

THE FEDERAL CIRCUIT DISAGREES OVER HOW TO ANALYZE PATENT ELIGIBILITY

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On March 8, 2018, the Court of Appeals for the Federal Circuit, in *Exergen Corp. v. Kaz USA, Inc.*, held that patent claims involving body temperature detection were directed to patent-eligible subject matter under § 101. The Federal Circuit also held that trial court findings regarding the second prong of the subject matter eligibility test under 35 U.S.C. § 101 ("§ 101")—whether claimed elements were routine, conventional, and well understood in the art—are findings of fact, entitled to the deference of clear error review. [1] The Court stated that although the question of subject matter eligibility is one of law, it can be based on underlying findings of fact, analogizing the inquiry to indefiniteness, enablement, and nonobviousness. The opinion is nonprecedential but provides insight into how Federal Circuit judges view the analytical framework for § 101.

BACKGROUND

The case involves two patents, US Patent No. 6,292,685 and U.S. Patent No. 7,787,938, which share "effectively identical" specifications. The patents contain both apparatus and method claims for measuring a person's body temperature by detecting the temperature of the skin directly above the superficial temporal artery and calculating the core body temperature as a function of ambient temperature and the surface skin temperature. The function involves applying a constant coefficient to both skin temperature and ambient temperature and a weighted difference of the two temperature readings. According to the specification, using the superficial temporal artery is particularly advantageous due to its consistent blood volume and congruent temperature to that of the heart.

The following are representative of the apparatus and method claims, respectively:

U.S. 6,292,685:

48. A body temperature detector comprising:

a radiation detector, and

electronics that measure radiation from at least three readings per second of the radiation detector as a target skin surface over an artery is viewed, the artery having a relatively constant blood flow, and that process the measured radiation to provide a body temperature approximation, distinct from skin surface temperature, based on detected radiation.

49. The body temperature detector of claim 48 wherein the artery is a temporal artery.

U.S. 7,787,398:

14. A method of detecting human body temperature comprising making at least three radiation readings per second while moving a radiation detector to scan across a region of skin over an artery to electronically determine a body temperature approximation, distinct from skin surface temperature.

24. The method of claim 14 wherein the artery is a temporal artery.

Exergen Corporation sued Kaz USA, Inc. [2] and two other competitors, Brooklands, Inc. and Thermomedics, Inc., who each make temperature-sensing devices. The courts consolidated the cases for the purpose of claim construction only and otherwise adjudicated the matters separately as *Exergen Corp. v. Brooklands, Inc.* [3] and *Exergen Corp. v. Thermomedics, Inc.* [4]

In the *Brooklands* and *Thermomedics* cases, the district courts held certain claims of the '685 and '398 patents invalid under § 101. In the Kaz case, "Kaz moved for summary judgment, asserting that the *Thermomedics* judgment had preclusive effect." [5] The district court denied the motion and found all asserted claims infringed and not invalid. [6] At trial, the district court did not submit any factual or legal issues to the jury regarding § 101. After trial, the district court denied judgment of invalidity under § 101, relying on the evidence presented at trial, the pleadings of the case, and the guidance of the jury verdict. [7] Kaz appealed, *inter alia*, the district court's denial of its motions with respect to patent validity under §101. [8]

PATENT ELIGIBILITY UNDER 35 U.S.C. § 101

The Federal Circuit panel split 2-1 in holding the claims patent eligible under § 101. The majority remarked that patent eligibility under § 101 is an issue of law reviewed de novo. [9] It then set forth the two-prong test under *Alice* [10] and *Mayo*: [11] (1) whether the claims at issue contain patent-ineligible concept, e.g., a law of nature; [12] and (2) whether they contain an "inventive concept" sufficient to "transform" the claimed abstract idea into a patent-eligible application. Despite § 101 analysis being an issue of law, the Court, held that the inquiry guiding the second prong—whether the claims contain a transformative, inventive concept rather than a well-understood, routine, and conventional activity—is a question of fact. Thus, such findings require clear error review and "deference must be given to the determination made by the fact finder on the issue." [13]

There was "no dispute in this case that the asserted claims employ a natural law to achieve their purpose[.]" namely, "'a method of detecting human body temperature' and 'a body temperature detector' which generally utilize temperature readings from the forehead skin and the ambient temperature to calculate an approximate core body temperature." [14] The dispute was whether the additional claimed steps, beyond calculating the temperature, presented a novel technique in this computation or added an inventive concept sufficient to transform the claims into patent-eligible subject matter. [15]

The district court analogized the present case to *Diamond v. Diehr*, [16] and found that the claimed elements transformed the underlying natural laws into "inventive methods and useful devices that noninvasively and accurately detect human body temperature." [17] Further, the majority was persuaded by the millions of dollars of testing and development over years of research, and that "the inventor determined for the first time the coefficient representing the relationship between temporal-arterial temperature and core body temperature and incorporated that discovery into an unconventional method of temperature measurement." [18]

The Court noted that the asserted claims "each recite a subset of three steps: (1) moving while laterally scanning ('685 patent claims 7, 14, and 17; '938 patent claims 17, 24, 33, 60, and 66); (2) obtaining a peak temperature

reading ('685 patent claim 7; '938 patent claims 60 and 66); and (3) obtaining at least three readings per second ('938 patent claims 17, 24, 39,40, 46, and 49)." [19]

Kaz asserted that these additional elements were known in the prior art but the Federal Circuit held that "simply being known in the prior art did not suffice to establish that the subject matter was not eligible for patenting." [20] "Something is not well understood, routine, or conventional merely because it is disclosed in a prior art reference. There are many obscure references that nonetheless qualify as prior art." [21] "The district court found that though these claim elements may have been known in the art, they were 'previously utilized to detect hot spots indicating injury or tumors, or surface temperature differentials,' not used to solve the problem of detecting arterial temperature beneath the skin." [22] The Federal Circuit also noted that Kaz had the burden of demonstrating whether the claims were routine, conventional, or well-understood in the prior art. [23] The Federal Circuit affirmed the district court on the § 101 issue.

DISSENT

Judge Hughes dissented from the majority's conclusion that the asserted claims were patent eligible. To Judge Hughes, the inventions were directed toward the law of nature that governs the relationship between core body temperature and forehead skin temperature and "begins and ends" with that patent ineligible concept. [24] Judge Hughes believed the novel feature of the inventions was the heat balance equation the inventors identified through empirical testing of the coefficient that governs the relationship between core body and forehead skin temperatures. Thus, Exergen's claimed inventions amounted "to nothing more than an observation of the natural phenomenon" and applying that observation to calculate a person's core body temperature. [25]

As for step two, Judge Hughes would have found that the district court clearly erred by finding the claims embody an inventive concept. He noted that temperature-detecting products that move while laterally scanning over an artery or forehead, obtain a peak temperature reading, and take plural skin temperature measurements per second have existed for decades. He argued that the district court legally erred by using a law of nature to supply an inventive concept. Rather than finding that the claim elements were not routine or conventional, the district court focused on whether those elements were routinely or conventionally *used* to calculate core body temperature. [26] The dissent states that the Federal Circuit had rejected this type of reasoning in *Ariosa*.

CONCLUSION

The opinion is nonprecedential but shows that patent eligibility under § 101 is still a subject of disagreement in the courts. The differing views of the majority and the dissent may arise in future litigation on patent subject matter eligibility. Most notably, the dissent took issue with how the majority analyzed whether the claim elements were transformative and inventive, and not "routine or conventional." Because the Court held that the inquiry into whether the elements involve well-understood, routine, and conventional activity is a question of fact, parties may approach these § 101 issues differently at the district court level, e.g., presenting more factual evidence.

[1] *Exergen Corp. v. Kaz USA, Inc.*, Nos. 2016-2315 and 2016-2341 (Fed. Cir. 2018)

[2] *Exergen Corp. v. Kaz USA, Inc.*, 172 F. Supp. 3d 366 (D. Mass. 2016)

[3] 125 F. Supp. 3d 307, 312–17 (D. Mass. 2015)

[4] 132 F. Supp. 3d 200, 203–208 (D. Mass 2015)

[5] *Kaz*, 2016-2315 and 2016–2341, at 5 (Fed. Cir. 2018)

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.* at 5

[10] *Alice Corp. v. CLS Bank Int'l.*, 132 S. Ct. 2347 (2014)

[11] *Mayo Collaborative Servs v. Prometheus Labs., Inc.*, 132 S. Ct. 1298 (2012)

[12] *Id.* citing *Alice*

[13] *Id.* at 10

[14] *Id.* at 7

[15] *Id.*

[16] 450 U.S. 175 (1981)

[17] *Kaz* 2016–2315 and 2016–2341, at 7–8 (Fed. Cir. 2018)

[18] *Id.* at 11–12

[19] *Id.* at 8

[20] *Id.*

[21] *Id.* at 10

[22] *Id.* at 7

[23] *Id.* at 11 n.4

[24] Hughes Dissent at 2 (quoting *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015))

[25] *Id.* at 4

[26] *Id.* at 7

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