

To the
district courts

DRAFT

Alleged infringement of European Patent 2 653 128 (13 176 863)
Patentee: Avent, Inc.

P R O T E C T I V E W R I T
IN POTENTIAL PRELIMINARY INJUNCTION PROCEEDINGS

1. Avent, Inc., represented by management, Alpharetta, GA 30004
(US)

2. Philips AVENT, represented by management, Glemsford, Suffolk
(UK)

3. Philips GmbH, represented by management, Hamburg

or another company of the Philips **group**

- presumed petitioners -

a g a i n s t

1. Stryker Corporation, represented by management,
4100 E. Milham, Kalamazoo, Michigan 49001 USA

2. Stryker Instruments, represented by management,
4100 E. Milham, Kalamazoo, Michigan 49001 USA

3. Stryker European Holdings, represented by management, ...**- presumed defendants -**

represented by Attorneys at Law of
 Wuesthoff & Wuesthoff
 Patentanwälte PartG mbH
 Schweigerstraße 2, 81541 München

participating patent attorney Rainer Röthinger
 Wuesthoff & Wuesthoff
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in the matter of alleged infringement of the German part of European patent **EP 2 653 128**.

We herewith indicate our appointment as authorized representative of Stryker Instruments and Stryker European Holdings for the case that one of the presumed petitioners should request issuance of a preliminary injunction due to alleged infringement of the German part of European patent **EP 2 653 128** and for the case of cease and desist claims as to the offering, placing on the market, and/or using or importing or owning for the aforementioned purpose

of an electrosurgical system for performing a procedure on a patient's body,
especially systems labeled "MultiGen™ 2",

are brought against the presumed defendants, and

we request

1. rejection of a potential request for issuance of a preliminary injunction,
as an auxiliary measure
2. granting the potential request for issuance of a preliminary injunction not without oral proceedings,
as a further auxiliary measure,

3. in case the court is willing to grant the request for issuance of a preliminary injunction, make the order of enforcement of same dependent on a security deposit of the petitioner, and,
4. in case of rejection of the injunction request or its withdrawal, order the petitioner to pay the costs of the injunction proceedings including the costs incurred by depositing this protective writ.

The presumed defendants only declare consent with informing the presumed petitioners of the protective writ in case a request for issuance of a preliminary injunction is pending.

REASONS

A. Parties

1. The presumed petitioner under 1. is patentee of the German part of European Patent EP 2 653 128 directed to control of energy delivery to multiple energy delivery devices and validated for and in force in Germany. A copy of EP 2 653 128 is enclosed as
- annex AG 1 -.

To evidence same, a relevant register excerpt of the German Patent and Trademark Office is enclosed as

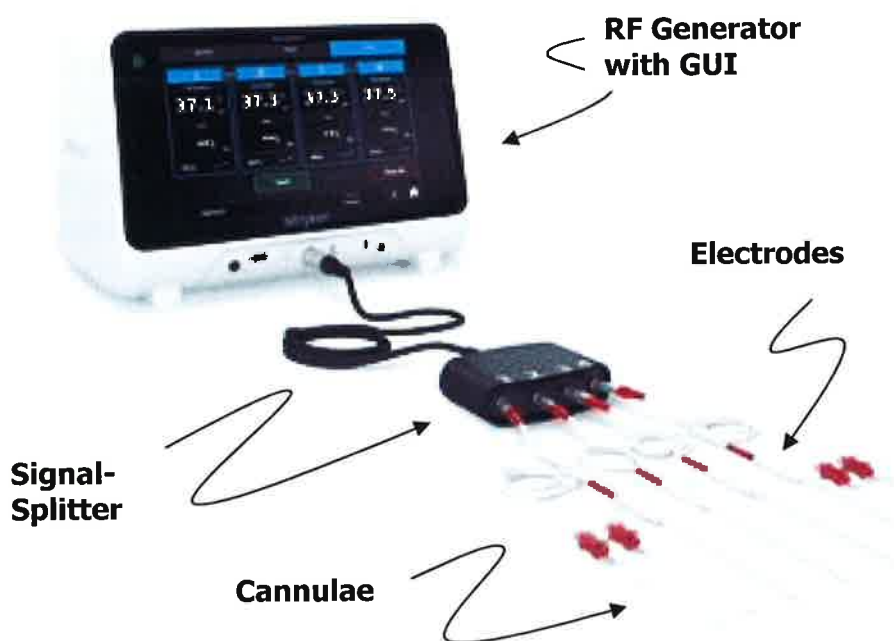
- annex AG 2 -.

The presumed petitioner under 3. is the company which took over the Avent company, including the presumed petitioners under 1. and 2..

2. The presumed defendants under 2. and 3. are subsidiaries of Stryker Corporation located in Kalamazoo, Michigan, USA. Stryker Corporation and its subsidiaries are one of the leading manufacturers and suppliers of orthopedic and medical products. Stryker Corporation inter alia specializes in manufacturing and supplying products for creating lesions of targeted nerve tissue for the treatment of pain.

B. Situation

1. The presumed defendant under 1./2. ? is about to launch a system for treatment of tissue by application of Radio Frequency (RF) energy in Europe. This system will first be presented on trade fair "World Institute of Pain" in Dublin, Ireland, on 9 -12 May 2018. Said system will be labeled "MultiGen™ 2" (referred to as 'MG2' in the following) and will be available to be ordered for Germany starting from/on the Dublin trade fair.
2. The 'MG2' system as shown below is an electrosurgical system for treating a patient's body with RF energy. Said system includes a Radio Frequency (RF) generator with a graphical user interface (GUI), a signal splitter with electrode ports and a plurality of electrodes connectable to the RF generator via the ports. In practice, electrodes connected to the RF generator and received in cannulae can be placed in contact with a patient to provide RF energy to the tissue of the patient for treating same. The generator provides a controlled energy source for treating the patient's tissue with RF energy. RF energy is only applied to one electrode at a time. Thus, no two electrodes deliver RF energy simultaneously.



The intended use of the 'MG2' system is for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications, and, especially, the creation of lesions of targeted nerve tissue for the treatment of pain.

Lesion creation may be accomplished using a monopolar or bipolar electrode configuration (see Figure 1 below, showing the 'MG2' system in use). A monopolar electrode configuration uses an electrode/cannula tip combination and a neutral return electrode (ground pad) to create a lesion (see left side of Figure 1 below). A bipolar electrode configuration uses two or more electrode/cannula tip combinations to create a lesion (see right side of Figure 1 below).

During lesion creation, targeted nerve tissue is exposed to RF energy using an active electrode tip projecting from a cannula. The application of RF energy causes a thermal reaction at the targeted nerve tissue site to create a lesion. The lesion inhibits the nerve tissue's ability to conduct electrical signals or pain.

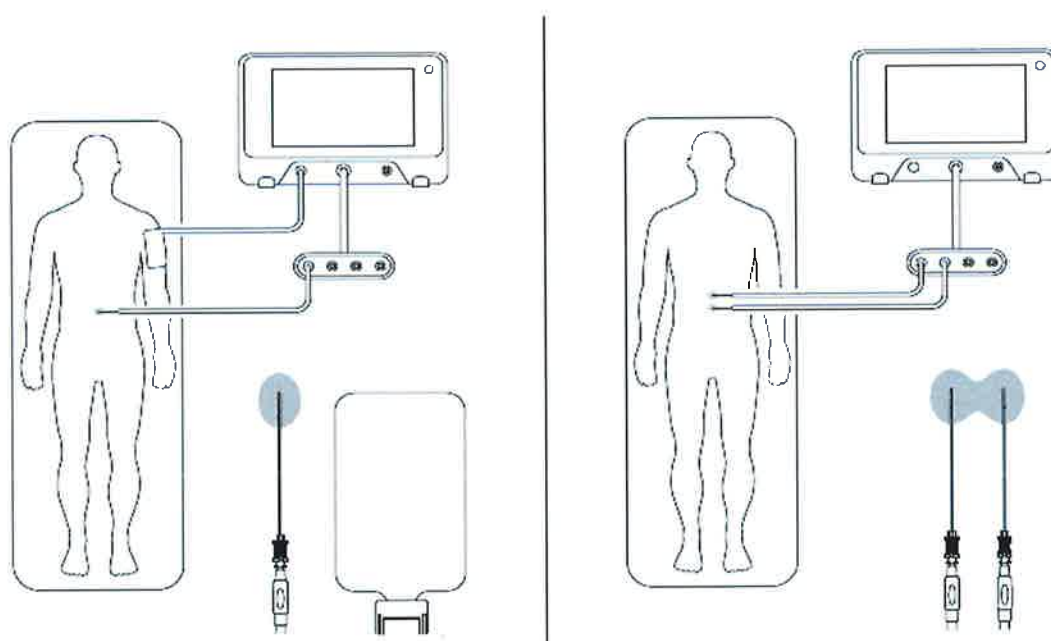


Figure 1 – Monopolar and Bipolar Lesion Creation

For use of the 'MG2' system in monopolar lesion mode (see left side of Figure 1), one electrode received in a cannula and a grounding pad are used, and, for use of the 'MG2' system in bipolar lesion mode (see right side of Figure 1), two electrodes received in respective cannulae and connected to adjacent electrode ports are provided.

The 'MG2' system also has a multi-lesion capability, i.e., it allows lesion creation at different tissue positions using multiple (up to four) electrodes.

The GUI of the 'MG2' system includes a touch screen. Different RF energy application modes of the 'MG2' system can be selected via the graphical user interface by a user touching the touch screen.

The following RF energy application modes can be selected for operation of the 'MG2' system: a sensory stimulation mode, a motor stimulation mode, a lesion pulse mode and a lesion thermal mode (highlighted in Figure 2 below).

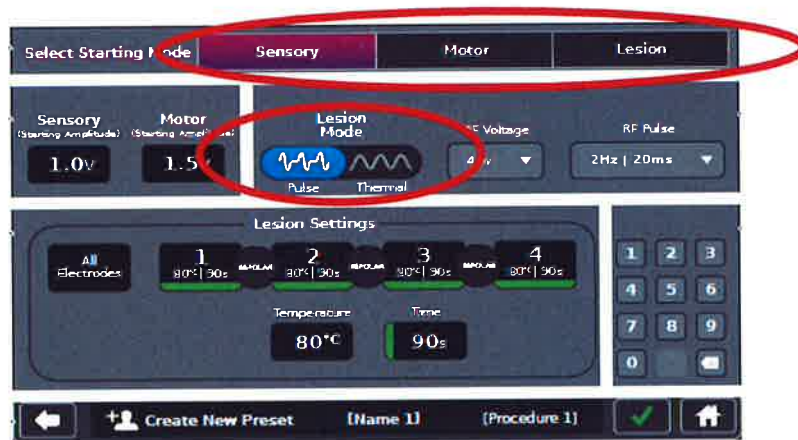


Figure 2 – Edit Screen of GUI

The 'MG2' system can be used in the sensory and motor stimulation modes in order to facilitate the proper placement of an electrode cannula before lesion creation.

Sensory stimulation mode

When the 'MG2' system is used in sensory stimulation mode, electrical pulses according to a value set by the user are emitted via the connected electrode(s) to trigger a pain response in the target sensory nerve tissue. These impulses reproduce the symptoms experienced by the patient and assist in the correct placement of the cannula close to the target sensory nerve tissue.

Motor stimulation mode

When the 'MG2' system is used in the motor stimulation mode, electrical impulses according to a value set by the user are emitted to trigger responses in target muscles and observe motion. These impulses assist in the correct placement of the cannula away from motor nerve tissue so as to prevent potential motor nerve damage.

Lesion pulse mode

When the 'MG2' system is used in the lesion pulse mode, the RF energy generator provides pluses or bursts of RF energy according to a user's voltage and pulse settings to the target nerve tissue in order to necrotize same. A timer immediately starts to count down from a specified preset time value during energy transfer and lesion creation.

Lesion thermal mode

When the 'MG2' system is used in the lesion thermal mode for necrotizing target nerve tissue, the RF energy generator provides a high dose of RF energy to the target nerve tissue to increase a lesion creation temperature to a preset value. Once the preset temperature is achieved, the timer begins to count down from a specified preset time value.

For all said four modes, the 'MG2' system may be used in the monopolar and/or bipolar configuration.

Monopolar configuration

The monopolar configuration is the default mode when a monopolar electrode is detected to be connected to an electrode port of the 'MG2' system (see Figure 3 below). In monopolar configuration, each electrode connected to an electrode port of the 'MG2' system, i.e., up to four electrodes concurrently (see Figure 1 above), may subsequently apply RF energy to the patient's body. A lesion is created at the monopolar electrode. In below Figure 3, a connected electrode has been detected for each of ports 1, 2, and 3 as becomes apparent from the fact that temperatures and other data are displayed for these ports 1, 2, and 3 on the graphical user interface. However, only the electrode connected to port 1 is operated as becomes apparent from the highlighting of the "1" field.



Figure 3 – Monopolar lesion creation using electrode 1

Also in below Figure 4, a connected electrode has been detected for each of ports 1, 2, and 3. However, the electrodes connected to ports 1 and 2 are operated as becomes apparent from the highlighting of the "1" and "2" fields.



Figure 4 – Monopolar lesion creation using electrodes 1 and 2

In below Figure 5, a connected electrode has been detected for each of ports 1, 2, 3, and 4, and all of the connected electrodes are operated (as becomes apparent from the highlighting of the "1", "2", "3", and "4" fields).



Figure 5 – Monopolar lesion creation using electrodes 1, 2, 3 and 4

Bipolar configuration

The bipolar configuration is a user selectable option when two or more monopolar electrodes are detected on adjacent electrode ports of the 'MG2' system, for example, on ports 1 and 2, ports 2 and 3, or ports 3 and 4 (see Figure 6 below). By touching on the graphical user interface the "bipolar" buttons for the electrodes connected to ports (1 and 2), (2 and 3), and/or (3 and 4), a bipolar configuration for said connected electrodes is selected.

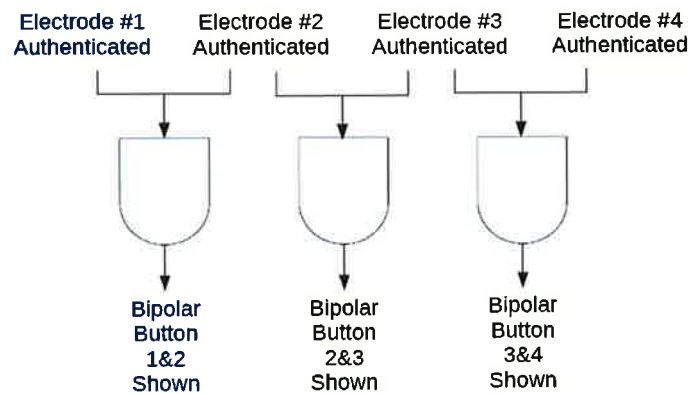


Figure 6 – possible bipolar configurations

A special case is the double bipolar configuration (see Figure 7 below) which may be selected in case an electrode is connected to each of the four ports of the 'MG2' system. As shown in Figure 7 below, by touching the bipolar buttons overlapping the control sections for the electrodes connected to ports 1 and 2 (referred to as electrodes 1 and 2 in the following) and those connected to ports 3 and 4 (referred to as electrodes 3 and 4 in the following), the bipolar configuration for electrodes 1 and 2 and the bipolar configuration for electrodes 3 and 4 are selected and the activation of said double bipolar configuration is indicated by merging of the control sections for electrodes 1 and 2 as well as the control sections for electrodes 3 and 4 on the graphical user interface and displaying the bipolar buttons assigned to said pairs of electrodes 1, 2, and 3, 4 in green.

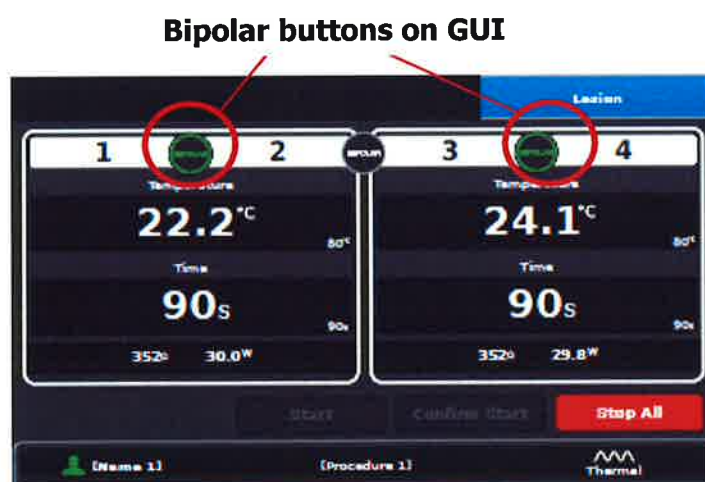


Figure 7 – Double bipolar lesion creation

Monopolar and bipolar combination configuration

For the 'MG2' system, it is also possible to have a configuration combining the use of monopolar and bipolar electrodes. Two such combined configurations are possible. For a total of three electrodes connected to the four available electrode ports of the 'MG2' system, electrodes connected to two adjacent electrode ports can be selected to be operated in bipolar configuration with a single monopolar electrode left. For an electrode connected to each of the four available electrode ports of the 'MG2' system, electrodes connected to two adjacent electrode ports, e.g., ports 1 and 2, 2 and 3, or 3 and 4, can be selected to be operated in bipolar configuration with the two remaining electrodes operated in monopolar configuration.

3. Even though no out-of-court communication has been taken place between the presumed parties, it is not to be excluded that one of the presumed petitioners is going to try to prevent the product launch in Germany – of high importance for the business performance of the presumed defendants – by a preliminary injunction.

However, given the factual and legal situation as well as the required consideration of the parties' interests as detailed in the following, there is no basis for issuance of a preliminary injunction.

C. Legal assessment of the facts

For the issuance of a preliminary injunction in the present case, a claim entitlement as well as grounds for injunction are missing.

I. Lack of claim entitlement

The protective right EP 2 653 128 B1 is not valid and, moreover, not infringed. Thus, no claim entitlement is given.

1. Subject-matter of EP 2 653 128 B1

The European Patent EP 2 653 128 B1 of the presumed petitioner defines in its independent claim 1:

- 1) An electrosurgical system for performing a procedure on a patient's body, the system comprising:
 - 2) a plurality of energy delivery devices, each energy delivery device comprising at least one electrode for delivering electrical energy to a tissue of the patient's body; and
 - 3) an electrical generator for coupling to the plurality of energy delivery devices such that an output of the generator can be delivered via the plurality of energy delivery devices to produce an effect on the tissue of the patient's body,
 - 3a) the generator comprising an energy controller for controlling a delivery of energy
 - 3b) such that an amount of energy delivered by at least one of the plurality of energy delivery devices is controlled during the procedure by varying an amount of time that the at least one of the plurality of energy delivery devices is delivering energy responsive to at least one measured parameter associated with the at least one of the plurality of energy delivery devices,
 - 4) wherein said energy delivery devices are electrosurgical probes and
 - 5) each of said electrosurgical probes is associated with at least one respective sensor for measuring said at least one parameter, and

- 6) wherein said at least one measured parameter is indicative of a property of the tissue to which energy is delivered,
- 7) wherein the generator is capable of automatically detecting the number of energy delivery devices coupled to the generator.

2. Prior Art

As shown in the following, all claimed features of EP 2 653 128 B1 already form part of the prior art. Therefore, the subject-matter as claimed in EP 2 653 128 B1 is not valid.

The following documents will be cited hereinafter:

D1 EP 2 653 128 B1,
(see **annex AG 1**)

D2 EP 2 653 128 A1, the laid-open publication of D1,
enclosed as

- **annex AG 3** -,

D3 WO 2006/096475 A1, published 14 September 2006,
enclosed as

- **annex AG 4** -,

D4 US 2006/0079886 A1, published 13 April 2006,
enclosed as

- **annex AG 5** -,

D5 DE 10 2005 007 769 A1, published 24 August 2006,
enclosed as

- **annex AG 6** -,

D6 WO 97/40760, published 6 November 1997,
enclosed as

- **annex AG 7** -,

D7 JP 2006-141695 A, published 8 June 2006,
enclosed as

- **annex AG 8** -,

D8 US 6,014,584, published 11 January 2000,
enclosed as

- **annex AG 9** -,

D9 JP 01077417 A, published 23 March 1989,
enclosed as

- **annex AG 10** -.

3. Invalidity of the subject-matter of claim 1 of EP 2 653 128 B1

a. Extension of subject-matter

In the European examination procedure, the Examining Division had made an amendment to independent claim 1 of the printed publication as annexed to the Communication pursuant to Rule 71(3) EPC by incorporating feature 7) therein. This amendment has been accepted by the Patentee, and the patent EP 2 653 128 B1 has been granted based on independent claim 1 comprising that feature 7). A copy of said Rule 71(3) Communication is enclosed as

- **annex AG 11** -.

Incorporation of feature 7) in independent claim 1 is allegedly based on the disclosure of paragraphs [0014] and [0039] of document D2 enclosed as **annex AG 3** (see Avent's letter dated 23 April 2014 submitted during European examination proceedings, second paragraph on page 1, enclosed as

- **annex AG 12** -,

and Avent's letter of 5 December 2014 submitted during European examination proceedings, second and third paragraphs on page 1, enclosed as

- **annex AG 13** -),

namely:

"[0014] In an additional broad aspect, embodiments of the present invention provide a method comprising: coupling a plurality of energy delivery devices to a generator capable of operating in a plurality of functional operating modes; automatically detecting a quantity of energy delivery devices coupled to the generator; selecting a current operating mode from the plurality of operating modes of the generator responsive to the detected quantity of energy delivery devices; and delivering energy in accordance with the current operating mode. "

"[0039] In some embodiments, generator 100 is capable of automatically detecting the number of energy delivery devices 150 coupled to generator 100, as will be described further herein below. Automatic detection of the number of energy delivery devices 150 coupled to generator 100 obviates the need for a user to manually indicate the number of energy delivery devices 150 coupled to generator 100. "

Regarding the above cited disclosure in document D2, the isolated definition of the generator being capable of automatically detecting the number of energy delivery devices coupled to the generator as defined in feature 7) is an intermediate generalization as it extends the claimed subject-matter beyond the content of the original disclosure.

- a) Quantity is defined throughout the disclosure of document D2 to have the same meaning as number (see, for example, paragraph [0040], column 8, line 10: "number (i.e. quantity)" and paragraph [0043], first sentence: "quantity of energy delivery devices 150 (i.e. the number of devices 150)"). In the above cited paragraph [0014] of document D2, automatic detection of a quantity of energy delivery devices coupled to the generator is inextricably linked to the following further features:
 - a.1) that a current operating mode is selected from a plurality of operating modes of the generator responsive to the detected quantity of energy delivery devices (see D2, paragraph [0014], penultimate method feature), and
 - a.2) that energy is delivered in accordance with the current operating mode (see D2, paragraph [0014], last method feature).

- b) The above cited paragraph [0039] of document D2 is a passage embedded in the detailed description. In fact, paragraph [0039] of document D2 defines the generator's automatic number detection capability only with reference to a specific generator 100 and makes reference to the further detailed description as to the concrete realization of said automatic number detection capability (see last part of first sentence of paragraph [0039] in column 7 of D2: "as will be described further below").

With reference to said specific generator 100, the automatic number detection capability of the generator 100 is described as being realized by provision of a detector 320 (see paragraph [0040], column 8, lines 6 to 11 of D2). Document D2 further describes that, in case the "generator 100 does not comprise a detector 320", "a user may manually input the number of energy delivery devices connected to generator 100" (see paragraph [0048], column 10 of D2).

Thus, in accordance with the detailed description (see paragraph [0040], column 8, lines 6 to 19 in view of paragraph [0048], column 10 of D2), for its automatic number detection capability:

- b.1) the generator 100 has to have the detector 320.

In further accordance with the detailed description (see paragraph [0040], column 8, lines 6 to 19 of D2), and as also explained in item a) above, the provision of the detector 320 to the generator 100 is inextricably linked to the presence of:

- b.2) a mode storage element 310,
b.3) a mode selector 320, and
b.4) the energy controller's capability of controlling energy delivery by generator 100 in accordance with an operating mode stored in mode storage element 310 and selected by mode selector 330 in dependence of the detected number of energy delivery devices connected to the generator.

Moreover, in the further context of the detailed description of document D2, at least the further system features described as non-optional throughout paragraphs [0026] to [0038] of document D2 are also inextricably linked to the capability of specific

generator 100 to automatically detect a quantity of energy delivery devices coupled thereto:

- b.5) The generator 100 comprises one or more output channels (see paragraph [0026], column 4, line 31 of D2).
- b.6) Each output channel comprises a switching means operatively coupled to the controller (see paragraph [0026], column 4, lines 33 to 35 of D2).
- b.7) The output channels are connected in parallel to the energy source and are independently controllable via the switching means (see paragraph [0028], column 4, lines 51 to 56 of D2).
- b.8) The controller is operable to interface with switching means in order to control the flow of current through one or more of the output channels (see paragraph [0030], column 5, lines 25 to 27 of D2).
- b.9) The energy delivery devices are either coupled to the energy source via distal connectors, cables, proximal connectors, generator connectors and output channels or via a single cable (see paragraph [0033], column 6, lines 12 to 16 and paragraph [0038], column 7, lines 19 to 21 of D2).

Neither features a.1) and a.2) nor features b.1) to b.9) are present in the subject-matter of granted claim 1 of document D1 and, therefore, feature 7) is an intermediate generalization that extends the claimed subject-matter beyond the content of the original.

b. Lack of Novelty

i) Document D3 (WO 2006/096475 A1)

The disclosure of document D3 (see **annex AG 4**) is novelty-destroying for the subject-matter of claim 1 of EP 2 653 128 B1. In the following, relevant passages of document D3 will be identified that disclose each of the features 1) to 7) of claim 1 of EP 2 653 128 B1.

Feature 1) – electrosurgical system:

Document D3 is directed to "structure and use of radiofrequency electrosurgical apparatus for treatment of tissue" (see page 1, first paragraph, first sentence of D3). "More particularly, [document D3] relates to an electrosurgical system having multiple ablation probes to

treat large volumes of tissue, particularly for the treatment of tumors in the liver and other tissues and organs" (see page 1, first paragraph, second sentence of D3). "The tissue ablation system 10 [of document D3] generally includes a plurality of tissue ablation probes 12 ... for introduction into the body of a patient for ablative treatment of target tissue" (see page 11, lines 10 to 13 of D3).

Thus, document D3 discloses feature 1).

Feature 2) – energy delivery devices:

Generally, the electrosurgical system of document D3 has multiple ablation probes (see page 1, first paragraph, second sentence of D3). As to a detailed embodiment, "[t]he tissue ablation system 10 includes a plurality of tissue ablation probes 12 ... for introduction into the body of a patient for ablative treatment of target tissue" (see page 11, lines 10 to 13 of D3). The ablation probes 12 are selectively provided with radio frequency (RF) power (see page 11, line 16 of D3). "[E]ach probe 12 includes ... an array of electrode tines 32 carried by the distal end 28 of the probe shaft 26" (see page 11, line 21 to page 12, line 2 of D3).

Therefore, the electrosurgical system of document D3 comprises a plurality of energy delivery devices, namely ablation probes 12, each of which including at least one electrode, namely an array of electrode tines 32, for delivering electrical energy, namely RF power, to a tissue of the patient's body, when the ablation probes 12 are introduced into the patient's body for ablative treatment of target tissue.

Thus, document D3 discloses feature 2).

Features 3), 3a) and 3b) – electrical generator with an energy controller:

The tissue ablation system of document D3 comprises an ablation source, such as an RF source (see page 5, lines 15, 16 of D3). In detail, "[t]he tissue ablation system 10 [further] includes ... a radio frequency (RF) generator 14 configured for generating RF power" (see page 11, lines 13, 14 of D3). "[A] power multiplexor 16 [of the system 10 is] configured for receiving the RF power from the RF generator via a standard RF cable 15 and selectively providing the RF power to the ablation probes 12" (see page 11, lines 14 to 16 of D3). The tissue ablation probes 12 are to be introduced into the patient's body for ablative treatment of target tissue (see page 11, lines 11 to 13 of D3). The power multiplexor 16 then provides the RF power to the ablation probes 12 in accordance with a particular pattern (see page 11, lines 14 to 17 in view of page 16, lines 14 to 23 of D3) and "[t]his pattern is then repeated

for subsequent time periods until completion of the ablation procedure" (see page 16, lines 23, 24 of D3).

The power multiplexor 16 subsequently delivers a nominal power signal to the tissue ablation probes 12 one after the other for a respective time period (see page 16, lines 14 to 23 in view of page 17, second paragraph, especially lines 8, 9 of page 17 of D3). The timing of said pattern, i.e., of the respective time periods for which nominal power is supplied, is controllable (see page 17, lines 2 to 4 of D3). The power multiplexor 16 comprises a control circuit 70 for respectively controlling the timing of nominal and attenuated power signal supply via each of the output connectors 21 to the tissue ablation probes 12 connected thereto by controlling respective switch elements 60 of a switch device 59 of the power multiplexor 16 (see page 19, line 15 to page 20, line 2 in view of page 18, line 16 to page 19, line 14 of D3). The control circuit 70 can control the timing of the switch device 59 in any one of a variety of manners (see page 21, lines 1, 2 of D3). According to one embodiment, the control circuit 70 can change the state of the switch device 59 "at a variable frequency" (see page 21, lines 15, 16 of D3), i.e., by varying the time periods for which nominal and attenuated power signals are supplied to the tissue ablation probes. In detail, "the control circuit 70 may change the state of the switch device 59 based on physiological parameters, such as temperature or impedance, that can be sensed and delivered back to the control circuit 70 during the ablation process" (see page 21, lines 15 to 19 of D3). "In the case of an impedance measurement, the control circuit can be connected to an electrode ... on each ablation probe 12 and the dispersive electrode to determine the impedance of the intervening tissue" (see page 21, lines 20 to 23 of D3). In the case of a "temperature measurement, a temperature sensor, such as a thermistor or thermocouple ... can be mounted to an electrode of each ablation probe 12 and then coupled to the control circuit 70" (see page 21, line 23 to page 22, line 2 of D3).

Accordingly, the electrosurgical system 10 of document D3 comprises an electrical generator, namely RF power generator 14. Via the power multiplexor 16, RF power of the RF power generator 14 is delivered to the tissue ablation probes 12 and has an effect on the tissue of the patient's body where the tissue ablation probes 12 are introduced. The RF power generator 14 comprises an energy controller, namely the power multiplexor 16, which controls the RF power signal supply to the tissue ablation probes 12. The amount of RF energy delivered by the tissue ablation probes 12 is controlled during the ablation process by varying the frequency of changing the state of the switch device 59, i.e., the time periods for which nominal and attenuated energy is delivered to the tissue ablation probes 12, in dependence of a sensed physiological parameter associated with at least one of the tissue ablation probes 12.

Thus, document D3 discloses features 3), 3a) and 3b).

Feature 4) – electrosurgical probes:

According to document D3, the energy delivering devices of the electrosurgical system 10 are electrosurgical probes, namely "tissue ablation probes 12 ... for introduction into the body of a patient for ablative treatment of target tissue" (see page 11, lines 10 to 13 of D3).

Thus, document D3 discloses feature 4).

Feature 5) – sensor:

According to document D3, in "case of a temperature measurement, a temperature sensor, such as a thermistor or thermocouple ... can be mounted to an electrode of each ablation probe 12" (see page 21, line 23 to page 22, line 2 of D3).

Therefore, document D3 discloses that each electrosurgical probe is associated with at least one sensor for measuring the at least one parameter associated with the energy delivering device(s) and responsive to which the amount of time that the energy delivering electrode(s) deliver energy is varied.

Thus, document D3 discloses feature 5).

Feature 6) – tissue property-indicative parameter:

According to document D3, "the control circuit 70 may change the state of the switch device 59 based on physiological parameters, such as temperature or impedance, that can be sensed and delivered back to the control circuit 70 during the ablation process" (see page 21, lines 15 to 19 of D3).

A physiological parameter, such as temperature at the ablation probe 12, when inserted into a patient's body tissue, or impedance of the intervening tissue between probes 12 (see page 21, line 20 to page 22, line 2 of D3), is a parameter indicative of a property of the tissue to which energy is delivered.

Thus, document D3 discloses feature 6).

Feature 7) – energy delivery device number detection:

According to document D3, if the number of ablation probes used is less than the number of output ports available, a “particular pattern followed by the power multiplexor 116 in delivering the power signals to the ablation probes 12 will depend on the number of used output connectors 21; i.e., the number of output connectors 21 to which ablation probes 12 are connected” (see page 25, lines 7 to 10 of D3). In further accordance with document D3, the power multiplexor 16 also comprises a control circuit 170 that is similar to control circuit 70 (see page 27, lines 16, 17 of D3) and the power multiplexor 16 can be incorporated into RF power generator 14 (see page 14, lines 18 to 20 of D3). “The control circuit 170 can determine the number of used output connectors 21 in any variety of manners” (see page 28, lines 17, 18 of D3). According to one embodiment, “the control circuit 170 can be configured to automatically sense the output connectors 21 that are to be used when the ablation probes 12 are mated with these output connectors 21” (see page 29, lines 4 to 6 of D3).

Therefore, the RF power generator 14 (including the power multiplexor 16 and, thus, its control circuit 170) is capable of automatically detecting the number of energy delivering devices, namely the tissue ablation probes 12, coupled to the generator 14.

Thus, document D3 discloses feature 7).

ii) Document D4 (US 2006/0079886 A1)

The disclosure of document D4 (see **annex AG 5**) is novelty-destroying for the subject-matter of claim 1 of EP 2 653 128 B1. In the following, relevant passages of document D4 will be identified that disclose each of the features 1) to 7) of claim 1 of EP 2 653 128 B1.

Feature 1) – electrosurgical system:

Document D4 discloses “a radiofrequency electrosurgical system employing multiple electrodes for producing large ablation volumes in tissue or producing multiple ablation volumes in tissue” (see page 1, paragraph [0003] of D4).

Thus, document D4 discloses feature 1).

Feature 2) – energy delivery devices:

"The electrosurgical system E comprises a plurality of electrodes 101, 102, and 103, that are inserted into an organ OR, which may represent any organ in the human body. Their distal tips 104, 105, and 106, respectively, are uninsulated and conductively exposed so that electrical currents induce heating within the tissue or organ OR" (see page 3, paragraph [0031] of D4). "These electrodes may be, for example, metal shafts with an insulated portion, except for an exposed distal tip" (see page 5, paragraph [0053], second sentence of D4).

Accordingly, document D4 discloses that the electrosurgical system E comprises a plurality of energy delivery devices, namely electrodes with an insulated metal shaft and an exposed distal tip, each comprising at least one electrode for delivering electrical energy to a tissue of the patient's body.

Thus, document D4 discloses feature 2).

Features 3), 3a) and 3b) – electrical generator with an energy controller:

- 1) The electrodes 101, 102, and 103 of the electrosurgical system E of document D4 are coupled to a generator 100 (see page 3, paragraph [0032], first sentence of D4). "The generator 100 will include a radiofrequency or high frequency type of generator 116 for generating electrosurgical energy to be applied to the organ" (see page 3, paragraph [0032] of D4). The electrode "distal tips 104, 105, and 106, respectively, are uninsulated and conductively exposed so that electrical currents induce heating within the tissue or organ OR" (see page 3, paragraph [0031], third sentence of D4).

Accordingly, document D4 discloses an electrical generator, namely generator 116, for coupling to the plurality of energy delivery devices, namely the electrodes 101, 102, and 103, such that an output of the generator 116 can be delivered via the plurality of energy delivery devices (electrodes 101, 102, and 103) to produce an effect on the tissue of the patient's body.

Thus, document D4 discloses feature 3).

- 2) "The generator 100 has control elements, e.g., a controller ... which may, for example, switch radiofrequency power sequentially to each of the electrodes" (see page 3, paragraph [0032], third sentence of D4).

Thus, document D4 discloses feature 3a).

- 3) According to document D4, "electrodes 101, 102, and 103 are independently activated with radiofrequency energy from generator 100" (see page 3, paragraph [0038], first sentence of D4). "The generator 100 includes a radiofrequency source 216 for supplying RF energy and a controller 217 for controlling the supply of RF energy to the multiple electrodes" (see page 4, paragraph [0042], second sentence of D4). "The controller 217 includes a switching mechanism 240 including a plurality of output channels for individually supplying RF energy to the multiple electrodes" (see page 4, paragraph [0043], first sentence of D4). During cauterization mode, "the controller 217 will then calculate the duty cycle of the power to be applied to maintain a desired temperature of the exposed portion 204 of the selected electrode 201" (see page 7, paragraph [0069], third sentence of D4). "If the temperature at the tip 204 goes above the predetermined limit, the controller 217 will adjust the duty cycle of the RF energy being applied to maintain the predetermine[d] temperature limit ..., e.g., lower the duty cycle" (see page 7, paragraph [0069], seventh sentence of D4).

Accordingly, document D4 discloses that the controller 217 of the generator 100 controls delivery of energy to the electrodes 101, 102, 103 such that an amount of energy delivered by at least one of the plurality of energy delivery devices, namely by electrode 201, is controlled during the procedure by varying an amount of time, i.e., by varying the duty cycle, that the at least one of the plurality of energy delivery devices, namely electrode 201, is delivering energy responsive to at least one measured parameter associated with the at least one of the plurality of energy delivery devices, namely responsive to the temperature of the tip 204 of electrode 201.

Thus, document D4 discloses feature 3b).

Feature 4) – electrosurgical probes:

According to document D4, the energy delivering devices of the electrosurgical system E are "metal shafts with an insulated portion, except for an exposed distal tip" (see page 5, paragraph [0053], second sentence of D4). These tip-ended metal shafts are electrosurgical probes.

Thus, document D4 discloses feature 4).

Feature 5) – sensor:

According to document D4, “the electrode includes a temperature sensor such as a thermocouple” (see page 5, paragraph [0052], first sentence of D4). During cauterization, the temperature of the tip 204 of selected electrode 201 is continuously monitored (see page 7, paragraph [0069], sixth sentence of D4). As the cauterization mode is entered after the ablation mode is completed, each electrode initially inserted into the patient’s body for ablation of tissue is to be removed again in the cauterization mode (see page 7, paragraph [0067] of D4). Accordingly, each electrode has a temperature sensor.

Thus, document D4 discloses feature 5).

Feature 6) – tissue property-indicative parameter:

According to document D4, the duty cycle of delivering energy to an electrode is varied depending on the temperature measured at the tip 204 of the electrode 201 (see page 7, paragraph [0069], third, sixth and seventh sentences of D4). As the temperature measured at the tip 204 of the electrode 201 is the temperature applied to the tissue to be cauterized, the measured temperature is indicative of a property of the tissue to which energy is delivered, namely the temperature of the tissue in direct contact with the electrode tip 204.

Thus, document D4 discloses feature 6).

Feature 7) – energy delivery device number detection:

According to document D4, “[a] series E(N) of N electrodes 201, 202, 203 is shown inserted into organ or bodily element OR and coupled to the switching mechanism 240 [of the controller 217 of the generator 100]” (see page 5, paragraph [0053], first sentence in view of page 4, paragraph [0043], first sentence and page 3, paragraph [0032], second sentence of D4). “The controller 217 will sequence power through each selected channel of the switching mechanism 240 to determine if an electrode is attached to the channel ... If the measured impedance is below a predetermined limit, the control mechanism will confirm an electrode is attached and repeat the process for each selected channel” (see page 6, paragraph [0060] of D4). By this particular power sequencing procedure, the controller 217 of the generator 100 automatically detects the number of energy delivery devices, namely electrodes, coupled to the generator 100.

Thus, document D4 discloses feature 7).

c. Lack of inventive step

The subject-matter of independent claim 1 of EP 2 563 128 B1 is furthermore not patentable because it lacks an inventive step.

i) Combination of documents D5 and D6 vs. independent claim 1**i.a) Features known from document D5****Feature 1) – electrosurgical system:**

Document D5 (see **annex AG 6**) teaches a high frequency energy device comprising a generator 10 for generating high frequency voltage and a number of electrodes for applying a high frequency current corresponding to the high frequency voltage to a patient's tissue (see abstract of D5).

Thus, document D5 teaches feature 1).

Feature 2) – energy delivery devices:

The high frequency energy device as taught by document D5 comprises a plurality of electrodes for applying a high frequency current corresponding to the generator's high frequency voltage to a patient's tissue (see abstract of D5), in accordance with feature 2).

Features 3), 3a) and 3b) – electrical generator with an energy controller:

The high frequency device as taught by document D5 comprises an electrical generator 10 for coupling to the plurality of electrodes such that an output of the generator 10 can be delivered via the plurality of electrodes to produce an effect on the tissue of the patient's body (see abstract and page 5, paragraph [0031] as well as Fig. 1 of D5), in accordance with feature 3).

Further, document D5 teaches that a controller 24 for controlling energy delivery is accommodated in a housing of the generator 10 (see page 4, paragraph [0022], first sentence of D5), in accordance with feature 3a).

Furthermore, document D5 teaches that the controller 24 controls the amount of energy delivered by the electrodes to the patient's body tissue by varying an amount of time that the electrodes are delivering energy responsive to a measured parameter associated with the electrodes, namely the number of the electrodes connected to the generator 10 (see page 4, paragraph [0021], energy delivery according to Fig. 3 vs. energy delivery according to Fig. 4 and page 6, end of paragraph [0036] of D5).

Thus, document D5 also discloses feature 3b).

Feature 4) – electrosurgical probes:

Document D5 teaches that the high frequency energy device comprises electrodes for applying a high frequency current corresponding to the high frequency voltage to a patient's tissue (see abstract of D5). As is clear from Fig. 1 of document D5, these electrodes 181, 182 are electrosurgical probes, in accordance with feature 4).

Feature 7) – energy delivery device number detection:

Document D5 teaches that the generator outputs comprise sensors for determining the number of electrodes connected to the outputs (see page 4, paragraph [0021], first sentence of D5). Accordingly, in line with the teaching of document D5, the generator 10 is capable of automatically detecting the number of energy delivery devices, i.e., electrodes, coupled to the generator 10 (see page 4, paragraph [0021], last sentence of D5).

In other words, document D5 also discloses feature 7).

i.b) Differing features 5) and 6) are known from document D6

Document D5 is silent about features 5) and 6) of independent claim 1.

According to features 5) and 6) of independent claim 1, the measured parameter responsive to which the energy delivery is controlled is indicative of a property of the tissue to which energy is delivered, wherein said tissue property parameter is measured by a sensor respectively associated with each electrosurgical probe.

These differing features have the technical effect that the control of the energy delivery to the patient's tissue is optimized in view of the surgical result to be achieved.

Thus, the objective technical problem underlying features 5) and 6) of claim 1 of the patent EP 2 653 128 (D1, see **annex AG 1**) is to provide an improved control for delivering energy to the patient's tissue, which is optimized in view of the surgical result to be achieved at the patient's tissue.

For solving this problem, the skilled person would consider document D6 (see **annex AG 7**), because document D6 relates to the same technical field as document D5, i.e., tissue ablation systems using high frequency energy (see abstract of D6), and teaches features 5) and 6).

Feature 5) – sensor:

Document D6 (see claim 11) teaches to provide each electrode of a plurality of probes of a medical apparatus for treatment by radiofrequency ablation of tissue with a respective temperature sensor for sensing the temperature of the electrodes. Document D6 thus teaches feature 5).

Feature 6) – tissue property-indicative parameter:

Document D6 (see claim 11) further teaches that the ablation of tissue at each electrode is independently controlled using closed loop feedback of the temperature of the electrode. According to claims 17 and 18 of document D6, each temperature sensor comprises a thermocouple at least partially embedded in the electrode. As the temperature measured by said thermocouple at the surface of the electrode is the temperature applied to the tissue to be treated, the measured temperature is indicative of a property of the tissue to which energy is delivered, namely the temperature of the tissue in direct contact with the electrode surface. Thus, document D6 teaches feature 6).

i.c) Combining the teachings of document D5 and D6 has been obvious

A modification of the teaching of document D5 by addition of the above-identified features of document D6 is already motivated by the teaching of document D5:

In fact, document D5 already teaches that it is an aim to further optimize the control of energy delivery to the patient's body tissue, and that it is especially conceivable to consider

further parameters for such optimization (see page 6, paragraph [0036], last sentence of D5). Moreover, optimization is always a goal of the skilled person.

Document D6 expressly teaches such "further parameters" as hinted at in paragraph [0036] on page 6 of document D5.

As a consequence, in view of the above-indicated objective problem, the person skilled in the art is motivated to combine the teachings of documents D5 and D6 as explained above, and, thereby, arrives at the subject-matter of independent claim 1 of EP 2 653 128 B1 in an obvious manner, i.e., without the necessity to perform an inventive step.

ii) Combination of document D6 with skilled person's knowledge vs. independent claim 1

ii.a) Features known from document D6

Feature 1) – electrosurgical system:

Document D6 (see **annex AG 7**) teaches a medical apparatus for treatment by radiofrequency ablation of tissue, comprising an RF energy generator and one or more probes each comprising a plurality of separate electrodes (see page 3, line 25 to page 4, line 2 and claim 11 of D6).

Thus, document D6 teaches feature 1).

Feature 2) – energy delivery devices:

The medical apparatus as taught by document D6 comprises one or more probes each comprising a plurality of separate electrodes, wherein energy supply to each electrode is controllable for tissue ablation (see page 4, lines 1, 2 and 7 to 10 and claim 11 of D6), in accordance with feature 2).

Features 3), 3a) and 3b) – electrical generator with an energy controller:

The medical apparatus as taught by document D6 comprises an RF energy generator and a programmable controller for independently regulating the amount of RF energy delivered to each electrode for ablation of tissue (see page 3, line 27 and page 4, lines 7 to 10 and claim 11 of D6), in accordance with feature 3).

It is evident that the programmable controller is functionally comprised by the RF energy generator, as defined by feature 3a).

Furthermore, document D6 teaches that energy delivery to each electrode can be interrupted independently when "at least one of the voltage, current, impedance and average power measured at the respective electrode exceeds a predetermined threshold" (see claim 20 of D6). Accordingly, document D6 teaches to vary an amount of time that the electrodes are delivering energy responsive to a measured parameter associated with the electrodes connected to the generator.

Thus, document D6 also discloses feature 3b).

Feature 4) – electrosurgical probes:

Document D6 teaches that the medical apparatus comprises probes (see claim 11 of D6), in accordance with feature 4).

Feature 5) – sensor:

Document D6 (see claim 11) teaches to provide each electrode of a plurality of probes of a medical apparatus for treatment by radiofrequency ablation of tissue with a respective temperature sensor for sensing the temperature of the electrodes. Document D6 thus teaches feature 5).

Feature 6) – tissue property-indicative parameter:

Document D6 (see claim 11) further teaches that the ablation of tissue at each electrode is independently controlled using closed loop feedback of the temperature of the electrode. According to claims 17 and 18 of document D6, each temperature sensor comprises a thermocouple at least partially embedded in the electrode. As the temperature measured by said thermocouple at the surface of the electrode is the temperature applied to the tissue to be treated, the measured temperature is indicative of a property of the tissue to which energy is delivered, namely the temperature of the tissue in direct contact with the electrode surface.

Thus, document D6 teaches feature 6) as well.

ii.b) Feature 7) belongs to the skilled person's knowledge

Document D6 is silent about feature 7) of the independent claim 1 of the patent EP 2 653 128 (D1).

Feature 7) defines the generator's capability of automatically detecting the number of energy delivery devices coupled to the generator.

This differing feature 7) has the effect that the number of energy delivery devices coupled to the generator is automatically known and does not have to be counted by the user and entered manually. The resulting object is to disburden the user from the mental/physical tasks of counting and inputting the number of connected energy delivery devices.

It is a straight-forward option for the skilled person to provide the apparatus to which the probes to be detected are connected, i.e., the generator, with such automated number detecting means. To perform said number detection automatically is also obvious to the skilled person, who is always looking for increase of efficiency.

Thus, inclusion of means for detecting the number of probes connected to the generator of D6 does not require inventive skills.

As a consequence, when considering the teaching of document D6 in view of the skilled person's knowledge, the skilled person arrives at the subject-matter of independent claim 1 of EP 2 653 128 B1 in an obvious manner, i.e., without the necessity to perform an inventive step.

iii) Combination of document D6 with at least one of documents D7, D8 and D9 vs. independent claim 1**iii.a) Features known from document D6**

As stated under section ii.a) above, features 1) to 6) of the independent claim 1 of EP 2 653 128 B1 are known from document D6.

iii.b) Differing feature 7) taught by each of documents D7, D8 and D9

Document D7 (see **annex AG8**) explicitly teaches an electrostimulator capable of detecting the number of electrodes coupled thereto (see abstract of D7).

Document D8 (see **annex AG9**) explicitly teaches that an electroporation therapy apparatus (as for example defined in column 2, lines 11 to 25 of D8) comprises a circuit for determining a determined number of electrode needles coupled to a connector connecting the electrode needles to a source for generating voltage pulses (see claim 1, especially feature c) of D8).

Even though in a more general context, also document D9 (see **annex AG10**) teaches that the number of loads connected to output connectors of a power source can be detected via a connection detector 7 (see abstract of D9).

In view of the above, adding either the number determining circuit taught by document D8 or the connection detector taught by document D9 to the tissue ablation system of document D6 is a straight-forward approach not necessitating use of inventive skills.

As a consequence, when considering a combination of the teaching of document D6 with the teaching of one of documents D7, D8 and D9, the skilled person arrives at the subject-matter of independent claim 1 of EP 2 653 128 B1 in an obvious manner, i.e., without the necessity to perform an inventive step.

4. Invalidity of subject-matter of dependent claims of EP 2 653 128 B1

In the following it will be shown that none of the dependent claims 2 to 8 of EP 2 653 128 B1 contains a feature justifying the presence of an inventive step over the cited prior art.

4.1 Dependent claim 2

Specifying the at least one sensor as a temperature sensor for sensing a temperature indicative of the temperature of a tissue, in which the energy delivery device with which the sensor is associated is inserted, is already known from each of documents D3, D4 and D6 (see **annexes AG 4, AG 5 and AG 7**, respectively).

According to document D3, in "case of a temperature measurement, a temperature sensor, such as a thermistor or thermocouple ... can be mounted to an electrode of each ablation probe 12" (see page 21, line 23 to page 22, line 2 of D3). Based on the physiological parameter 'temperature', i.e., the temperature measured at the tissue in contact with the energy delivering electrode, the energy delivery time frames for the electrodes are controlled (see page 21, lines 15 to 19 of D3 as well as the arguments presented in above section IV.1, Features 3), 3a) and 3b)).

According to document D4, "the electrode[, which is a device for delivering energy to the patient's body,] includes a temperature sensor such as a thermocouple" (see page 5, paragraph [0052], first sentence of D4 and above section IV.1, Feature 2)). "[T]he duty cycle of the power to be applied [to selected electrode 201 is controlled so as] to maintain a desired temperature of the exposed portion 204 of the selected electrode 201" (see page 7, paragraph [0069], third sentence of D4). The temperature measured on the exposed electrode portion 204 is the temperature to which the tissue in contact with the exposed electrode portion 204 is heated. Thus, said measurement is indicative of the temperature of the tissue to which energy is applied.

Document D6 (see claim 11) teaches to provide each electrode of a plurality of probes for treatment by radiofrequency ablation of tissue with a respective temperature sensor for sensing the temperature of the electrodes. According to claims 17 and 18 of document D6, each temperature sensor comprises a thermocouple at least partially embedded in the electrode. As the temperature measured by said thermocouple at the surface of the electrode is the temperature applied to the tissue to be treated, the measured temperature is indicative of the temperature of the tissue to which energy is delivered, i.e., the temperature of the tissue in direct contact with the electrode surface.

Therefore, the feature of dependent claim 2 of EP 2 653 128 B1 is not novel vis-à-vis the disclosure of each of documents D3 and D4 and also not based on an inventive step over a combination of the teachings of documents D5 (see **annex AG 6**) and D6 or of the teaching of document D6 either with the skilled person's knowledge alone or additionally with the teaching of one of documents D7, D8 and D9 (see **annexes AG 8, AG 9 and AG 10**, respectively) for the reasons already presented under sections c. i), ii) and iii) above and supplemented in the foregoing paragraph.

4.2 Dependent claim 3

Specifying the at least one measured parameter as being selected from the group consisting of temperature and impedance is already known from each of documents D3, D4 and D6 (see **annexes AG 4, AG 5 and AG 7**, respectively).

For the measured parameter being the temperature, reference is made to section 4.1 above. In regard to the measured parameter being the impedance, the following is noted:

According to document D3, "the control circuit 70 may change the state of the switch device 59 based on physiological parameters, such as temperature or impedance, that can be sensed and delivered back to the control circuit 70 during the ablation process" (see page 21, lines 15 to 19 of D3). "In the case of an impedance measurement, the control circuit can be connected to an electrode ... on each ablation probe 12 and the dispersive electrode to determine the impedance of the intervening tissue" (see page 21, lines 20 to 23 of D3).

According to document D4, "[t]he digital values of the current and voltage will then be sent to module 248 to calculate impedance and power at the active electrode, which will further be used for controlling the RF energy output" (see page 4, paragraph [0043], last sentence of D4). Based on the calculated impedance, the duty cycle for the electrodes is controlled (see page 6, paragraph [0062] of D4).

According to the teaching of document D6, RF energy delivery to each electrode is independently interrupted when the impedance measured at the respective electrode exceeds a predetermined threshold (see claim 20 of D6).

Therefore, the feature of dependent claim 3 of EP 2 653 128 B1 is not novel vis-à-vis the disclosure of each of documents D3 and D4 and also not based on an inventive step over a combination of the teachings of documents D5 (see **annex AG 6**) and D6 or of the teaching of document D6 either with the skilled person's knowledge alone or additionally with the teaching of one of documents D7, D8 and D9 (see **annexes AG 8, AG 9 and AG 10**, respectively) for the reasons already presented under sections c. i), ii) and iii) above.

4.3 Dependent claim 4

The presence of a measurement interface operable to receive tissue property indicative parameter signals from the sensors of the energy delivery devices and to interface with the energy controller is an inherent feature of the electrosurgical systems of documents D3, D4

and D6 (see **annexes AG 4, AG 5 and AG 7**, respectively) in view of each of their electrode duty cycle controls:

According to document D3, the amount of RF energy delivered by the tissue ablation probes 12 is controlled during the ablation process by varying the frequency of changing the state of the switch device 59, i.e., the time periods for which nominal and attenuated energy is delivered to the tissue ablation probes 12, in dependence of a sensed physiological parameter associated with at least one of the tissue ablation probes 12 (see arguments presented under above section b. i), Features 3), 3a) and 3b)).

Document D4 discloses that the controller 217 of the generator 100 controls delivery of energy to the electrodes 101, 102, 103 such that an amount of energy delivered by at least one of the plurality of energy delivery devices, namely by electrode 201, is controlled during the procedure by varying an amount of time, i.e., by varying the duty cycle, that the at least one of the plurality of energy delivery devices, namely electrode 201, is delivering energy responsive to at least one measured parameter associated with the at least one of the plurality of energy delivery devices, namely responsive to the temperature of the tip 204 of electrode 201 (see arguments presented under above section b. ii), Features 3), 3a) and 3b)).

Document D6 (see claim 11) teaches that the ablation of tissue at each electrode is independently controlled using closed loop feedback of the temperature of the electrode.

Therefore, the feature of dependent claim 4 of EP 2 653 128 B1 is not novel vis-à-vis the disclosure of each of documents D3 and D4 and also not based on an inventive step over a combination of the teachings of documents D5 (see **annex AG 6**) and D6 or of the teaching of document D6 either with the skilled person's knowledge alone or additionally with the teaching of one of documents D7, D8 and D9 (see **annexes AG 8, AG 9 and AG 10**, respectively) for the reasons already presented under sections c. i), ii) and iii) above, in view of the skilled person's knowledge according to the first paragraph of present section 4.3.

4.4 Dependent claim 5

Moreover, the provision of a detector for detecting a quantity of energy delivery devices coupled to the generator is a feature already known from each of documents D3, D4, D5, D7, D8 and D9 (see **annexes AG 4, AG 5, AG 6, AG 8, AG 9 and AG 10**, respectively).

According to document D3, "the control circuit 170 can be configured to automatically sense the output connectors 21 that are to be used when the ablation probes 12 are mated with these output connectors 21" (see page 29, lines 4 to 6 of D3). Thus, the control circuit 170 of the generator 14 comprises detecting circuitry and, thus, a detector for detecting the quantity of energy delivery device coupled to the output connectors 21 of the generator 14.

According to document D4, "[t]he controller 217 will sequence power through each selected channel of the switching mechanism 240 to determine if an electrode is attaches to the channel ... If the measured impedance is below a predetermined limit, the control mechanism will confirm an electrode is attached and repeat the process for each selected channel" (see page 6, paragraph [0060] of D4). Thus, the controller 217 of the generator 100 comprises detecting circuitry and, thus, a detector for detecting the quantity of energy delivery device coupled to the output channels of the generator 100.

According to document D5, electrode connecting means 171, 172 of the generator 10 comprise sensor means for detecting the number/quantity of coupled electrodes (see page 4, paragraph [0021] of D5). Thus, the sensor means are means for detecting the quantity of energy delivery devices coupled to the generator electrode connecting means 171, 172. Accordingly, document D5 teaches provision of the detector of dependent claim 5 of the patent EP 2 653 128 (D1).

Document D7 teaches an electrostimulator capable of detecting the number of electrodes coupled thereto (see abstract of D7). Consequently, the electrostimulator has to have electrode number detecting means, i.e., a detector.

Document D8 teaches that an electroporation therapy apparatus (as for example defined in column 2, lines 11 to 25 of D8) comprises a circuit for determining a determined number of electrode needles coupled to a connector connecting the electrode needles to a source for generating voltage pulses (see claim 1, especially feature c) of D8).

Even though in a more general context, also document D9 teaches a connection detector 7 for detecting the number of loads connected to output connectors of a power source (see abstract of D9).

It is also known from each of documents D3, D4, D5, D7 and D8 that functional operation modes for controlling the energy delivery devices in dependence of the number of energy delivery devices are provided and can be selected.

According to document D3, "[t]he control circuit 70 may be configured to control the timing of the switch device 59 in any one of a variety of manners" (see page 21, lines 1, 2 of D3). "The particular pattern followed by the power multiplexor 116 in delivering the power signals to the ablation probes 12 will depend on the number of used output connectors 21; i.e., the number of output connectors 21 to which ablation probes 12 are connected" (see page 25, lines 7 to 10 of D3). In view of this control, the generator 14 is capable of operating in a plurality of functional operating modes, wherein the presence of a storage element for storing the operating modes associated with the quantity of energy delivery devices, i.e., electrodes, and the presence of a mode selector for selecting a current operating mode from the operating modes applicable to the quantity of energy deliver devices are respective inherent features of the generator 14.

Thus, according to document D3, as the power signal delivery to the ablation probes 12 is to follow a pattern dependent on the number of output connectors in use, the control circuit 70 is configured to control the energy delivery in accordance with said pattern.

Also according to document D4, "the switching among electrodes will depend on how many electrodes are selected for the procedure[, wherein] [e]ach electrode employed in the procedure will have a minimum off time following a period of activation" (see page 6, paragraph [0063], first and second sentence of D4). Electrode control modes dependent on the number of selected electrodes are described in paragraphs [0063] and [0064] on pages 6 and 7 of document D4. Also in view of this control, the generator 100 is capable of operating in a plurality of functional operating modes, wherein the presence of a storage element for storing the operating modes associated with the quantity of energy delivery devices, i.e., electrodes, and the presence of a mode selector for selecting a current operating mode from the operating modes applicable to the quantity of energy deliver devices are respective inherent features of the generator 100.

Thus, according to document D4, as the power signal delivery to the electrodes is to follow a pattern dependent on the number of output connectors in use, the generator 100 is configured to control the energy delivery in accordance with said pattern (see paragraphs [0063] and [0064] on pages 6 and 7 of D4).

As also according to document D5, the energy delivery control is based on the number of electrodes connected to the generator 10 (see page 4, paragraph [0021] of D5), the above reasoning that a mode storage element and a mode selector as defined in dependent claim 5 of the patent EP 2 653 128 (D1, see **annex AG 1**) are inherent features of the electrosurgical system applies.

As a precautionary measure, in case the above reasoning relying on inherent features as to the disclosure of documents D3, D4 and D5 is not followed, reference is made to document D7 explicitly teaches that an electrode energization pattern suiting the number of electrodes in use is automatically selected and output by an electrostimulator (see abstract, especially last sentence, of D7).

Document D8 teaches, for an electroporation therapy apparatus (as for example defined in column 2, lines 11 to 25 of D8), that the energy delivery control addresses the number of connected electrode needles detected by a number determination circuit of the apparatus (see claim 1, features c) and d) of D8).

In a more general context, also document D9 teaches that the number of loads connected to output connectors of a power source are to be detected via a connection detector 7 so as to control the energy supply to said loads in dependence of the number of load connections to the output connectors (see abstract of D9).

As also according to each of documents D8 and D9, the energy delivery control is based on the number of electrodes connected to an energy source (see respective paragraphs above), the above reasoning that a mode storage element and a mode selector as defined in dependent claim 5 of the patent EP 2 653 128 (D1) are inherent features of the electrosurgical system or that these features of dependent claim 5 of the patent EP 2 653 128 at least are rendered obvious by the additional teaching of document D7 applies.

In view of the above, the feature of dependent claim 5 of EP 2 653 128 B1 is not novel vis-à-vis the disclosure of documents D3 and D4 and also not based on an inventive step over a combination of the teachings of documents D5 and D6 or of the teaching of document D6 either with the skilled person's knowledge alone or additionally with the teaching of at least one of documents D7, D8 and D9 for the reasons already presented under sections c. i), ii) and iii) above and supplemented in the present section 4.4).

Moreover, the feature of dependent claim 5 of EP 2 653 128 B1 is at least not based on an inventive step over a combination of the teachings of one of documents D3 and D4 with the teaching of document D7 or over a combination of the teachings of documents D5 and D6 or of the teaching of document D6 either the teaching of document D7 and the skilled person's knowledge or additionally with the teaching of one of documents D8 and D9.

4.5 Dependent claim 6

As to the features of dependent claim 6 of EP 2 653 128 B1 reference is made to the arguments presented with regard to the features 3), 3a) and 3b) of independent claim 1 of EP 2 653 128 B1 under above sections 3. b. i) and ii), 3. c. i), ii) and iii) as well as to the arguments made with regard to the feature of dependent claim 4 of EP 2 653 128 B1 under 4.3 above.

For the reasons presented as to the features 3), 3a) and 3b) of independent claim 1 and the feature of dependent claim 4 of EP 2 653 128 B1, also the features of dependent claim 6 of EP 2 653 128 B1 are not novel vis-à-vis the disclosure of documents D3 (see **annex AG 4**) and D4 (see **annex AG 5**) and also not based on an inventive step over a combination of the teachings of documents D5 (see **annex AG 6**) and D6 (see **annex AG 7**) or of the teaching of document D6 either with the skilled person's knowledge alone or additionally with the teaching of one of documents D7, D8 and D9 (see **annexes AG8, AG 9 and AG 10**, respectively).

4.6 Dependent claim 7

Regarding the features of dependent claim 7, directly controllable parameters, for example, are voltage and current as well time of energy delivery and an indirectly controllable parameter, for example, is temperature. If voltage output of the generator is modified, the current supplied to an electrode connected to the generator is affected and modified in dependence of the modified voltage output, which in turn has a modifying effect on the temperature measured at the tissue next to the electrode. The same is true for a modification of the timing of the energy delivery, which also has a modifying effect on the temperature measured at the tissue next to the electrode.

Each of documents D3, D4 and D5 (see **annexes AG 4, AG 5 and AG 6**, respectively) discloses duty cycle power control in dependence of a target temperature at the tissue site (see arguments present above with reference to features 3), 3a), and 3b) under sections 3. b. i) and ii), 3. c. i), ii) and iii), and, thus, the features of dependent claim 7 of EP 2 653 128 B1. Thus, also the features of dependent claim 7 of EP 2 653 128 B1 are not novel vis-à-vis the disclosure of documents D3 and D4 and also not based on an inventive step over a combination of the teachings of documents D5 and D6 (see **annex AG 7**) or of the teaching of document D6 either with the skilled person's knowledge alone or additionally with the

teaching of one of documents D7, D8 and D9 (see **annexes AG8, AG 9 and AG 10**, respectively).

4.7 Dependent claim 8

Coupling the plurality of energy delivery devices to the electrical generator via a single cable is also already known from document D3 (see **annex AG 4**) and D8 (see **annex AG 9**).

According to Fig. 1 of document D3, a single cable 15 couples three probes to the generator 14.

Also according to Fig. 3 of document D8, a single cable couples a plurality of electrode needles 314, i.e., energy delivery devices in the form of needles having electrodes, of the generator 300.

When having the aim to reduce the number of cables used for coupling a plurality of energy delivery devices at least at the generator side, the solution taught by Fig. 1 of document D3 or the solution taught by Fig. 3 of document D8 may be used to respectively modify the electrosurgical systems of each of documents D4 and D5 (see **annexes AG 5 and AG 6**, respectively) in an obvious manner, as documents D3, D4 and D5 relate to the same technical field of electrosurgical systems having a plurality of energy delivery devices coupled to a generator.

Therefore, the feature of dependent claim 8 of EP 2 653 128 B1 is not novel vis-à-vis the disclosure of document D3 and also not based on an inventive step over a combination of the teachings of either documents D4 and D8 or documents D5, D6 (see **annex AG 7**) and D8 or of the teaching of document D6 either with the teaching of document D8 and the skilled person's knowledge or additionally with the teaching of one of documents D7 (see **annex AG 8**) and D9 (see **annex AG 10**) for the reasons already presented under sections 3. b. i), ii) and 3. c. i), ii) and iii) above and supplemented in the two foregoing paragraphs.

5. Conclusion

European patent EP 2 653 128 B1 extends beyond the relevant application documents in their originally filed version.

Moreover, each of documents D3 and D4 alone already destroys novelty of independent claim 1 of EP 2 653 128 B1.

Finally, through a straight-forward and easy-to-implement combination of the teachings of the documents as cited for lack of an inventive step in chapters 3. c. i), ii) and iii) above, an electrosurgical system according to independent claim 1 of EP 2 653 128 B1 can be achieved by the skilled person without having to apply inventive skills. Therefore, the subject-matter of independent claim 1 of EP 2 653 128 B1 does not involve an inventive step.

Summarizing the above, the German part of European patent EP 2 653 128 B1 is invalid in its entirety due to extension of subject-matter, lack of novelty and lack of inventive step.

6. Grounds for non-infringement of independent claim 1 of EP 2 653 128 B1 by the 'MG2' System

Independent claim 1 of EP 2 653 128 B1 requires the generator of the electrosurgical system to be capable of automatically detecting the number of energy delivery devices coupled to the generator (feature 7)).

i) What does automatic number detection (feature 7) of claim 1) mean in accordance with EP 2 653 128 B1?

In accordance with Art. 69(1) EPC, the scope of protection of a European patent is defined by the patent claims. However, the description and drawings are to be considered for interpreting the claims.

Feature 7) of independent claim 1 of EP 2 653 128 B1 requires the generator to be capable of automatically detecting the *number* of energy delivery devices coupled to the generator.

Dependent claim 5 of EP 2 653 128 B1 defines for the generator to further comprise a detector for detecting a *quantity* of energy delivery devices coupled to the generator.

As it is unclear from the claims how the terms "number" and "quantity" differ in their meaning, Art. 69(1) EPC justifies the consultation of the description of EP 2 653 128 B1 in this regard.

Paragraph [0019] in column 5 of EP 2 653 128 B1 resolves this unclarity by indicating the terms "number" and "quantity" to essentially have the same meaning ("a detector 320 for detecting the number (i.e. quantity) of energy delivery devices 152 operatively coupled to generator 100").

Moreover, said paragraph also clarifies that the capability of the generator to automatically detect the number of energy delivery devices coupled to the generator is to be interpreted in line with EP 2 653 128 B1 as the generator being designed to perform an exact count of the connected energy delivery devices. Said latter understanding of feature 7) of independent claim 1 of EP 2 653 128 B1 is a clear consequence of the fact that, according to paragraph [0019] in view of the first sentence of paragraph [0020] in column 5 of EP 2 653 128 B1, selection options for generator operating modes are made available to a user *depending on the detected number of connected electrodes*.

In view of the above, automatic detection of the number of connected electrodes is to be understood in line with EP 2 653 128 B1 as the generator's capability to count the number of the electrodes coupled to the generator.

ii) Essence of feature 7) for grant of independent claim 1 for EP 2 653 128 B1

Feature 7) of independent claim 1 has been first included into independent claim 1 in response to the extended European search report on 23 April 2014 by the applicant (see **annex AG 12**).

In response to the Communication pursuant to Art. 94(3) EPC dated 26 May 2014, features 4), 5) and 6) have been included in but feature 7) has again been removed from independent claim 1 (see **annex AG 13**).

Finally, by an Examiner's amendment to the claims of the documents intended for grant as annexed to the Communication under Rule 71(3) EPC, feature 7) was re-entered into independent claim 1. According to the comments on sheet 2 of the Communication under Rule 71(3) EPC on the Examiner's amendments performed in the printed publication, re-inclusion of feature 7) into independent claim 1 was necessary for the subject-matter of independent claim 1 being patentable over the cited prior art (see **annex AG 11**).

By paying the fee for grant and submitting translations of such amended claims in line with the printed publication, the Applicant accepted the fact that feature 7) is an essential feature for the patentability of the claimed electrosurgical system of EP 2 653 128 B1.

iii) 'MG2' system does not determine the number of connected electrodes when detecting if an electrode is actually connected to an individual port

The 'MG2' system detects for each individual one of the four ports of the RF energy generator if an electrode is connected thereto or not (see Figure 8 below). If an electrode is detected to be connected, this is highlighted on the graphical user interface by showing a colored frame around the control section assigned to each connected electrode, by illuminating the number of the electrode port to which an electrode is connected ("1", "2" and "3" in below Figure 8), and by displaying settable details for all connected electrodes within their colored frames.



Figure 8 – GUI with connected electrodes detected for ports 1, 2, and 3

The electrode detection mechanism is based on a simple binary decision for an individual electrode (connected vs. not connected) and does not qualify as a counting in the sense of feature 7). When, as such, detecting that an individual electrode is connected, the generator of the 'MG2' system does not count the quantity of electrodes coupled to the generator in accordance with feature 7).

Moreover, the approach of detecting that an individual electrode is connected has been prior art, as also acknowledged by the patentee. In his letter of reply dated 19 July 2012 and enclosed as

the patentee states in the US examination proceedings for the parallel US patent application US 12/528,193 (meanwhile granted a US patent no. 8,343,146) that "identification of which device is attached, [but] not how many devices are attached" may not be regarded as determining a quantity of an attached plurality of devices.

Accordingly, detecting for each individual port of the RF energy generator of the 'MG2' system if an electrode is connected cannot be considered a detection of the number of the connected electrodes, i.e., a determination of the quantity of the electrodes coupled to the generator, as defined by feature 7) of granted independent claim 1 of patent EP 2 653 128.

iv) 'MG2' system does not determine the number of connected electrodes when used in bipolar configuration

When electrodes are detected to be connected to two adjacent ports of the 'MG2' system, e.g., ports (1 and 2), (2 and 3), or (3 and 4), a bipolar configuration may be selected for said electrodes present in adjacent ports (1 and 2), (2 and 3), or (3 and 4) by the user activating the bipolar button on the GUI between the control sections assigned to said electrodes coupled to adjacent ports (see Figure 9 below, in which electrodes are shown detected to be coupled to ports 1, 2 and 3, with the electrodes connected to ports 1 and 2 selected for bipolar configuration).



Figure 9 – Graphical user interface showing electrodes connected to ports 1 and 2 selected for bipolar configuration

It is important to note that when two electrodes are connected to the 'MG2' system, but the ports these two electrodes are connected to are no adjacent ones, a bipolar configuration for

the 'MG2' system is not possible. In other words, the bipolar configuration does not only require two electrodes to be connected to the 'MG2' system, but additionally necessitates (and verifies) the presence of electrodes in two adjacent ports of the 'MG2' system. In fact, for electrodes detected to be connected to ports 1 and 3 with no electrodes connected to ports 2 and 4 or for electrodes detected to be connected to ports 2 and 4 with no electrodes connected to ports 1 and 3, no bipolar configuration is selectable for the 'MG2' system, even though electrode connection is detected for two ports. Accordingly, the 'MG2' system does not count "to two" for selection of a bipolar configuration.

Moreover, a bipolar configuration is also selectable for the 'MG2' system (as shown in Figure 1 above) when electrodes are connected to three or all four of the ports. A possible bipolar configuration for the 'MG2' system with electrodes connected to ports 1, 2, and 3 (referred to as electrodes 1, 2, and 3 in the following) is shown in Figure 9 above, with electrodes 1 and 2 selected for bipolar configuration. Alternatively, it would also be possible to select electrodes 2 and 3 for bipolar configuration. In case each of the four ports of the 'MG2' system (as shown in Figure 1) has an electrode connected thereto, a double bipolar configuration can be selected by selecting the electrodes connected to ports 1 and 2 for bipolar configuration and by also selecting the electrodes connected to ports 3 and 4 for bipolar configuration.

Again, what is essential for the option of bipolar configuration selection is the presence of connected electrodes in two adjacent ports. Even though, for the graphical user interface of Figure 9 above, the question if an electrode is connected to the ports of the 'MG2' system is answered to the positive for ports 1, 2 and 3, i.e., a total of 3 ports, the 'MG2' system does not automatically detect that the number of connected electrodes is three. The same is also true for each of all four ports of the 'MG2' system having an electrode connected thereto. Thus, for selection of a bipolar configuration, the 'MG2' system neither counts to three nor to four even though three or even four electrodes are connected.

Summarizing the above, the determination of whether or not a bipolar mode can be selected is different from counting to two since if even two electrodes are connected, but not to adjacent ports, the bipolar mode cannot be selected. As such, the determination of whether or not a bipolar mode can be selected is nothing more than a logical decision of whether or not electrodes are connected to two adjacent ports.

v) No counting in any other electrode configuration of mode of operation

As has become apparent from the description of the 'MG2' system in section B. 2) above, the 'MG2' system does not have any electrode configuration or mode of operation that would require counting the number of electrodes (e.g., to determine if exactly three electrodes are connected).

vi) No realization of feature 7) and thus no infringement of claim 1

Thus, at least feature 7) of independent claim 1 of EP 2 653 128 B1 is not realized by the 'MG2' system.

As a consequence, the 'MG2' system may not be regarded as an infringement of the electro-surgical system claimed by independent claim 1 of EP 2 653 128 B1.

II. Summary

In view of the factual and legal situation, a potential request for issuance of a preliminary injunction is unfounded due to lack of claim entitlement as well as lack of grounds for injunction and, thus, may not have a prospect of success.

Finally, we kindly ask for being informed by telephone in case one of the presumed petitioners should request issuance of a preliminary injunction. Even for the case the request is withdrawn after its submission without the court deciding thereupon, we ask to be informed respectively.

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Enclosures

Annexes AG 1 to AG 14



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AG 11

Application No. 13 176 863.2 - 1666	Ref. 57.56.104794/06	Date 29.04.2016
Applicant Avent, Inc.		

Communication under Rule 71(3) EPC

1. Intention to grant

You are informed that the examining division intends to grant a European patent on the basis of the above application, with the text and drawings and the related bibliographic data as indicated below.

A copy of the relevant documents is enclosed.

1.1 In the text for the Contracting States:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MT NL NO PL PT RO SE
SI SK TR

Description, Pages

2, 6-40 as originally filed

1, 41 filed in electronic form on

23-04-2014

Claims, Numbers

1-8 filed in electronic form on

05-12-2014

Drawings, Sheets

1/12-12/12 as originally filed

With the following amendments to the above-mentioned documents proposed by the division

Description, Pages 1, 2, 6, 8, 9, 13, 14, 16-20, 22, 24, 25, 27, 32-35, 37-41

Delete Previous: 3-5

Claims, Numbers 1

Comments**DESCRIPTION**

Pages 1, 2, 6, 8, 9, 17-20, 22, 24, 25, 27, 32-35, 37-41: Description adapted to amended claims (Art. 84 EPC)

Page 1: Mention of relevant prior art in the description (Rule 42(1) EPC)

Pages 3-5: (PAGE DELETED) - Description adapted to amended claims (Art. 84 EPC)

Pages 6, 41: Deletion of vague statement about scope of protection (Guidelines, F-IV, 4.4)

Pages 13, 14, 16: Deletion of inclusions by reference (Guidelines, F-III, 8)

Page 42: (PAGE DELETED) -

CLAIMS

Page 43, Claim 1: Amendment for compliance with Art. 54, 56 EPC, in particular in view of D3 (this entailed the inclusion of the technical feature of former claim 2 into claim 1 and the corresponding renumbering of the remaining claims)

1.2 Bibliographic data

The title of the invention in the three official languages of the European Patent Office, the international patent classification, the designated contracting states, the registered name(s) of the applicant(s) and the other bibliographic data are shown on **EPO Form 2056** (enclosed).

2. Invitation

You are invited, **within a non-extendable period of four months** of notification of this communication,

2.1 to EITHER approve the text communicated above and verify the bibliographic data (Rule 71(5) EPC)

(1) by filing a translation of the claim(s) in the other two official languages of the EPO

Fee code	EUR
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(2a) by paying the fee for grant including the fee for publication:
minus any amount already paid (Rule 71a(5) EPC):

007	925.00
	0.00

Total amount:	925.00
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(3) by paying additional claims fees under Rule 71(4) EPC;
number of claims fees payable: 0
minus any amount already paid (Rule 71a(5) EPC):

016	0.00
	0.00

Total amount:	0.00
---------------	------

Important: If the translations of the claims and fees have already been filed and paid respectively in reply to a previous communication under Rule 71(3) EPC, e.g. in the case of resumption of examination after approval (see Guidelines C-V, 6), **agreement as to the text to be granted** (Rule 71a(1) EPC) must be expressed within the same time limit (e.g. by approving the text and verifying the bibliographic data, by confirming that grant proceedings can go ahead with the documents on file and/or by stating which translations of the claims already on file are to be used).

Note 1: See "Important notes concerning fee payments" below.

Note 2: Any overpaid "minus" amounts will be refunded when the decision to grant (EPO Form

2006A) has been issued.

Note 3: For the calculation of the grant fee under Article 2(2), No. 7, RFees (old fee structure), the number of pages is determined on the basis of a clean copy of the application documents, in which text deleted as a result of any amendments by the examining division is not shown. Such clean copy is made available via on-line file inspection only.

2.2 OR, in the case of disapproval, to request reasoned amendments or corrections to the text communicated above or keep to the latest text submitted by you (Rule 71(6) EPC).

In this case the translations of the claims and fee payments mentioned under point 2.1 above are NOT due.

The terms "amendment(s)" and "correction(s)" refer only to amendments or corrections of the application documents and not of other documents (e.g. bibliographic data, the designation of the inventor, etc.).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the examining division requesting that you correct this deficiency (Rule 137(4) EPC).

2.3 Bibliographic data

Where you request a change or correction of bibliographic data in response to the Rule 71(3) communication, this will **not** cause the sending of a further communication under Rule 71(3) EPC. You will still have to pay the fees and file translations in reply to the Rule 71(3) communication in the case of 2.1 above, unless you also file a reasoned request for amendments or corrections in response to the Rule 71(3) communication (see case 2.2 above).

3. Loss of rights

If neither of the two possible actions above (see points 2.1 or 2.2) is performed in due time, the European patent application will be deemed to be withdrawn (Rule 71(7) EPC).

4. Further procedure

4.1 In the case of point 2.1 above

- 4.1.1** The decision to grant the European patent will be issued, and the **mention of the grant** of the patent will be published in the European Patent Bulletin, if the requirements concerning the translation of the claims and the payment of all fees are fulfilled and there is agreement as to the text to be granted (Rule 71a(1) EPC).

Note on payment of the renewal fee:

If a renewal fee becomes due before the next possible date for publication of the mention of the grant of the European patent, publication will be effected only after the renewal fee and any additional fee have been paid (Rule 71a(4) EPC).

Under Article 86(2) EPC, the obligation to pay renewal fees to the European Patent Office terminates with the payment of the renewal fee due in respect of the year in which the mention of the grant of the European patent is published.

Note on payment of the designation fee(s):

If the designation fee(s) become(s) due after the communication under Rule 71(3) EPC, the mention of the grant of the European patent will not be published until these fees have been paid (Rule 71a(3) EPC).

- 4.1.2** After publication, the **European patent specification** can be downloaded free of charge from the EPO publication server <https://data.epo.org/publication-server> or ordered from the Vienna sub-office upon payment of a fee (OJ EPO 2005, 126).

4.1.3 Filing of translations in the contracting states

As regards translation requirements prescribed by the contracting states under Article 65(1) EPC, please consult the website of the European Patent Office

www.epo.org → Law & practice → Legal texts, National law relating to the EPC

www.epo.org → Law & practice → All Legal texts → London Agreement

In the case of a valid extension or validation

As regards translation requirements prescribed by the extension or validation states, please consult the website of the European Patent Office

www.epo.org → Law & practice → Legal texts, National law relating to the EPC

Failure to supply a prescribed translation in a contracting state, or in an extension or validation state may result in the patent being deemed to be void *ab initio* in the state concerned (Art. 65(3) EPC).

4.2 In the case of 2.2 above

If the present communication under Rule 71(3) EPC is based on an auxiliary request and, within the time limit, you maintain the main request or a higher ranking request which is not allowable, the application will be refused (Art. 97(2) EPC).

If the examining division gives its consent to the requested amendments or corrections, it will issue a new communication under Rule 71(3) EPC; otherwise, it shall resume the examination proceedings (Rule 71(6) EPC).

5. Filing of a divisional application

Any divisional application relating to this European patent application must be filed directly with the European Patent Office in Munich, The Hague or Berlin and will be in the language of the proceedings for the present application, or if the latter was not in an official language of the EPO, the divisional application may be filed in the language of the present application as filed (see Article 76(1) and Rule 36(2) EPC). Any such divisional application must be filed while the present application is still pending (Rule 36(1) EPC; Guidelines A-IV, 1.1.1).

6. Important notes concerning fee payments

6.1 For all payments, please refer to the relevant **fee code(s)**.

6.2 Automatic debiting procedure

The fee for grant, including the fee for publication, and any additional claims fees due under Rule 71(4) EPC will be debited automatically on the date of filing of the translations of the claims, or on the last day of the period of this communication. However, if the designation fee(s) become(s) due as set out in Rule 71a(3) EPC and/or a renewal fee becomes due as set out in Rule 71a(4) EPC, these should be paid separately by another permitted way of payment in order not to delay the publication of the mention of the grant. The same applies in these circumstances to the payment of extension and validation fees. For further details see the Arrangements for the automatic debiting procedure (AAD) and accompanying information from the EPO concerning the automatic debiting procedure (Annexes A.1 and A.2 to the Arrangements for deposit accounts (ADA) in Supplementary publication - OJ EPO 3/2015).

Note: If a waiver is expressed in response to a Rule 71(3) communication (see OJ EPO 2015, A52), the fee for grant, including the fee for publication/printing, and any additional claims fees will not be debited automatically. These fees must be paid separately by another means of payment allowed under the Rules relating to Fees.

6.3 Important information relating to fee amounts

Following any amendment to the Rules relating to Fees, the amount(s) mentioned in this communication may be different from the amount(s) **actually due on the date of payment**. The latest version of the Schedule of

fees and expenses, published as a Supplement to the Official Journal of the EPO, is also available on the EPO website (www.epo.org) and can be found under www.epo.org/schedule-of-fees, which allows the viewing, downloading and searching for individual fee amounts, both current and previous.

Please note that procedural fees are usually adjusted every two years, on even years, with effect from 1 April.

Examining Division:

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Enclosures: Text intended for grant
 EPO Form 2056

AG-12

European Patent Office
D-80298 München
Germany

date 23 April 2014
your ref
our ref 57.56.104794/06

VIA ONLINE FILING

Dear Sirs

European Patent Application No. 13176863.2 (2653128)
Kimberly-Clark Incorporated

In response to the EPO Communication pursuant to R69 EPC dated 28 October 2013, I enclose herewith an amended set of claims responsive to the extended European Search Report and amended pages 1 and 41 of the description to replace pages 1, 41 and 42 currently on file.

Claim 1 has been amended based on paragraph [0039] of the description.

Claims 11 and 12 have been deleted. We explicitly reserve the right to reintroduce any deleted subject matter, or to file one or more divisional applications directed thereto.

US 6183468 ("D1") has been identified in the description at page 1. It is considered that two-part form is not appropriate in the present case.

D1 discloses a single electrosurgical probe with a number of electrode regions as shown in Fig. 2. D1 fails to disclose that the generator is capable of automatically detecting the number of energy delivery devices coupled to it.

Claim 1 is thus novel.

Starting from D1, the present invention provides an electrosurgical system with improved ease-of-use and flexibility. The plurality of energy delivery devices allow the apparatus to be operated in a variety of different modes wherein e.g. energy may be delivered to a number of different sites simultaneously (see paragraphs [0032] and [0040-41] for instance). By arranging the generator to automatically detect the number of energy delivery devices, a suitable operating mode or parameter may then be selected without the user having to manually indicate the number of connected devices – see paragraph [0039]. The apparatus and use of the apparatus of the present invention can therefore be highly automated and require very little user input.

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There is no hint or suggestion of these features in D1. In D1 the number of energy delivery devices is fixed and there would be no reason to modify the generator to be capable of detecting their number. It is only with the benefit of hindsight the skilled person would arrive at an apparatus within the scope of claim 1. Claim 1 is therefore inventive over D1.

DE 10 2005 007 769 ("D2") discloses an apparatus comprising multiple probes for working concurrently on multiple sites – see [0007] of D2. A switching device is provided so that power is alternately supplied to the multiple electrodes. Only one electrode is ON at any given time. This switching is performed rapidly based on a predetermined periodic sequence as described in paragraphs [0012-0014].

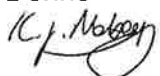
Although D2 mentions that more complicated cycles can be used (e.g. in paragraph [0015-0016]), there is no disclosure of a controller that varies the amount of time that the energy delivery devices are delivery energy responsive to at least one measured parameter. Claim 1 is therefore novel at least for this reason.

Starting from D2, the present invention provides an apparatus with improved ease-of-use and power control. As described for instance in paragraphs [0061] and [0076], controlling the amount of time for which power is applied to a site can be advantageously used to control energy delivery. In the present invention this is highly automated, based on one more measured parameters (for instance, in embodiments, temperature or impedance). In this way, the power delivery can be optimised in use without requiring significant user input.

D2 does not hint or suggest at dynamically controlling the time for which power is delivered. D2 only contemplates setting a certain pulse sequence before the operation is performed. Again, it is only with the benefit of hindsight the skilled person would arrive at an apparatus within the scope of claim 1. Claim 1 is also therefore inventive over D2.

It is submitted that the application is now in order for grant. As a precaution however, oral proceedings are provisionally requested should the Examining Division be minded to refuse the application at any stage.

Yours faithfully
Dehns



Katherine Mabey

Encs/txp/lju

AG 13

European Patent Office
D-80298 München
Germany

date 5 December 2014
your ref
our ref 57.56.104794/06

VIA ONLINE FILING

Dear Sirs

European Patent Application No. 13176863.2 (2653128)
Kimberly-Clark Incorporated

In response to the Communication dated 26 May 2014, we enclose herewith an amended set of claims.

The features of previous claims 2 and 3 have been incorporated into claim 1, and the feature of the generator automatically detecting the number of energy delivery devices coupled to the generator has been removed. Claim 1 is also supported throughout the description, for instance at paragraphs [0015-0019].

The feature of the generator automatically detecting the number of energy delivery devices coupled to the generator has been retained in new dependent claim 2 (based on paragraphs [0014] and [0039]).

Previous claims 2 and 3 have been deleted and the remaining claims have been renumbered accordingly and amended for consistency with claim 1.

In D2, the "Zeitslots", as disclosed in paragraph [0021], are dependent on the number of connected energy delivery devices, and not on a measured, i.e. sensed, tissue parameter as required by amended claim 1. Claim 1 is therefore novel over D2.

The problem starting from D2 is that set out in our letter dated 23 April 2014, i.e. that of providing an apparatus with improved ease-of-use and power control. In the present invention, the delivery of power can be optimised in use without requiring significant user input. D2 only contemplates setting a certain pulse sequence before the operation, based simply on the number of connected devices. There is no hint or suggestion of instead adjusting the parameters during the procedure based on a measured tissue parameter and this would not be obvious.

D1 discloses a single electrosurgical probe. Amended claim 1 is also therefore novel over D1.

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• Alex Gittins MA

There is no suggestion in D1 of providing multiple probes. However, even if the skilled person were to consider providing multiple probes, each of these probes would be operated, independently of each other, in the manner described in D1. There is no pointer in D1 to provide multiplexed power delivery across different probes, potentially contacting different tissue sites. Claim 1 is also therefore inventive over D1.

We believe that the claims are now in order for grant, however in order to streamline proceedings we would propose deferring making any amendments to the description, should the Examiner consider them necessary, until a set of claims has been agreed. The Examiner is also invited to propose suitable description amendments when issuing a Communication under Rule 71(3) EPC if they desire. As a precaution, should the Examining Division be minded to refuse this application at any stage then we request that oral proceedings be appointed.

Yours faithfully
Dehns

A handwritten signature in black ink, appearing to read 'K. Mabey', written over the printed name.

Katherine Mabey

encs/lmb

AG 14

Serial Number: 12/528,193
Response Dated July 19, 2012
Response to Non-Final Office Action Dated March 9, 2012

ATTORNEY DOCKET NUMBER: BPM-10-PCT-US (64649478US09)

REMARKS

In the Non-Final Office Action, claims 1-4, 9 and 10 were rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Thompson et al. (U.S. Patent No. 6,830,569). Claims 1-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Thompson et al. in view of the teaching of Panescu et al. (U.S. Patent No. 6,165,169).

In this Amendment, Applicants have amended claims 1, 3 and 10 and canceled claim 2. Accordingly, claims 1 and 3-13 are pending. Claims 1, 9 and 10 are independent claims.

Applicants have amended independent claims 1 and 10 to include substantially the subject matter recited in now-canceled claim 2. In particular, claims 1 and 10 now recite respectively a system and method wherein multiple devices are employed to deliver energy to a body. Detection of the number of such devices is performed, and then energy is delivered based on one of multiple operating modes, the operating mode selected being based on the detected quantity of devices. Claim 9, not amended herein, recites a related method. Paragraphs 0039 – 0047, for example, of the present Specification provide support for this claimed subject matter.

Applicants respectfully submit that the cited references do not disclose or suggest such subject matter. For example, Thompson et al. does not disclose a system device or the like in which a quantity of an attached plurality of devices is determined and then an operational mode for energy delivery is selected based on the detected quantity. This reference teaches identification of which device is attached, not how many devices are attached. Accordingly, Applicants respectfully submit that independent claims 1, 9 and 10 are patentable under Section 102(b) in view of Thompson et al.

As to the Section 103(a) rejection, the Office Action concedes for purposes of this rejection that Thompson et al. does not disclose detection of the number of devices and relies on Panescu et al. to allegedly show such subject matter. Again, with this reference, no disclosure exists of using a plurality of devices, detecting the number of such devices, and then providing energy according to preset operational modes based

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on the detected number. Instead, this reference teaches identifying the type of device, not the quantity of devices. Therefore no *prima facie* case of obviousness has been made out for any of claims 1, 9 or 10 in view of Thompson et al. and Panescu et al.

In view of the above, Applicants respectfully request reexamination and reconsideration of the present claims, withdrawal of all rejections of claims 1 and 3-13 under Sections 102(b) and 103(a).

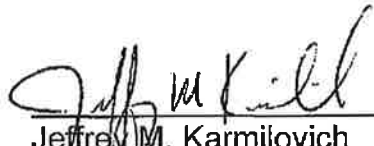
In summary, Applicants respectfully submit that the present claims patentably define over the cited references for at least the reasons set forth above. As such, it is believed that the present application is in complete condition for allowance and favorable action is respectfully requested. Examiner Peffley is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,

DORITY & MANNING, P.A.

July 19, 2012
Date


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