJORS, and MICHAEL A. VALEK, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims relating to simulation of liver tumor ablation, which have been rejected as being directed to patent-ineligible subject matter. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] Appellant identifies the Real Party in Interest as Siemens Healthcare GmbH. Appeal Br. 1.

STATEMENT OF THE CASE

"[I]ncreasing interest has been focused on ablative approaches for the treatment of unresectable liver tumors. Rather than extirpation, this technique uses complete local in situ tumor destruction. . . . Radiofrequency ablation (RFA) is the most commonly used" method. Spec. ¶ 3. "The RFA procedure is performed by placing a probe within the target area, the tumor. . . . [T]he success of the procedure depends on the optimal placement of the probe and heat delivery." *Id.* ¶¶ 4–5. The Specification discloses "a method and system for interactive patient-specific simulation of tumor ablation." *Id.* ¶ 6.

Claims 1–57 are on appeal. Claim 1 is illustrative and reads as follows:

1. A method for interactive patient-specific simulation of liver tumor ablation, comprising:

estimating, from medical image data of a patient, a patient-specific anatomical model of a liver of the patient and a venous system of the liver;

generating a computational domain from the patient-specific anatomical model of the liver;

simulating blood flow in the liver and the circulatory system of the liver based on the patient-specific anatomical model;

simulating heat diffusion due to ablation based on a virtual ablation probe position corresponding to a possible ablation probe position for an ablation procedure for the patient and the simulated blood flow in the liver and the circulatory system of the liver by solving a bio-heat equation at each of a plurality of nodes of the computational domain; and

computing cellular necrosis in the liver based on the simulated heat diffusion and updating tissue parameters based on a computed cellular state to provide a predicted necrotic extent resulting from the ablation procedure for the patient with the possible ablation probe position.

Claims 20 and 39 are also independent and are directed to an apparatus and a computer readable medium, respectively, for carrying out the method of claim 1.

DISCUSSION

The Examiner has rejected claims 1–57 under 35 U.S.C. § 101 "because 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." Ans. 3. Specifically, the claimed method "models heat diffusion based on simulated stimuli, i.e. a virtual ablation probe[,] by solving a biologically adapted heat equation. The claimed method relies on calculations of fluid dynamics to model three dimensional blood flow as a function of time." *Id.* The Examiner finds that "[t]he claims as a whole are directed to solving dynamics equations which model system behavior as a function of time. Mathematical calculations are drawn to an abstract idea." *Id.* at 4.

The Examiner finds that additional elements in the claims are routine, conventional, and well understood and "do not provide meaningful limitation(s) to transform the abstract idea into a patent eligible application of the abstract idea such that the claim(s) amounts to significantly more than the abstract idea itself." *Id.* at 4–5.

Appellant argues that "claim 1 involves computer-based simulations of blood flow, heat diffusion, and cellular necrosis. Accordingly, one skilled in the art would understand that method of independent claim 1 clearly relates to the computer-related technology computer-based simulation of liver-tumor ablation." Appeal Br. 5.

Specifically, "[t]he method recited in independent claim 1 simulates heat diffusion for a possible ablation probe position for an actual ablation procedure for the patient and computes the cellular necrosis to provide a predicted necrotic extent resulting from the ablation procedure with the possible ablation probe location." *Id.* at 6. Appellant argues that the claimed method allows

> evaluat[ing] whether the possible probe position will result in a successful ablation procedure for the patient. Therefore, the method of independent claim 1 clearly provides a technological improvement to conventional techniques for planning of liver tumor ablations and selection of the ablation probe location for liver tumor ablations.

Id. "A prediction of whether an ablation procedure with a certain ablation probe position will be successful clearly improves the actual ablation procedure, as it reduces the chances of ablation being performed with the ablation probe at a sub-optimal position." *Id.* at 10.

We agree with Appellant that the claims are not directed to a patent-ineligible abstract idea. An invention is patent-eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. However, the Supreme Court has concluded that "[l]aws of nature, natural phenomena, and abstract ideas" are not patentable under 35 U.S.C. § 101. *See, e.g.*, *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014).

To determine if a claim falls into an excluded category, we apply a two-step framework, described in *Mayo* and *Alice*. *Id.* at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). We first determine what the claim is "directed to." *See Alice*, 573

U.S. at 219 ("On their face, the claims before us are drawn to the 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.").

Patent-ineligible abstract ideas include certain 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)). In contrast, patent-eligible inventions include physical and chemical processes, such as "molding rubber products" (*Diamond v. Diehr*, 450 U.S. 175, 192 (1981)); "tanning, dyeing, making water-proof cloth, vulcanizing India rubber, smelting ores" (*id.* at 182 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1854))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claimed method employed a mathematical formula, but the Supreme Court held that "[a] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula." *Diehr*, 450 U.S. at 176; *see also id.* at 192 ("We view respondents' claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula."). The Supreme Court noted, however, that a claim "seeking patent protection for that formula in the abstract . . . is not accorded the protection of our patent laws, . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment." *Id.* (citing

Benson and *Flook*); *see, e.g.*, *id.* at 187 ("It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.").

If the claim is "directed to" an abstract idea, we turn to the second step of the *Alice* and *Mayo* framework, and "examine 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 (alterations in original)). "[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. *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 (Jan. 7, 2019) ("Revised Guidance"). Under that guidance, we first determine whether the claim recites:

> (1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts; certain methods of organizing human activity such as a fundamental economic practice; or mental processes); and
>
> (2) additional elements that integrate the judicial exception into a practical application (*see* MPEP § 2106.05(a)–(c), (e)–(h)).

See 84 Fed. Reg. at 54–55. Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then determine whether the claim:

> (3) adds a specific limitation beyond the judicial exception that is not a "well-understood, routine, conventional activity" in the field (*see* MPEP § 2106.05(d)); or
>
> (4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

See 84 Fed. Reg. at 56.

Guidance Step 2(a), Prong 1

Claim 1 recites "simulating heat diffusion . . . by solving a bio-heat equation at each of a plurality of nodes of [a] computational domain." Independent claims 20 and 39 include the same claim language.

Regarding this step, the Specification states that "[a] bio-heat equation is . . . solved on an isotropic Cartesian grid using the Lattice Boltzmann method." Spec. ¶ 18. "Two main simplifications for solving the coupled bio-heat equations are the Pennes model and the Wulff-Klinger (WK) model." *Id.* ¶ 31. "The Pennes model may be expressed as: $(1-\varepsilon)\rho_t c_t \frac{\partial T}{\partial t} = (1-\varepsilon)Q + (1-\varepsilon)\nabla.(d_t \nabla T) + H(T_{b0} - T)$." *Id.* ¶ 32. "The Wulff-Klinger model can be expressed as: $(1-\varepsilon)\rho_t c_t \frac{\partial T}{\partial t} = (1-\varepsilon)Q + (1-\varepsilon)\nabla.(d_t \nabla T) + \varepsilon\rho_b c_b \mathbf{v}.\nabla T$." *Id.* ¶ 33. The variables in the above equations are defined in the Specification's ¶ 34. "[E]mbodiments of the present invention solve the bio-heat equation by combining the Pennes and Wulff-Klinger models." *Id.* ¶ 36.

Thus, although claim 1 does not recite any specific mathematical equations or formulas, the limitation of "solving a bio-heat equation at each of a plurality of nodes" is a recitation of a mathematical concept. Therefore, claim 1 recites an abstract idea.

Guidance Step 2(a), Prong 2

Even though claim 1 recites a mathematical concept, it may still be patent-eligible if "the claim as a whole integrates the recited judicial exception into a practical application of the exception"; i.e., whether the claim "appl[ies], rel[ies] on, or use[s] the judicial exception in a manner that imposes a meaningful limit on the judicial exception." 84 Fed. Reg. at 54. This analysis includes "[i]dentifying whether there are any additional elements recited in the claim beyond the judicial exception(s)" and "evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application." *Id.* at 54–55.

Here, claim 1 as a whole integrates the recited mathematical concept into a practical application. In addition to mathematical calculations, claim 1 includes using medical image data from a specific patient to "estimat[e] . . . a patient-specific anatomical model of a liver of the patient and a venous system of the liver," which is then used to generate a computational domain for simulating blood flow and heat diffusion, in order to compute cellular necrosis "to provide a predicted necrotic extent resulting from the ablation procedure for the patient with the possible ablation probe position." Claim 1.

Appellant's Specification states that "the success of the procedure depends on the optimal placement of the probe and heat delivery with

respect to the circulation system and tissue properties of the liver and tumors. Different placements may have different results." Spec. ¶ 5. Conventionally, "[t]o place the probe at the target location, the physician relies on intra-operative imaging techniques, such as ultrasound." *Id.*

The Specification states that the claimed method "provides . . . for interactive patient-specific simulation of tumor ablation." *Id.* ¶ 6. The Specification states that the method allows "fast patient-specific simulation of liver tumor ablation that can be utilized with near real time interaction in a clinical setting." *Id.* ¶ 19. The Specification also states that the Lattice Boltzmann method (LBM) implementation "can be implemented on a massively parallel architecture" so that "liver tumor ablation simulations can be performed efficiently in response to user interactions, which allows a user to interactively plan liver tumor ablation therapy using the simulations in a clinical setting." *Id.*

Thus, as described in the Specification, the claimed method includes the use of medical image data from a specific patient, which allows a clinician to predict the effect of a tumor ablation procedure, in that patient, with an ablation probe in different positions. We agree with Appellant that "[a] prediction of whether an ablation procedure with a certain ablation probe position will be successful" represents an improvement in the technical field of liver tumor ablation, because "it reduces the chances of ablation being performed with the ablation probe at a sub-optimal position." Appeal Br. 10.

We therefore conclude that, even though claim 1 recites a mathematical concept, as a whole it integrates that concept into a practical

application; specifically, calculating a particular set of recited parameters to simulate a liver tumor ablation procedure in a specific patient, thereby increasing the likelihood that the procedure will be successful. Therefore, the claimed method, as a whole, is not "directed to . . . [a] patent-ineligible concept." *Alice*, 573 U.S. at 217. The same analysis applies to independent claims 20 and 39. *Cf. id.* at 226 ("[T]he system claims are no different from the method claims in substance.").

The Examiner reasons that "planning a procedure and selection per se are abstract ideas that can be performed as a mental process. Appellants have not provided evidence that the information derived from their model is practically applied such that an improvement is realized in the 'real world.'" Ans. 6.

We do not agree with this position. Claim 1 is directed to a "method for interactive *patient-specific* simulation of liver tumor ablation" that includes "estimating, from medical image data of a patient, a *patient-specific anatomical model* of a liver of the patient." Claim 1 (emphasis added). Thus, the claim language makes clear that the method is directed to simulating the effect of a liver tumor ablation procedure, not as an abstraction, but in a specific patient.

As discussed above, the Specification states that the claimed method "allows a user to interactively plan liver tumor ablation therapy using the simulations in a clinical setting." Spec. ¶ 19. Simulating the effect obtained with an ablation probe in different positions is helpful because "the success of the procedure depends on the optimal placement of the probe and heat delivery. . . . Different placements may have different results." *Id.* at ¶ 5.

Thus, the evidence supports Appellant's position that the claimed method provides a real-world technological improvement to the process of ablating a liver tumor in a patient.

In summary, we reverse the rejection of independent claims 1, 20, and 39 under 35 U.S.C. § 101. Claims 2–19, 21–38, and 40–57 depend from one of claims 1, 20, or 39 and we therefore reverse the rejection of these claims as well, for the reasons discussed above.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
1–57	§ 101		1–57

REVERSED