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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/326,045	12/14/2011	John R. Semler	P-76521-US	4002

137540 7590 01/28/2020

Pearl Cohen Zedek Latzer Baratz LLP
Given Imaging Ltd.
1500 Broadway, 12th Floor
New York, NY 10036

EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
01/28/2020	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHN R. SEMLER

Appeal 2019-000298
Application 13/326,045
Technology Center 3700

Before KEVIN F. TURNER, JEREMY M. PLENZLER, and
LEE L. STEPINA, *Administrative Patent Judges.*

STEPINA, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1, 2, 4–10, 12–15, and 17–21. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real parties in interest as Given Imaging Ltd., Covidien Sales LLC, and Medtronic PLC. Appeal Br. 1.

CLAIMED SUBJECT MATTER

The claims are directed to a process for determining the location of an ingested capsule as it transitions between segments of the digestive tract. Spec. ¶ 2. As stated by Appellant, "the general object is to provide a method for determining the movement of an ingestible capsule from a first segment of the gastrointestinal [("GI")] tract to a second segment of the gastrointestinal tract based on pressure and pH." *Id.* ¶ 8.

Claim 1, reproduced below, is illustrative of the claimed subject matter.

> 1. A method of determining a location of an ingested capsule comprising a pH sensor and a pressure sensor, the method comprising the steps of:
>
> recording pH measurements from said pH sensor as a function of time as said capsule moves through at least a portion of a gastrointestinal tract;
>
> recording pressure measurements from said pressure sensor as a function of time as said capsule moves through at least the portion of said gastrointestinal tract;
>
> conditioning the recorded pressure measurements by filtering out sets of data points whose peaks are above or below a predetermined threshold;
>
> detecting contractions from the conditioned pressure measurements, wherein a contraction is detected by an increase in pressure over a baseline pressure and a subsequent return below the baseline pressure;
>
> deriving a frequency of the contractions as a function of time and said pressure measurements; and
>
> determining whether said capsule is at a first position between the ileum and the caecum[2] of said gastrointestinal tract based on a correlation between a variation in said frequency of contractions and a variation in said pH.

[2] The term "caecum" may also be spelled "cecum."

Appeal Br. 22 (Claims App.).

REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
D'Andrea	US 2003/0191430 A1	Oct. 9, 2003
Meron	US 6,950,690 B1	Sept. 27, 2005
Iddan	US 2005/0228308 A1	Oct. 13, 2005
Horn	US 2006/0069317 A1	Mar. 30, 2006
Takizawa	US 7,144,366 B2	Dec. 5, 2006
Catherine J. Pfister et al., *Development of a Three-Channel, 24-h Ambulatory Esophageal Pressure Monitor*, 36 IEEE Transactions on Biomedical Engineering, 487–490, Apr. 1989 (hereinafter "Pfister")		

REJECTIONS

I. Claims 1, 2, 4–10, 12–15, and 17–19 are rejected under 35 U.S.C. § 101 as being directed to a judicial exception without significantly more.

II. Claims 1, 5–7, 13, 14, and 20 are rejected under 35 U.S.C. § 103(a) as unpatentable over Iddan, Pfister, and Horn.

III. Claims 2, 8, 9, 15, 17–19, and 21 are rejected under 35 U.S.C. § 103(a) as unpatentable over Iddan, Pfister, Horn, and Meron.

IV. Claims 4 and 12 are rejected under 35 U.S.C. § 103(a) as unpatentable over Iddan, Pfister, Horn, and D'Andrea.

V. Claim 10 is rejected under 35 U.S.C. § 103(a) as unpatentable over Iddan, Pfister, Horn, and Takizawa.

OPINION

Rejection I–Eligibility (Claims 1, 2, 4–10, 12–15, and 17–19)

In determining that claim 1 recites a judicial exception without significantly more, the Examiner finds that claim 1 is "directed to the abstract idea of determining the location of a swallowable capsule within the gastrointestinal tract based on measured characteristic physiological parameters of the gastrointestinal tract." Final Act. 2. More generally, the Examiner characterizes the steps recited in claim 1 as (i) collecting, analyzing, and manipulating data or (ii) diagnosing an abnormal condition. *See id.* at 2–3. The Examiner concludes that the remaining limitations recited in claim 1, "when considered both individually and as a whole[,] do not amount to significantly more than the abstract idea." *Id.* at 4.

Appellant argues that the method of claim 1 improves the existing technological process of locating an in-vivo capsule. *See* Appeal Br. 12–16. Specifically, Appellant contends that prior art methods of locating such capsules based on detecting radio frequency ("RF") signals, acceleration, and pH levels were less accurate than the method recited in claim 1. *See id.* at 12–13.

In response, the Examiner finds that any improvement provided by the claimed method is merely an improvement to the abstract idea to which claim 1 is directed, not an improvement in technology that transforms the abstract idea into a patent-eligible invention. *See* Ans. 11–12.

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 long interpreted 35 U.S.C. § 101 to include implicit exceptions: "[l]aws of nature, natural phenomena, and abstract

ideas" are not patentable. *E.g.*, *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (internal quotation marks and citation omitted).

In determining whether a claim falls within an excluded category, we are guided by the Supreme Court's two-step framework, described in *Mayo* and *Alice*. *See Alice*, 573 U.S. at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). In accordance with that framework, we first determine what concept the claim is "directed to." *Id.* 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, or protecting against risk.").

Concepts determined to be abstract ideas, and, thus, patent ineligible, 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, 67 (1972)). Concepts determined to be patent eligible include physical and chemical processes, such as "molding rubber products" (*Diamond v. Diehr*, 450 U.S. 175, 191 (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 (1853))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

If the claim is "directed to" an abstract idea, we turn to the second step of the *Alice* and *Mayo* framework, where "we must 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 (internal citation 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.* (alteration in the original) (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.*

In January of 2019, the PTO published revised guidance on the application of § 101. 2019 REVISED PATENT SUBJECT MATTER ELIGIBILITY GUIDANCE, 84 Fed. Reg. 50 (Jan. 7, 2019) (hereinafter "Memorandum"). Under Step 2A of that guidance, we first look to 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* MANUAL OF PATENT EXAMINING PROCEDURE ("MPEP") §§ 2106.05(a)–(c), (e)–(h) (9th Ed., Rev. 08.2017, 2018)).

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look, in Step 2B, to whether the claim:

> (3) adds a specific limitation beyond the judicial exception that is not "well-understood, routine, conventional" 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 Memorandum.

Step 1 – Statutory Category

Claim 1 recites "[a] method of determining a location of an ingested capsule" (Appeal Br. 22 (Claims App.)), and, therefore, falls into the *process* category of statutory subject matter.

Step 2A, Prong 1 – Recitation of Judicial Exception

Claim 1 also recites, in part, "recording pressure measurements from [a] pressure sensor as a function of time[, and] conditioning the recorded pressure measurements by filtering out sets of data points whose peaks are above or below a predetermined threshold." *Id.* Conditioning data by excluding high and low points is an evaluation that can be performed in the human mind, or with pen and paper. *In re BRCA1 & BRCA2-Based Hereditary Cancer Test Pat. Litig.*, 774 F.3d 755, 763 (Fed. Cir. 2014) (concluding that the concept of "comparing BRCA sequences and determining the existence of alterations" is an "abstract mental process"); *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1350 (Fed. Cir. 2014) (finding that "a process of organizing information through mathematical correlations" is an abstract idea). Thus, the conditioning step

of claim 1 is a mental process, which is one of the groupings of abstract ideas identified in the Memorandum.

The outcome of our analysis under Step 2A, Prong 1, requires us to proceed to Step 2A, Prong 2. *See* Memorandum, 84 Fed. Reg. at 54.

Step 2A, Prong 2 – Integrated Into a Practical Application

In Step 2A, Prong 2, we determine whether the recited judicial exception is integrated into a practical application of that exception by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception(s); and (b) evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application. *See* Memorandum. This evaluation requires an additional element or a combination of additional elements in the claim to apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the exception. *See id.*

One way the claim may integrate the exception into a practical application is by improving another technology or technical field (*see Alice*, 573 U.S. at 225; Memorandum, 84 Fed. Reg. at 55), and, as noted above, Appellant argues that the method recited in claim 1 provides such an improvement (Appeal Br. 12–16; Reply Br. 3–4). Specifically, Appellant refers to paragraphs 4, 5, and 35 of the Specification as supporting a finding that, as compared to prior art methods, the method recited in claim 1 provides a more accurate result in detecting the location of the ingested capsule. Appeal Br. 12–13; Reply Br. 3.

Discussing prior art processes, paragraph 4 of the Specification explains that the using RF signals to detect ingested capsules may require multiple antennas and that the results of tracking via RF may be impacted by patient movement and by the type of bodily tissue surrounding the capsule. The Specification also teaches that accelerometers may be used to determine capsule location, "but such methods also have disadvantages, such as drift, non-linear progression and rotational inaccuracy." Spec. ¶ 4. Paragraph 5 of the Specification discusses prior art detection of ingested capsules via pH measurement and explains that one drawback to such a method is that "often there are not significant pH variations correlated with certain regions of the gastrointestinal tract, and patients with gastrointestinal maladies may have abnormal readings." The Specification further discloses that the use of pH and pressure measurements, in combination, to locate an ingested capsule improves accuracy by reducing errors in detection created by changes in pH caused by bacterial overgrowth. Spec. ¶ 37.

The Federal Circuit addressed the patent-eligibility of a similarly claimed tracking method in *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017) and determined that the claims were "directed to a new and useful technique for using sensors to more efficiently track an object on a moving platform," and, therefore, not directed to an abstract idea. *Thales*, 850 F.3d 1349. We reproduce the method claim at issue in *Thales* below.

> 22. A method comprising determining an orientation of an object relative to a moving reference frame based on signals from two inertial sensors mounted respectively on the object and on the moving reference frame.

Id. at 1345–1346. Finding that claim 22 in Thales was directed to an improvement of a technology, the court said, "[j]ust as claims directed to a new and useful technique for defining a database that runs on general-purpose computer equipment are patent eligible . . . so too are claims directed to a new and useful technique for using sensors to more efficiently track an object on a moving platform." *Id.* at 1349.

Like claim 22 in *Thales*, claim 1 on appeal recites a method of determining a position of a physical object using measurements from two different sensors (two inertial sensors in *Thales*—a pH and a pressure sensor in claim 1). In *Thales*, the court found that the recited method used "inertial sensors in a non-conventional manner *to reduce errors in measuring the relative position* and orientation of a moving object on a moving reference frame." *Id.* at 1348–1349 (emphasis added). Like the claim at issue in Thales, the method recited in claim 1 is directed to providing more accurate location information. *See* Spec. ¶¶ 4, 5, and 37. In light of the similarities between patent-eligible claim 22 in Thales and claim 1 on appeal, we agree with Appellant that claim 1 is directed to an improvement in technology. Accordingly, claim 1 integrates the recited mental process into a practical application, and, therefore, claim 1 is not *directed to* an abstract idea. Consequently, we do not sustain the rejection of claim 1, and claims 2 and 4–6 depending therefrom, under 35 U.S.C. § 101, and we need not proceed to step 2B (*see* Memorandum). Independent claims 7 and 15 are substantially similar in scope to claim 1, and, for the same reasons, we do not sustain the rejection of claims 7 and 15 and associated dependent claims 8–10, 12–14, and 17–19.

Rejection II–Iddan, Pfister, Horn (Claims 1, 5–7, 13, 14, and 20)

Appellant argues for the patentability of the claims subject to Rejection II, as a group. Appeal Br. 20. We select claim 1 as representative of the group, and claims 5–7, 13, 14, and 20 stand or fall with claim 1.

The Examiner relies on Iddan to disclose many of the steps recited in claim 1, including recording pH measurements as a function of time and detecting contractions, and relies on Pfister to teach the step of conditioning recorded pressure measurements. Ans. 15 (citing Iddan ¶¶ 29, 30, 33, 34, 40, 42, 43, 55; Pfister 13–14). The Examiner finds that Iddan and Pfister "fail to disclose a step of deriving a frequency of the contractions as a function of time and said pressure measurements." *Id.* at 16.

To address this deficiency, the Examiner turns to Horn, finding this reference teaches "peristaltic contractions that may occur naturally in the GI tract may occur in different frequencies and/or with durations in different organs in the GI tract . . . may be used to identify a location in the GI tract." *Id.* (citing Horn ¶ 25). The Examiner also finds that Horn discloses using image data (which incorporate the frequency data) and other data to determine the location of the in-vivo capsule. Ans. 15–19 (citing Horn ¶¶ 20, 23, 25; Fig. 2). The Examiner finds that the data other than image data may include pH measurements. *See id.* at 17–18. Thus, the Examiner finds that Horn discloses the use both of the frequency of peristaltic contractions and pH measurements in order to determine location within the GI tract.

Appellant argues that Horn fails to disclose or suggest deriving a frequency of contractions as a function of time and pressure measurements.

Appeal Br. 17–19.[3] Specifically, Appellant contends, "*at most* Horn (at paragraph [0025]) discloses determining contractile activity based on a variation in *image intensity*, which is not the same as 'deriving a *frequency* of the contractions *as a function of* time and *said pressure measurements*', as recited in independent claim 1." *Id.* at 20. Appellant argues "Horn, para. [0025], merely teaches a vague relationship between contraction frequency, image intensity, and location. This cannot teach or suggest the more precise relationship between variation in contraction frequency and location, as claimed. No frequency as such is derived in Horn, para. [0025]." Reply Br. 5.

The Examiner has the better position on this point. Paragraph 25 of Horn states "the peristaltic contractions that may occur naturally in the GI tract may occur in different frequencies and/or with durations in different organs in the GI tract[, and] . . . specific regions in the GI tract may have characteristic frequency patterns of contractile activity." Accordingly, Horn teaches that different frequencies of peristaltic contractions correspond to different parts of the GI tract. Horn further teaches that this frequency data is conveyed as image intensity. "Contractile activity may result, for example, in a change of intensity of image frames." *Id.* Horn further explains that this change in image intensity is used to determine the location of the in-vivo capsule. "[A] change in a pattern of intensity levels, or an event in the pattern of intensity levels may be used to detect transition from one region in the GI tract to another." *Id.* Thus, Horn uses the frequency of

[3] Appellant does not contest the Examiner's rationale for making the proposed modification to the process disclosed by Iddan. *See* Appeal Br. 17–21.

contractions, *communicated based on image intensity*, to determine the location of the in-vivo capsule. The fact that the frequency of contractions is conveyed in the form of a change in intensity of image frames does not undermine the Examiner's finding that Horn teaches using the frequency to identify a location in the GI tract. Rather, a person of ordinary skill in the art would understand that because Horn teaches that certain frequencies of contractions correspond to particular parts of the GI tract, and Horn determines location based on these frequencies, Horn must determine what the frequencies are in order to produce the proper change in intensity of image frames. Accordingly, a preponderance of the evidence supports the Examiner's finding that Horn meets the "deriving a frequency of the contractions as a function of time and said pressure measurements" requirement in claim 1.

Appellant asserts, "Horn does not disclose utilizing 'a variation in said pH', let alone correlating 'a variation in said pH' and 'a variation in said frequency of contractions.'" Appeal Br. 19.

Appellant's argument regarding the failure of Horn to disclose using a variation in pH is unavailing inasmuch as Horn explicitly discloses the use of pH variation to determine the location of an in-vivo capsule. [4] Horn ¶¶ 23, 27.

Appellant next argues "Horn does not disclose or suggest 'determining whether said capsule is at a first position between the ileum and the caecum of said gastrointestinal tract based on a correlation between

[4] The Examiner also finds that paragraph 5 of Appellant's Specification admits that pH levels have been correlated with transitions from the stomach to the small bowel and from the distal small bowel to the colon. Ans. 24.

a variation in said frequency of contractions and a variation in said pH', as recited in independent claim 1." Appeal Br. 19. In this regard, Appellant argues "considering any two of pixel parameters, structure related parameters, or sensor parameters such as pH or temperature is not the same as 'a correlation between a variation in said frequency of contractions and a variation in said pH.'" *Id.*

In response, the Examiner interprets the term "correlation" as recited in claim 1, stating, "Appellant's [S]pecification does not provide nor refer to any mathematical function to compute a correlation but merely refers to a comparison of the *simultaneous changes* in the graphs of the respective variables (i.e.[,] any two of pH, pressure, and frequency of contractions) to corroborate the location of the capsule." Ans. 23 (emphasis added). In light of this interpretation, the Examiner finds the simultaneous use of two distinct parameters (a variation in said frequency of contractions and a variation in said pH) to determine the location of the in-vivo capsule in Horn amounts to using a correlation between these parameters.

In reply, Appellant argues "Horn merely states that a confidence level of a transition between GI tract regions increases when more than one parameter indicates a shift in value at the same time or location: this cannot teach or suggest the correlation of the specific parameters claimed." Reply Br. 6.

We agree with the Examiner that the use of the determination of a variation in pH *in combination with* a determination of a variation in a frequency of contractions amounts to using a correlation between these two parameters. Appellant's Specification states, "[b]y basing location on both pH and pressure patterns, one can more accurately determine the movement

of ingested capsule 20 from one segment of the gastrointestinal tract to a second segment of the gastrointestinal tract of a subject." Spec. ¶ 35. The Specification further explains, "[i]n comparing patterns from a subject with the reference templates for both pH and pressure, if there is a correlation between a variation in pH B and a variation in frequency of contractions D and/or motility index F, then a determination of the capsule's location may be more accurate" and "[w]ithout this correlation, the capsule being located at or near the ileo-caecal junction is less certain." *Id.* Thus, like the use of variation in pH and contraction frequency disclosed by Horn, Appellant's determination of a "correlation" amounts to determining where both parameters provide an indication of a particular location, thus enhancing the likelihood of an accurate determination of location in the GI tract. Accordingly, the Examiner's interpretation of the term "correlation" is consistent with Appellant's Specification, and the Examiner properly applied this interpretation in finding that Horn discloses basing its determination on a correlation between parameters, as claimed.

As for the determining that the capsule is located in a "first position between the ileum and the caecum," the Examiner states:

> Since pH has been correlated with two transitions in the gastrointestinal tract (e.g.[,] the transition between the stomach and the small bowel and the transition between the small bowel and the colon), in using pH to determine the location of a capsule as taught by Horn et al. (see at least par 0022-0023 & 0027), Horn et al. clearly teach a method comprising determining whether a capsule is at the ilea-caecal transition (i.e.[,] a first position between the ileum and the caecum) of said gastrointestinal tract based on a variation (i.e.[,] noticeable/significant change) in said pH.

Ans. 27.

Horn states "[t]he confidence level that a transition from one region to another, e.g., a transition from the *small intestine to the cecum* occurred and/or that an event was identified may be determined (**206**)." Horn ¶ 29 (emphasis added). Horn also describes using a change in color or pixel value to determine a transition from the small bowel to the large intestine. *See id.* ¶ 34. Horn explains, "[a]rrival to a specific location, for example, the *cecum* may be identified." *Id.* ¶ 23 (emphasis added). Thus, the Examiner's finding that Horn teaches determining whether a capsule is in a position between the ileum and the caecum is supported by a preponderance of the evidence.

We have considered all of Appellant's arguments in support of the patentability of claim 1, but find them unavailing. Accordingly, we sustain the rejection of claim 1. Claims 5–7, 13, 14, and 20 fall with claim 1.

Rejections III–V— Iddan, Pfister, Horn, Meron, D'Andrea, Takizawa (Claims 2, 4, 8, 9, 10, 12, 15, 17–19, and 21)

Appellant does not make arguments for the patentability of claims 2, 4, 8, 9, 10, 12, 15, 17–19, and 21 aside from those discussed above regarding claim 1. *See* Appeal Br. 20–21. Accordingly, for the same reasons, we sustain the rejections of claims 2, 4, 8, 9, 10, 12, 15, 17–19, and 21 (Rejections III–V).

CONCLUSION

The Examiner's rejections are affirmed.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1, 2, 4–10, 12–15, 17–19	101	Eligibility		1, 2, 4–10, 12–15, 17–19
1, 5–7, 13, 14, 20	103(a)	Iddan, Pfister, Horn	1, 5–7, 13, 14, 20	
2, 8, 9, 15, 17–19, 21	103(a)	Iddan, Pfister, Horn, Meron	2, 8, 9, 15, 17–19, 21	
4, 12	103(a)	Iddan, Pfister, Horn, D'Andrea	4, 12	
10	103(a)	Iddan, Pfister, Horn, Takizawa	10	
Overall Outcome			1, 2, 4–10, 12–15, 17–21	

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

AFFIRMED