UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/043,665	03/09/2011	Richard A. Willyard	H-EB-00285 (1544-203)	9294

90039 7590 01/17/2019

Covidien LP
Attn: IP Legal
5920 Longbow Drive
Mail Stop A36
Boulder, CO 80301-3299

EXAMINER	
HUPCZEY, JR, RONALD JAMES	

ART UNIT	PAPER NUMBER
3794	

NOTIFICATION DATE	DELIVERY MODE
01/17/2019	ELECTRONIC

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

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mail@cdfslaw.com
rs.patents.two@medtronic.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RICHARD A. WILLYARD and JOSEPH D. BRANNAN

Appeal 2018-002665
Application 13/043,665[1]
Technology Center 3700

Before LINDA E. HORNER, MICHAEL J. FITZPATRICK, and JILL D. HILL, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants seek our review under 35 U.S.C. § 134(a) of the Examiner's rejections of claims 1–5, 7–9, 11, and 17–20, which are all of the pending claims. Final Office Action (March 6, 2017) ("Final Act."). We have jurisdiction under 35 U.S.C. § 6(b).

---

[1] Appellants identify Covidien LP, which is a wholly-owned subsidiary of Medtronic PLC, as the real party in interest. Appeal Brief (August 14, 2017) ("Appeal Br."), at 2.

The Examiner rejected the pending claims as unpatentable over various combinations of the prior art. Appellants seek reversal of the rejections because the Examiner relied on an unreasonably broad interpretation of the claim language in order to find the claimed subject matter in the prior art. For the reasons explained below, we agree with Appellants that the Examiner's claim interpretation is unreasonably broad, and that under the correct interpretation, the Examiner has not shown that the prior art discloses the claimed subject matter. Thus, we REVERSE.

CLAIMED SUBJECT MATTER

The claimed subject matter relates to methods of directing energy to tissue using electrosurgical devices including systems for thermal-feedback-controlled rate of fluid flow to a fluid-cooled antenna assembly. Specification (March 9, 2011) ¶ 1. Claims 1 and 9 are independent. Claim 1, reproduced below with the disputed limitations italicized for emphasis, is illustrative of the subject matter on appeal.

> 1. A method of directing energy to tissue by using a fluid-cooled antenna assembly of an energy applicator, the method comprising:
>
> connecting the energy applicator to a hub, the hub coupled to a coolant supply system for providing fluid to the antenna assembly of the energy applicator, the coolant supply system having a coolant source, a first coolant supply line, a second coolant supply line, and a third coolant supply line in fluid communication with the coolant source, the first coolant supply line connected between the coolant source and a fluid-movement device, the second coolant supply line directly connected between a pressure transducer and the fluid-movement device, and the third coolant supply line directly connected between a flow-control device and the antenna assembly;
>
> positioning the energy applicator in tissue;

activating the energy applicator via an electrosurgical generator;

measuring a temperature of the fluid in the antenna assembly;

controlling a thermal-feedback-controlled rate of fluid flow based on the measured temperature of the fluid in the antenna assembly;

providing fluid to the antenna assembly at the thermal-feedback-controlled rate of fluid flow using a feedback control system including the flow-control device, the flow control device including a valve and an electro-mechanical actuator, and the feedback control system including a processor unit; and

connecting the pressure transducer to the valve, the pressure transducer disposed within the coolant supply system;

wherein *the pressure transducer outputs a signal at a pressure below a burst pressure of a pressure relief valve to indicate to the electrosurgical generator that the fluid-cooled antenna assembly has coolant flowing therethrough* and wherein the processor unit triggers a shut-off of the electrosurgical generator based on pressure levels of the coolant in the fluid-cooled antenna assembly; and

wherein the processor unit outputs a signal indicative of an error code if a predetermined time elapses between energy delivery to the fluid-cooled antenna assembly and detection of the signal outputted by the pressure transducer.

Corrected Appeal Brief (September 14, 2017) at 19–20 (Claims Appendix).

EVIDENCE

Rudie	US 5,300,099	Apr. 5, 1994
Eshel	US 7,018,398 B2	Mar. 28, 2006
Gharib	US 7,255,680 B1	Aug. 14, 2007
Bek et al.	US 7,422,587 B2	Sept. 9, 2008
Elmouelhi et al.	US 2008/0269737 A1	Oct. 30, 2008
Gellman	US 2009/0082837 A1	Mar. 26, 2009
Watson	US 8,187,261 B2	May 29, 2012
Subramaniam	US 8,702,693 B2	Apr. 22, 2014

REJECTIONS

The Final Office Action includes the following rejections:

1. Claims 1–3, 5, 9, 17, 19, and 20 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bek, Watson, Elmouelhi, and Subramaniam.
2. Claim 4 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bek, Watson, Elmouelhi, Subramaniam, and Eshel.
3. Claim 7 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bek, Watson, Elmouelhi, Subramaniam, and Gellman.
4. Claims 8 and 11 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bek, Watson, Elmouelhi, Subramaniam, and Gharib.
5. Claim 18 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bek, Watson, Elmouelhi, Subramaniam, and Rudie.

ANALYSIS

First Ground of Rejection

In the rejection of claim 1, the Examiner found that Bek discloses substantially all of the recited method steps, including using a fluid-cooled antenna assembly having a pressure transducer connected to a valve within a coolant supply system. Final Act. 3–4. The Examiner found that Bek fails to disclose, among other limitations, a shut-off function based on pressure levels of the coolant and output of a signal indicative of an error code if a predetermined time elapses between energy delivery and detection of the signal outputted by the pressure transducer. *Id.* at 4–5. The Examiner found that Elmouelhi teaches detecting flow issues using a pressure sensor and performing a shut-off of ablation therapy in response to such issues. *Id.* at 6 (citing Elmouelhi ¶¶ 25, 28, 96). The Examiner determined that it would have been obvious to use this shut-off functionality in Bek, and that in providing such a combination, Bek's method would be modified to check that fluid is flowing within the system by sensing the pressure after a given amount of time from when the energy is delivered by the generator and, if an issue exists, shutting off the generator. *Id.* (citing Elmouelhi ¶¶ 31–36). The Examiner made similar findings about the subject matter of independent claim 9. *Id.* at 8–12.

Appellants argue that the Examiner erred in this first ground of rejection because Elmouelhi does not describe issuing an error code based on "the elapsing of a time period." Appeal Br. 9. Appellants assert that checking fluid flow at some point after energy delivery to detect an error is not equivalent to outputting an error code "if a predetermined amount of time elapses between energy delivery and detection of a pressure transducer signal." *Id.* at 10 (emphasis omitted). As an example, Appellants explain that if Elmouelhi's system checks fluid flow at time *T* after energy delivery and does not detect a fluid problem, the system would not issue an error signal, but if the system detects a fluid problem at time *T*, the system would issue an error signal. *Id.* Appellants argue that this example shows that "the error signal in Elmouelhi has nothing to do with elapse of time." *Id.* By contrast, according to Appellants, the system of claim 1 would output an error code if time period *T* elapses between energy delivery and detection of a pressure transducer signal. *Id.*

The Examiner rejects Appellants' argument as based on an unduly narrow interpretation of "predetermined time" because the disclosure "does not give any insight as to how the time is 'predetermined', a specific start or end point for the time that has 'elapsed', or if any specific amount is required to elapse as the 'predetermined time' between the energy delivery and detection." Examiner's Answer (November 17, 2017) ("Ans."), at 4. The Examiner explains that "an amount of time (a 'predetermined time') would necessarily have to elapse between energy delivery and the detection of a signal as in Elmoulhi [sic] by the pressure transducer before an error code would be outputted by the processor unit." *Id.* at 5. The Examiner thus interprets "predetermined time" as "the time between energy delivery and the detection of a signal by the pressure transducer indicative of an error within the fluid system." *Id.*

Appellants reply that the Examiner's interpretation of "predetermined time" as referring to the elapse of any amount of time is unreasonably broad because it "reads the word 'predetermined' out of the claims." Reply Brief (January 17, 2018) ("Reply Br."), at 2.

We look to Appellant's Specification to discern the broadest reasonable interpretation of "predetermined time" as that phrase would be understood by one of ordinary skill in the art in light of the Specification. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) (The Office "determines the scope of claims . . . not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.'") (quoting *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004)). Appellants' Specification describes that processor unit 82 may be configured to output a signal indicative of an error code "if a certain amount of time elapses between the point at which energy delivery to the probe 100 is enabled and when the pressure signal is detected, e.g., to ensure that the fluid-movement device 60 is turned on and/or that the probe 100 is receiving flow of fluid before the antenna assembly 112 can be activated." Spec. ¶ 51. We understand this description to mean that the system senses a pressure signal, at predetermined elapsed time *T* after enabling delivery of energy to probe 100, and issues an error code if no pressure signal is sensed at this predetermined time. In other words, the system infers a problem with fluid-movement device 60 and/or flow control device 50 if pressure sensor 70 does not detect fluid flow at a predetermined elapsed time after enabling delivery of energy to the probe.

The Specification further describes this self-check as follows:

> Electrosurgical system 10 may be adapted to override PWM control of the flow-control device 50 to hold the valve 52 open upon initial activation of the antenna assembly 112. For this purpose, a timer may be utilized to prevent the control device 50 from operating for a predetermined time interval (e.g., about one minute) after the antenna assembly 112 has been activated. In some embodiments, the predetermined time interval to override PWM control of the flow-control device 50 may be varied depending on setting, e.g., time and power settings, provided by the user. In some embodiments, the electrosurgical power generating source 28 may be adapted to perform a self-check routine that includes determination that the flow-control device 50 is open before enabling energy delivery between the electrosurgical power generating source 28 and the probe 100.

Id. ¶ 74. Because pressure sensor 70 resides between fluid movement device 60 and flow control device 50 and downstream of pressure relief valve, if fluid movement device 60 were operating and flow control device 50 were not opened, pressure sensor 70 would not sense a pressure signal below burst pressure after an elapsed predetermined time because once the pressure rises above a burst pressure of the pressure relief valve, the pressure relief valve would open and allow the fluid from fluid movement device 60 to bypass pressure transducer 70. As claimed, if after a predetermined time elapses from energy delivery, pressure transducer has not outputted a signal at a pressure below a burst pressure of a pressure relief valve, then the system is programmed to infer that fluid is not reaching the antenna assembly, either because fluid movement device 60 is not turned on or because flow control device 50 is not open.

Thus, Appellants' Specification provides an example in which the valve of the flow control device is opened for a predetermined time period (e.g., one minute) after delivery of energy to the device to ensure that fluid is flowing properly to the fluid-cooled antenna assembly. We interpret "predetermined time" in light of the description in the Specification to mean a preset amount of time, such that the system looks for an error after a preset amount of time elapses after delivery of energy to the device. Contrary to the Examiner's position, Appellants' Specification explains generally how this predetermined time is set. Spec. ¶ 74 (describing that the predetermined time that the valve remains open for conducting the self-test may be varied depending on time and power settings provided by the user). We agree with Appellants that the Examiner's interpretation of "predetermined time" to encompass any amount of time after delivery of energy to the device is unreasonably broad in light of the claim language itself and the description provided in Appellants' Specification.

Turning to the prior art, Elmouelhi does not teach taking a predetermined elapsed time into account in determining if an error has occurred. Elmouelhi's system uses a sensor to measure actual flow rate of a cooling fluid to a patient via a catheter. Elmouelhi ¶¶ 33, 34. Elmouelhi describes that the sensor may be positioned between a generator (e.g., fluid pump) and the target tissue and may detect the pressure of the fluid as it flows through a tube. *Id.* ¶ 34. Elmouelhi describes that a low pressure reading may indicate for example that the fluid pump is malfunctioning, and in such case, the generator may provide an error message. *Id.* Elmouelhi describes that "[i]n some embodiments, the therapy delivered to patient 12 is automatically stopped in response to an irregular pressure reading." *Id.*

Although Elmouelhi's system checks to see if the appropriate amount of cooling fluid is flowing through the system, it performs this check differently from the manner claimed. Elmouelhi does not take into account whether a predetermined time has elapsed between energy delivery to system and detection of a signal from a pressure transducer. Rather, Elmouelhi's sensor tests continuously for a pressure that fails to match the expected pressure at the target flow rate. Elmouelhi ¶ 36 ("In some embodiments, the sensor provides constant feedback to generator 14 and adjustments to the therapy parameters are made based on that feedback").

For this reason, we find that the Examiner based the rejection on an unreasonably broad interpretation of the claim language to find that the prior art discloses all the limitations of the independent claims. Thus, we do not sustain the rejection of independent claims 1 and 9, and their dependent claims 2, 3, 5, 17, 19, and 20, as unpatentable over Bek, Watson, Elmouelhi, and Subramaniam.

Second through Fifth Grounds of Rejection

The remaining grounds of rejection of dependent claims 4, 7, 8, 11, and 18 depend on the same erroneous claim interpretation of independent claims 1 and 9. Thus, for the same reasons discussed above, we also do not sustain the second through fifth grounds of rejection.

DECISION

The decision of the Examiner rejecting claims 1–5, 7–9, 11, and 17–20 is reversed.

REVERSED