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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL H. SLAYTON and PETER G. BARTHE

Appeal 2020-000985
Application 13/545,931
Technology Center 3700

Before ANTON W. FETTING, AMEE A. SHAH, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

FETTING, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE[1]

Michael H. Slayton and Peter G. Barthe (Appellant[2]) seeks review under 35 U.S.C. § 134 of a final rejection of claims 7–17 and 19–30, the

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[1] Our decision will make reference to the Appellant's Appeal Brief ("Appeal Br.," filed July 8, 2019) and the Examiner's Answer ("Ans.," mailed August 29, 2019) and Final Action ("Final Act.," mailed June 7, 2018).
[2] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. The Appellant identifies the real party in interest as Guided Therapy Systems, LLC (Appeal Br. 2).

only claims pending in the application on appeal. We have jurisdiction over the appeal pursuant to 35 U.S.C. § 6(b).

The Appellant invented a form of acoustic treatment of tissue. Specification para. 5.

An understanding of the invention can be derived from a reading of exemplary claim 7, which is reproduced below (some paragraphing added).

> 7. A method for providing acoustic treatment of a medium, said method comprising:
>
> a) localizing a region of interest in the medium;
>
> b) computing, without feedback from monitoring parameters, a spatio-temporal treatment function, e(x,y,z,t)
>
> that produces a desired temperature function T(x,y,z,t) in the region of interest,
>
> the spatio-temporal treatment function e(x,y,z,t) defining an ultrasound intensity at the time t at distinct locations x,y,z in the region of interest;
>
> c) delivering acoustic energy from an energy source into the region of interest
>
> by controlling the energy source with spatial and temporal parameters derived from the spatio-temporal treatment function e(x,y,z,t),
>
> thereby producing the desired temperature function T(x,y,z,t) in the region of interest,
>
> thereby triggering an effect in the region of interest.

The Examiner relies upon the following prior art:

Name	Reference	Date
Truckai	US 6,773,409 B2	Aug. 10, 2004
Moonen	US 2009/0326420 A1	Dec. 31, 2009
Gustus	US 2010/0076299 A1	Mar. 25, 2010

Claims 7–17, 19–22, and 25–30 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Moonen and Gustus.

Claims 23 and 24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Moonen, Gustus, and Truckai.

ISSUES

The issues of obviousness turn primarily on whether the prior art describes the claim limitations.

FACTS PERTINENT TO THE ISSUES

The following enumerated Findings of Fact (FF) are believed to be supported by a preponderance of the evidence.

Facts Related to Appellant's Disclosure

01. "The spatial and/or temporal control can also be facilitated through **open-loop and closed-loop feedback arrangements**, such as through the monitoring of various spatial and temporal characteristics. As a result, control of acoustical energy within six degrees of freedom, e.g., spatially within the X, Y and Z domain, as well as the axis of rotation within the XY, YZ, and XZ domains, can be suitably achieved to generate conformal distribution of elevated temperature of variable shape, size, and orientation. For example, through such spatial and/or temporal control, energy source can enable the regions of elevated temperature distribution possess controlled [sic] that is based on the function." Spec. para. 32.

02. "[T]he acoustic energy source 102 may be programmable to perform predictable and/or repeatable spatial and temporal energy

transduction **with or without feedback** from a variety of monitoring parameters, such as tissue parameters, pressure, amplitude, energy absorption, and attenuation." Spec. para. 64.

Facts Related to the Prior Art

Moonen

03. Moonen is directed to the treatment of biological tissue using hyperthermia. Moonen para. 1.

04. Moonen describes therapies using local hyperthermia as locally heating a target area or region of a biological tissue. When this type of therapy is used for gene therapy, the heat may be used for its action on a heat-sensitive promoter for example. Heat can also be used to necrotize biological tissue and for tumor ablation. Moonen para. 2.

05. Moonen describes a thermal treatment device as follows: the spatial distribution of the treatment points is three-dimensional; the control unit can determine the spatial and energy distribution of the treatment points to be performed in relation to a spatial distribution of required energy defined by a temperature regulation system to treat the target region; the control unit can determine the spatial distribution of required energy to treat the target region according to a Proportional-Integral-Derivative regulation system [such a system by definition incorporates feedback]; determining the spatial and energy distribution of the treatment points to be performed comprise deconvolution means the spatial distribution of required energy to treat the target region, using a spatial energy distribution characteristic of one treatment

point; determining the spatial and energy distribution of the treatment points to be performed comprise means to determine the treatment point corresponding to the maximum spatial distribution of remaining energy to treat the target region, the spatial distribution of remaining energy corresponding to the spatial distribution of required energy to treat the target region subtracted by the spatial energy distributions characteristic of the previous treatment points; the control unit can determine the spatial and energy distribution of the treatment points to be performed, such that

$$E^0(\vec{r}) = E^{REQUIRED}(\vec{r}) \text{ and } \Gamma^0(\vec{r}) = 0$$

$$\left| \begin{array}{l} \text{let } \vec{r}_n \text{ such that } E^n(\vec{r}_n) = \max(E^n(\vec{r})) \\ E^{n+1}(\vec{r}) = E^n(\vec{r}) - R \cdot E^n(\vec{r}_n) \cdot E^{1PC}(\vec{r} - \vec{r}_n) \\ \Gamma^{n+1}(\vec{r}) = \Gamma^n(\vec{r}) + R \cdot E^n(\vec{r}_n) \cdot \delta(\vec{r} - \vec{r}_n) \end{array} \right.$$

Moonen paras. 21–27.

06. Moonen describes the control unit controlling the energy provided by the energy generating means in relation to a time-shifted temperature regimen for each treatment point. Moonen para. 29.

07. Moonen describes temperature mapping including the area to be heated as carried out by MRI. This is particularly dedicated to the monitoring of temperature maps and guiding of the ultrasound system. On the basis of this data, the position and intensity of the next focusing points are evaluated on the basis of the anatomical and thermal maps. The coordinates and the power of the next focal points are transmitted to energy generating means. A

generator produces and amplifies the ultrasound electric signals that are phase-shifted so that the matrix transducer connected thereto emits an ultrasound wave focused on the chosen focal point P. The rise in temperature induced inside the focusing point therefore allows the thermal dose to be obtained that is needed to achieve necrosis. Moonen paras. 75–77.

08. Moonen describes electronic shifting of the focal point, as compared with mechanized shifting of the transducer, as most useful for controlling temperature spatially, because it allows travel over a large number of points to be heated per second. In addition, since the transducer remains immobile, this movement of the focal point does not create any imaging artefact related to change in magnetic susceptibility. Electronic moving of the focusing point does not have any limitations regarding speed but, the electric signal generator used requires a certain time for data transfer before switching all the paths to the new desired value. Therefore, there is a minimum time between each change in the position of the focal point. Moonen paras. 83–84.

09. Moonen describes testing the principle of electronic shifting of the focal point and proper functioning of the matrix transducer by moving the focusing point 4 points around a square with sides of 8 mm. This trajectory was repeated cyclically every 0.5 s by changing the position of the focusing point every 125 ms with a constant electric power of 200 W. By simultaneously conducting 5 slices of 4 mm (echo time 18 ms) every 3.9 s, the heating observed in FIGS. 6a to 6b appears to derive from 4 focusing

points simultaneously. This method of moving the focal point is very rapid since there is no longer any maximum displacing speed but just a minimum electronic signal switching time of 60 ms with the generator used. This technique is also very accurate. Moonen paras. 113–114.

10. Moonen describes the spatial distribution of the set temperature as generally chosen to be uniform over the entire tumour, and zero outside thereof, for the purpose of obtaining homogeneous treatment of the target region whilst best protecting adjacent tissues. Therefore, the temperature schedule is a square function whose amplitude varies according to the previously defined set time. Moonen para. 163.

Gustus

11. Gustus is directed to treatment for luminal diseases, particularly for atherosclerotic plaque, vulnerable or "hot" plaque, and the like. Gustus para. 4.

12. Gustus describes inducing desirable temperature effects on body tissue using non-RF energy. The desirable temperature effects include mildly heating the tissue for treating atherosclerotic lesions and other disease states. Gustus para. 11.

13. Gustus describes using an ultrasound energy source. Gustus para. 16.

14. Gustus describes adjusting the treatment energy in response to feedback from the tissue analyzer during heating of the body tissue. Gustus para. 21.

15. Gustus describes adjusting or tuning the energy to gently heat the atherosclerotic materials. Characteristics of the energy, including the frequency, power, magnitude, delivery time, delivery location, and/or patterns or combinations thereof may be predetermined before diagnosis or treatment of a specific patient, the energy characteristics being transmitted without feedback, such as by employing open-loop dosimetry techniques. Such predetermined characteristic tuning may be based on prior treatment of atherosclerotic materials, prior clinical trials, and/or other development work. Some embodiments may tune the energy directed to a particular patient based on in situ feedback, and many embodiments may employ some predetermined characteristics with others being feedback-controlled. Gustus para. 100.

ANALYSIS

Claims 7–17, 19–22, and 25–30 rejected under 35 U.S.C. § 103(a) as unpatentable over Moonen and Gustus

Claims 7 and 25 are the only claims argued on their own merits. The remaining claims are argued from the patentability of independent claim 7. The issue surrounding claim 7 is whether the art describes or shows to be predictable the "without feedback" limitation in step (b). We begin by construing claim 7 and limitation (b).

Claim 7 recites three steps and a result. The steps are: (a) localizing a region of interest; (b) computing, without feedback from monitoring parameters, a spatio-temporal treatment function; and (c) delivering acoustic energy from an energy source into the region of interest by controlling the energy source with spatial and temporal parameters derived from the spatio-temporal treatment function. The result is producing the desired temperature function T(x,y,z,t) in the region of interest, thereby triggering an effect in the region of interest.

In particular, step (b)'s computing a treatment function is separate from step (c)'s delivering the energy. It is step (b) that recites "without feedback." That is, the claim requires that the computation be done without feedback. Step (c), i.e., the delivery of acoustic energy, itself is silent as to feedback.

We know that the "without feedback" limitation modifies "computing" because that phrase immediately follows the word "computing." The treatment function that is computed in step (b) provides the spatial and temporal parameters recited in step (c) that are used in controlling the energy source that delivers the acoustic energy. The claim is silent as to the relationship between the parameters recited in step (c) and the use of feedback in the control of the energy source to deliver energy in the region of interest. Thus, for example the claim does not preclude monitoring the energy intensity being delivered in the region of interest to provide feedback so as to ensure an appropriate treatment. The Specification is of little help as to construing the computing "without feedback" limitation, as it only refers to feedback in paragraphs 28, 32, and 64, and there only to apply feedback or lack thereof to the equivalent of step (c).[3] The Specification describes no particular benefit or unexpected result to either using or not

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[3] The "without feedback" limitation was added to claim 7 by amendment filed May 22, 2015.

using feedback. Thus, the Specification does no more than inform one that either modality is possible.

Thus, step (b) is construed as computing a spatio-temporal treatment function e(x,y,z,t) that produces a desired temperature function T(x,y,z,t) in the region of interest which function is used to determine space and time parameters for step (c). The spatio-temporal treatment function e(x,y,z,t) defines an ultrasound intensity at the time t at distinct locations x,y,z in the region of interest. The computation is performed without feedback from monitoring parameters.

We also note for purposes of our analysis below, that the delivery in step (c) is of a generalized acoustic energy to some unspecified medium, that may be part of something living or non-living, to achieve some unspecified effect. Although, the preamble recites that it is a method for providing acoustic treatment of a medium, neither the preamble nor the body of the clam specifies the treatment other than that it arises from acoustic energy delivery.

The Examiner determines that Moonen describes all of claim 7 except for the absence of feedback. The Examiner further determines that Gustus describes similarly computing and applying an energy treatment function, with the option of using or not using feedback. Final Act. 2–3. These determinations are undisputed. Instead, the Appellant contends no one would combine the two references in the manner the Examiner suggests because the manner in which Moonen applies its energy relies on feedback "to provide treatment of biological tissue without significantly heating tissues adjacent to the focused area." Appeal Br. 9. The Appellant concludes that "the proposed modification would render Moonen unsatisfactory for its intended purpose and the proposed modification or combination changes the principle of operation of Moonen." *Id.* at 9–10.

We do not find this argument persuasive. Moonen's principle of operation is using the ability to electronically direct the focus of ultrasound without moving the transducer, instead moving the focus of the emanated energy using some function in space and time. The programming of such movement is by definition of space and time a function of the form e(x,y,z,t).

Moonen describes the application of the foregoing in the context of using hyperthermia to necrotize tumors. In such a setting, feedback provides a measure of protection to ensure only certain targeted tissue is treated.

However, Moonen describes proof of concept type testing to show that the focal point can be electronically moved in some test medium according to some space and time formula to achieve an effect in a region of interest. FF 09. In such a setting, there is no safety concern as with necrotizing tumors, and thus feedback is not required. Furthermore, Appellant's claim 7 broadly encompasses Moonen's proof of concept testing where feedback is not necessary.

In short, the problem with Appellant's argument is that it does not consider the full extent of the teachings in Moonen and does not take into account the breadth of claim 7.

It is generally obvious to remove a step where the function of the step is not needed. *In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975) (deleting a prior art switch member and thereby eliminating its function was an obvious expedient). It would not be necessary to add the feedback equipment and attendant cost to simply test the accuracy of applying Moonen's function as

Moonen does. All of claim 7's limitations are met during such testing on non-living target matter. Thus, we find the Appellant's arguments unpersuasive.

Dependent claim 25 additionally recites "the spatio-temporal treatment function, e(x,y,z,t) is *e = a(t) [u(x - x1) - u(x - x2)] [u(y - y1) - u(y - y2)] [u(z - z1) - u(z - z2)] g(x,y,z),* where *u(y)* is a step function, *a(t)* represents the time excitation, and *g(x,y,z)* represents the spatial modulation within the regions bound by *[x1, x2}, [y1, y2], and [z1, z2]*." A step function is in general a constant non-zero value over some range and zero elsewhere. Thus, it essentially masks some other function to which it is applied to narrow the scope of that function. Although this formula is expressed as an equality suggesting precision, the expression of both time and spatial modulation as generalized functions of unrestricted scope means this expression is ultimately that of masking these functions according to spatial coordinates for each specific set of (x, y, z) coordinates.

The Examiner applies Moonen paragraph 163 (Final Action 6), to which the Appellant correctly contends that this paragraph describes a temperature function rather than a treatment function. Appeal Br. 21–22. We agree with the Examiner's answer that

> the square function in [0163] is defined for a 'temperature schedule' and this is in reference to the 'spatial distribution of the set temperature', which is the treatment function. As such, the Examiner understands that the temperature schedule is a parameter that is a part of the treatment function, which is defined by which an energy distribution reaches a temperature [0029]. Any 'temperature function' would be defined as the result of the energy distribution in tissue, which corresponds to the claim 7 limitation that merely sets forth that the treatment function f(x,y,z,t) produces a desired temperature function T(x,y,z,t). Since the temperature function is a result or an

> application of a treatment function, the step function in [0163] of Moonen relates to the treatment function.

Ans. 9.

Claims 23 and 24 rejected under 35 U.S.C. § 103(a) as unpatentable over Moonen, Gustus, and Truckai

These claims are not separately argued.

CONCLUSIONS OF LAW

The rejection of claims 7–17, 19–22, and 25–30 under 35 U.S.C. § 103(a) as unpatentable over Moonen and Gustus is proper.

The rejection of claims 23 and 24 under 35 U.S.C. § 103(a) as unpatentable over Moonen, Gustus, and Truckai is proper.

CONCLUSION

The rejection of claims 7–17 and 19–30 is affirmed.

In summary:

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
7–17, 19–22, 25–30	103(a)	Moonen, Gustus	7–17, 19–22, 25–30	
23, 24	103(a)	Moonen, Gustus, Truckai	23, 24	
Overall Outcome			7–17, 19–30	

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2011).

<u>AFFIRMED</u>