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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 ULRICH KATSCHER, OLIVER LIPS,
CHRISTIAN FINDEKLEE, CHRISTOPH LEUSSLER,
KAY NEHRKE, DANIEL WIRTZ,
and JOHANNES ADRIANUS OVERWEG

_____

Appeal 2019-001667
Application 13/521,228
Technology Center 3700

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Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1] under 35 U.S.C. § 134 involving claims to a therapeutic apparatus. The Examiner rejected the claims as failing to comply with the written description requirement and as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm the obviousness rejections, but designate our affirmance as a new ground of rejection.

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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 Party in Interest as Koninklijke Philips N.V. (*see* App. Br. 1).

Statement of the Case

Background

"In radiation therapy, ionizing radiation is used to selectively destroy regions of tissues within the body of a subject. Radiation therapy is typically used to kill cancerous tumors" (Spec. 1:6–8). "A difficulty with radiation therapy is that the ionizing radiation may cause damage to healthy tissue that lies along the path of the ionizing radiation" (Spec. 1:9–10).

Appellant's "invention relates to a radiation therapy system . . . with magnetic resonance guiding" (Spec. 1:2–3). "Controlling the heating of tissue using the tissue heating system with the magnetic resonance thermometry data allows more accurate heating of tissue and reduces the likelihood of damaging healthy tissue" (Spec. 4:11–13).

The Claims

Claims 1, 23–34 and 36–41 are on appeal. Claim 1 is reproduced below, reformatted with bracketed letters to aid in identifying elements during the discussion below:

1. A therapeutic apparatus comprising:

[a] a magnetic resonance imaging system configured to repeatedly acquire magnetic resonance thermometry data and image data from nuclei of a subject located within an imaging volume;

[b] a tissue heating system configured to heat a heated volume, the heated volume being within and smaller than the imaging volume;

[c] a radiation therapy system configured to irradiate a selected irradiation volume of the subject, the irradiation volume being within and smaller than the heated volume; and

[d] a controller configured to control the magnetic resonance imaging system, the tissue heating system and the

radiation therapy system according to a control plan, wherein the controller is configured to:

[d][i] receive a treatment plan,

[d][ii] reconstruct the acquired magnetic resonance image data into images of a portion of a subject in the imaging volume,

[d][iii] register at least one of the magnetic resonance images with the treatment plan,

[d][iv] control the tissue heating system to heat the heating volume,

[d][v] acquire magnetic resonance thermometry data repeatedly during the heating of the heated volume and processing the magnetic resonance thermometry data into magnetic resonance thermal maps,

[d][vi] in response to the thermal maps indicating that the heated volume exceeds a first temperature, controlling the radiation therapy system to irradiate the irradiation volume,

[d][vii] during the irradiating, control the magnetic resonance image system to repeatedly acquire the magnetic resonance thermometry data and the magnetic resonance image data,

[d][viii] during the irradiating, repeatedly process the magnetic resonance thermometry data into the thermometry maps and the magnetic resonance image data into the images,

[d][ix] in response to the images showing motion of the subject, control the radiation therapy system to shift the irradiating zone to compensate for the motion of the subject such that the selected irradiation volume continues to be irradiated as the subject moves,

[d][x] in response to a region of the subject outside of the heated volume and within the imaging volume exceeding a second temperature which second temperature is a temperature difference below the first

> temperature, controlling the irradiation system to stop irradiating the irradiation volume and the tissue heating system to stop heating the heating region.

The Issues[2]

A. The Examiner rejected claims 1, 23–34 and 36–41 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Final Act. 2).

B. The Examiner rejected claims 1, 23–25, 30, 32–34, 36, and 40 under 35 U.S.C. § 103(a) as obvious over Myhr[3] and Röll[4] (Final Act. 3–5).

C. The Examiner rejected claims 26 and 37 under 35 U.S.C. § 103(a) as obvious over Myhr, Röll, Zhu, and Govind[5] (Final Act. 5).

D. The Examiner rejected claims 31 and 41 under 35 U.S.C. § 103(a) as obvious over Myhr, Röll, and Avinash[6] (Final Act. 5–6).

E. The Examiner rejected claim 27 under 35 U.S.C. § 103(a) as obvious over Myhr, Röll, and Maki[7] (Final Act. 6).

F. The Examiner rejected claims 28, 29, 38, and 39 under 35 U.S.C. § 103(a) as obvious over Myhr, Röll, Maki, and Skliar[8] (Final Act. 6–7[9]).

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[2] We appreciate that the Examiner withdrew the obviousness rejections in the Advisory action and then reinstated them as a new ground in the Examiner's Answer without the required signature of a TC Director (*see* MPEP § 1207.03(I)). Because our reasoning differs from that of the Examiner, we will designate our affirmance as a New Ground.
[3] Myhr, WO 2008/152411 A1, published Dec. 18, 2008.
[4] Röll et al., DE 102007060189 A1, published Feb. 19, 2009.
[5] Govind et al., US 5,690,109, issued Nov. 25, 1997.
[6] Avinash et al., US 2005/0113673 A1, published May 26, 2005.
[7] Maki et al., US 2005/0070961 A1, published Mar. 31, 2005.
[8] Skliar et al., US 2011/0137147 A1, published June 9, 2011.
[9] Although the Examiner rejected claim 29 separately from claims 28, 38, and 39 both rejections relied on the same set of references. Therefore, we

A. 35 U.S.C. § 112, first paragraph

The Examiner asserts that "[i]t is unclear as to what values are used for the first and second temperatures or how they are determined. The specification merely discloses a temperature difference between the first temperature and the second temperature. Applicant fails to provide any guidance used by one skilled in the art to make such determinations" (Final Act. 2).

Appellant responds:

> One of skill in the art of radiation therapy understands typical temperatures that are used in radiation therapy to kill tumor cells without harming surrounding healthy cells. All the claims require is that the second temperature (i.e., at which irradiation is stopped) is *below* the first temperature (i.e., at which irradiation is started). In addition, threshold values, for example temperature values, are known in the art.

(App. Br. 8).

We are not persuaded by the Examiner's position. We first note that the issue addressed by the Examiner appears to be enablement, not written description. There is express support for the language added to claim 1 in the Specification (*see* Spec. 6, second paragraph). The Examiner provides no evidence or persuasive reasoning that Appellant was not in possession of the temperature limitations recited in claim 1. Moreover, the Examiner does not establish that claim 1 is not enabled by the Specification.

> [T]he question of undue experimentation is a matter of degree. The fact that some experimentation is necessary

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address the Examiner's rejection of claims 28, 29, 28, and 39 as a single rejection.

> does not preclude enablement: what is required is that the amount of experimentation "must not be unduly extensive."

PPG Indus. Inc. v. Guardian Indus. Corp, 75 F.3d 1558, 1564 (Fed. Cir. 1996). The Examiner cites no evidence that selection of temperatures would have been unpredictable in any way or that anything other than routine experimentation would have been required to use the recited temperatures.

Accordingly, we reverse the rejection under 35 U.S.C. § 112, first paragraph.

B. 35 U.S.C. § 103(a) over Myhr and Röll

The Examiner finds that "Myhr discloses a therapy apparatus as described above but fails to disclose the operation of the radiation therapy system as set forth" in claim 1 (Ans. 4). The Examiner finds Röll teaches "a therapy apparatus that combines MRI, a tissue heating system and a radiation therapy system" (*id.*). The Examiner finds Röll teaches "controlling the irradiation of the target volume in accordance with the control of temperature and expansion of areas with increased temperature" and "that the aim is to avoid an increase of the temperature outside the target volume" (*id.*).

The Examiner finds it obvious "to have modified Myhr such that the irradiation is controlled based on the temperatures detected in both the imaging region and the irradiation volume in order to achieve the desired effect without harming healthy tissue" (Ans. 4).

The issue with respect to this rejection is: Does a preponderance of the evidence of record support the Examiner's conclusion that Myhr and Röll render the claims obvious?

Findings of Fact

1. Myhr teaches, regarding element (a) of claim 1, that "[u]sing an MRI machine for monitoring enables spatial monitoring and mapping of the region of interest, i.e. providing maps or gradients of pO_2, temperature, pH and/or CO_2 in a region of interest. The MRI machine can also monitor as a function of time by taking repeated measurements" (Myhr 7).

2. Myhr teaches, regarding element (b), that "[a]n electromagnetic energy source may be a standalone component of the system" (Myhr 8) and that mapping "data can be used to either correct the focus of the energy source which is applying the hyperthermia" (Myhr 7).

3. Myhr teaches, regarding element (c), "other applied treatment modalities such as radiotherapy. . . . The direction and focus of the radiotherapy and/or chemotherapy can then be altered so as to target those areas where the treatment will be effective, without applying the toxic treatments to regions which will not benefit from that treatment" (Myhr 14–15).

4. Myr teaches, regarding element (d), that:

> the computation unit is connected to the energy source or further treatment modality so as to be able to control the energy source or further treatment modality. By using the calculated data as a feedback mechanism connected to the energy source or treatment modality, better control of the treatment can be carried out. For example, the focus of the energy source can be monitored by spatially detecting temperature increases. If the spatially detected increases are not sufficiently coincident with the region of interest, the direction of the energy source can be corrected. Similarly, if the temperature increases are not high enough or are too high, the focus and/or intensity of the energy source can be adjusted to increase or decrease the hyperthermia. The direction

> and/or focus of a further treatment modality can also be adjusted or corrected in a similar manner.

(Myhr 9).

> 5. Myhr teaches, regarding elements (d)(i) and (d)(ii), that:
>
> [b]y modelling [sic]the region of interest (e.g. a tumor) before treatment, i.e. spatially [sic] mapping tissue in the region of interest (which can be done via a variety of techniques including MRI and CT scans) and mapping the location of the region of interest with respect to reference points on the subject, it is possible to determine the levels of hyperthermia and pO_2, pH, and/or CO_2 in relation to the position of the region of interest, i.e. the position within the body. This data can be used to either correct the focus of the energy source which is applying the hyperthermia (e.g. to maintain accurate targeting of the region of interest) and/or control the directionality of the further treatment modality (e.g. to control the direction and/or focus of applied radiation and/or applied ultrasound) to maximise [sic] the treatment effectiveness. Other factors, such as timing, intensity, fractionation and overall treatment time, i.e. total energy applied, can also be calculated more accurately using modelling of the region of interest.
>
> Further, by mapping and modelling [sic] the region surrounding the region of interest, the direction and focus of the energy source and/or the other treatment modalities can be selected so as to avoid obstacles such as bones and air pockets which could otherwise attenuate the energy and reduce treatment effectiveness. Navigation, guiding and tracking of the energy source and treatment modalities can be effected throughout the duration of the treatment.

(Myhr 7).

> 6. Myhr teaches, regarding element (d)(iv), that
>
> [t]he computer can determine if the applied hypothermia is sufficiently coincident with the region of interest and it can evaluate how long it takes for the hyperthermia to reach a

> desired level. The computer can use this analysis for feedback and control of the energy source to correct the focus, direction and/or intensity of the applied hyperthermia.

(Myhr 14).

7. Myhr teaches, regarding elements (d)(v), (d)(vii), and (d)(viii), that the "MRI machine can also monitor as a function of time by taking repeated measurements" and function in "providing maps or gradients of . . . temperature . . . in a region of interest" (Myhr 7, *cf*. FF 1).

8. Myhr teaches, regarding element (d)(vi), that the "direction and focus of the radiotherapy and/or chemotherapy can then be altered so as to target those areas where the treatment will be effective, without applying the toxic treatments to regions which will not benefit from that treatment" (Myhr 15).

9. Röll teaches, regarding elements (a) and (c), "combined radiation and magnetic devices conceivable to combine an open C-shaped magnet having an irradiation device and generate a therapy beam only on the inside of a magnet of the magnetic resonance apparatus" (Röll ¶ 5).

10. Röll teaches, regarding element (b), the "target volume [is] simultaneously heated by means of the HIFU device and irradiated by the irradiation apparatus, wherein both operations can be monitored by the imaging device. Thus, a radiation effect of the irradiation device is limited to the target volume and thus optimally protected surrounding healthy tissue controls" (Röll ¶ 16).

11. Röll teaches, regarding element (d), a "control unit 9 is connected to the image forming apparatus 1, the irradiation device 3 and the HIFU Vorrichutng 5 and receives from the image forming apparatus 1 to

obtain position and saturated the target volume and on the temperature in and around the target volume" (Röll ¶ 35).

12. Röll teaches, regarding element (d)(i), a "treatment plan" (Röll 31–32).

13. Röll teaches, regarding elements (d)(ii) and (d)(iv),

> a medical imaging device for determining and / or monitoring of the position and size of a target volume, and temperatures in the target volume, and an irradiation device to irradiate the target volume with the treatment radiation, and HIFU device (HIFU: "High Intensity Focused Ultrasound") for irradiating the target volume with ultrasound to increase the temperature in the target volume.

(Röll ¶ 15).

14. Röll teaches, regarding elements (d)(iii), to register the image with the treatment plan, specifically teaching "[c]ontrol of the position and size of a target volume of the object in the radiation therapy apparatus by means of the medical imaging device" (Röll ¶ 19).

15. Röll teaches, regarding element (d)(ix), that:

> Upon irradiation often results in the problem that the objective of the irradiation in the body is movable.
>
> So, for example, moves a tumor in the abdominal area during the respiratory process. . . .
>
> Therefore, it has been proposed to control the position of the irradiation target in the body during irradiation by imaging, in order to control the beam in accordance with or, where appropriate, to stop the irradiation, and thus increase the success of the therapy.

(Röll ¶ 2).

16. The Examiner also finds, regarding element (d)(ix), that "use of feedback to control the treatment will inherently compensate for changes to

the region of interest including those caused by motion (breathing) of the subject" (Final Act. 4).

17. Röll teaches, regarding element (d)(x), that "the aim of the regulation of the HIFU device from it, to avoid an increase of the temperature outside the target volume" (Röll ¶ 29).

18. Röll teaches, regarding temperature differences in claims 23 and 24, that "[f]or radiotherapy of people is therefore proposed that the target temperature to be chosen such that approximately 39 deg. C does not fall below about 43 deg C. are not exceeded" (Röll ¶ 30).

19. Avinash teaches that:

> [t]he motion of the lungs or other respiratory organs of interest, such as the diaphragm, may be measured in a variety of ways. As one of ordinary skill in the art will readily apprehend, the type of data gating desired, i.e., prospective or retrospective, may determine the type of motion data acquired. In some cases, the motion data of interest may be derived using the image scanner . . . itself. For example, pre-acquisition imaging techniques, such as navigator pulses in MR systems, scout images in CT systems or fluoroscopic images in other generalized X-ray applications, may be employed to determine the motion of the lungs, diaphragm, chest wall, and so forth, as indicators of respiration. Pre-acquisition motion detection and measurement typically involves determining the position of the organ or organs of interest by a pre-acquisition measurement using the imaging system . . . . Subsequent image acquisition can then occur during similar states of organ motion or subsequently acquired image data may be selected for processing and reconstruction based upon a similar state of organ motion.

(Avinash ¶ 22).

Principles of Law

A prima facie case for obviousness "requires a suggestion of all limitations in a claim," *CFMT, Inc. v. Yieldup Int'l Corp*., 349 F.3d 1333, 1342 (Fed. Cir. 2003) and "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 418 (2007).

Analysis

We adopt the Examiner's findings concerning the scope and content of the prior art (Ans. 3–5; FF 1–18), and agree with the Examiner that the claims are obvious over Myhr and Röll. We address below Appellant's arguments.

As already noted above, because our reasoning and evidentiary basis differs somewhat from that of the Examiner, we designate our affirmance of the obviousness rejections as new grounds of rejection to ensure procedural due process for Appellant.

Claim 1

Appellant contends "Röll discloses that the irradiation start temperature is lower than the irradiation stop temperature. . . . the temperature *inside* the target volume is the determining factor in Röll of whether or not to stop irradiation, not the temperature *outside* of the target volume" (Reply Br. 5). Appellant contends "claim 1 calls for stopping the irradiation based on temperature outside of the target volume and Röll stops irradiation based on temperature in the target volume" (*id.*). Appellant also contends that "if the heating is occurring at area close to a periphery of the heating volume, then the temperature outside the heating volume adjacent

periphery may be higher than a temperature at a portion of the heating volume that is spaced from the periphery" (*id.* at 6).

We find these arguments unpersuasive because Röll teaches "to avoid an increase of the temperature outside the target volume" (FF 17). Thus, Röll recognizes the same concern as that recited in element (d)(x) of claim 1 of "in response to a region of the subject outside of the heated volume . . . exceeding a second temperature . . . controlling the irradiation system to stop irradiating the irradiation volume and tissue heating system." Indeed, Röll teaches "a radiation effect of the irradiation device is limited to the target volume and thus optimally protected surrounding healthy tissue controls" (FF 10). Röll teaches to achieve this goal by, "where appropriate, to stop the irradiation, and thus increase the success of the therapy" (FF 15).

Moreover, Myhr also teaches "to target those areas where the treatment will be effective, without applying the toxic treatments to regions which will not benefit from that treatment" (FF 3, 8). Myhr further teaches "[i]f the spatially detected increases are not sufficiently coincident with the region of interest, the direction of the energy source can be corrected" (FF 4). Thus, we conclude that the ordinary artisan would have found that Myhr and Röll reasonably suggested modification of the irradiation temperature to a lower temperature when the healthy tissue volume outside the treated volume is exceeding a desired temperature.

Claims 32 and 33

Appellant contends "claims 32 and 33 also recite controlling the irradiation system to stop irradiating the irradiation volume and the tissue heating system to stop heating the heating volume in response to temperature

in a region outside of the heated volume" (Reply Br. 6). We find this argument unpersuasive for the same reasons as claim 1 discussed above.

Claims 23, 24 and 33

Appellant contends that "Röll discloses a temperature range of 4° C. Dependent claim 24 and independent claim 33, for example, recite that temperature difference is at least 5° C." (Reply Br. 7). Appellant contends "the Examiner alleges that this temperature selection recited in claims 23, 24 and 33 would be obvious one of skill in the art to achieve optimum results without undue experimentation. However, the Examiner provides no evidence to support this position" (*id.*).

We are not persuaded. As Appellant acknowledges, "Röll discloses a temperature range of 4° C." (Reply Br. 7; *cf.* FF 18 "the target temperature to be chosen such that approximately 39 deg. C does not fall below about 43 deg C."). Röll's use of the words "approximately" and "about" reasonably suggests that the temperatures are, within at least degree, results effective variables, and therefore encompass ranges from 38 to 44 degrees C. or a 6 degree range, encompassing the recitations in claims 23, 24, and 33. *See In re Aller*, 220 F.2d 454, 456 (CCPA 1955) ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."). Appellant provides no evidence that the temperature range recited in claims 23, 24, or 33 are anything other than optimized ranges identified by routine experimentation. Appellant also does not rebut the Examiner's finding that the ordinary artisan, interested in minimizing tissue damage caused by excessive temperature as taught by both Myhr and Röll, would have

recognized temperature of tissue as an optimizable variable, particularly as Myhr and Röll teach measurement of such temperatures (FF 1, 5, 8, 10, 18)

Conclusion of Law

A preponderance of the evidence of record supports the Examiner's conclusion that Myhr and Röll render the claims obvious.

C–F. 35 U.S.C. § 103(a)

Appellant does not separately argue these rejections (*see* Reply Br. 4–7). As set forth above, we found no deficiency in the Examiner's rejection as it relates to claims 1, 32, and 33. Thus, Appellant fails to establish error in the Examiner's prima facie case as it relates to the rejection of the remaining claims.

DECISION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 23–34, 36–41	112 ¶ 1	Written Description		1, 23–34, 36–41
1, 23–25, 30, 32–34, 36, 40	103(a)	Myhr, Röll	1, 23–25, 30, 32–34, 36, 40	
26, 37	103(a)	Myhr, Röll, Zhu, Govind	26, 37	
31, 41	103(a)	Myhr, Röll, Avinash	31, 41	
27	103(a)	Myhr, Röll, Maki	27	
28, 29, 38, 39	103(a)	Myhr, Röll, Maki, Skliar	28, 29, 38, 39	

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
Overall Outcome			1, 23–34, 36–41	

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