PATENT
Heartstream Ref. 93-003-US1.C2
Hewlett-Packard Ref. 90980060-4

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Bradford E. Gliner, et al.	*Group Art Unit*: 3305
Serial No.: 08/946,843	*Examiner*: K. Schaetzle
Filing Date: 8 Oct 1997	
Title: **ELECTROTHERAPY METHOD AND APPARATUS**	

DECLARATION OF DANIEL J. POWERS UNDER 37 C.F.R. §. 1.132

I, Daniel J. Powers, declare as follows:

1. I am a Project Manager with the Hewlett-Packard Company and am responsible for developing defibrillators.

2. I have been employed by the Hewlett-Packard Company since April of 1998 (when Hewlett-Packard acquired Heartstream, Inc.). I began working at Heartstream in January of 1993.

3. I have a B.S. in Electrical Engineering from the University of Michigan at Ann Arbor.

4. I have over 10 years of experience in the field of medical products, specializing in defibrillator design and development. I have a high degree of familiarity with defibrillator circuits.

5. I am one of the inventors for the above-referenced patent application.

6. I have reviewed the Office action dated 20 Jan 1999, which was issued by the U.S. Patent and Trademark Office in connection with the prosecution of this application. In reviewing the Office action, I also reviewed U.S. Patent 5,634,938 to

Swanson and European Patent EP 0491649 to Pless which were cited by the Examiner in support of his argument.

7. In the Office action dated 20 Jan 1999, the Examiner contends that Swanson teaches an external biphasic defibrillator. The Examiner directs Applicants' attention to col. 6, lns. 47-65 of Swanson in support of his argument which provides:

> The system **10** ... represents an implantable ***or external*** defibrillator system. In an implantable system, electrodes **18** and **20** may be implanted on or about the heart, one may be subcutaneous, and each may comprise one or more electrode, though only one is shown for each. In the case of an ***external*** defibrillator, the circuitry may be disposed external to the body of a patient but connect with implantable electrodes. Alternatively, the external unit may connect with at least two cutaneous electrodes placed on the body.
>
> Swanson, U.S. Patent 5,634,938, col. 6, lines 55-65 (emphasis added).

8. As an electrical engineer in the engineering arts, I would be unable to build a high voltage, high energy biphasic external defibrillator based on these statements in combination with the remainder of the reference, which specifically teaches how to build an implantable biphasic defibrillator.

9. Even if higher voltage switches were used in the Swanson et al. circuit, the circuit could not be used in an external defibrillator. The Swanson circuit depends on the load being stable and well controlled; this results because the electrodes are attached to the heart internally. As a result, there is no means described in Swanson for protecting against a load fault. Since load faults may occur in the external application of defibrillator electrodes, any circuit that is used must provide a means for protecting the circuit against the load faults. Developing a circuit design that protects the circuit from load faults is a major design challenge.

10. Swanson contrasts its teaching against conventional devices, which use 125 μF capacitors charged to 780 volts, by teaching that:

> The lower voltage needed to charge the capacitor C3 simplifies the design of the pulse generator circuitry. This allows ***switches to be used with lower voltage and current ratings***. Switches with lower

> ratings are more readily available, and reliability is improved if peak voltages and currents are reduced.
>
> Swanson, U.S. Patent 5,634,938, col. 7, lines 58-64 (emphasis added).

Thus Swanson recognizes the advantage of using switches with lower voltages and current ratings. However, nowhere does Swanson address the problems associated with using switches with higher voltage and current ratings which would necessarily be required for a high voltage, high energy external defibrillator.

11. In order to build a high voltage, high energy biphasic defibrillator which is used externally, the circuit must be designed so that it can withstand voltages in excess of 1500 volts. This design must take into consideration the fact that readily available switches have an upper limit voltage rating of 1200-1400 volts. The circuit of Swanson would be unable to tolerate voltages in excess of 1500 volts.

12. Because of the higher voltages present in the external defibrillator, a major design challenge becomes terminating phase one. This problem is further exacerbated by shorter phase durations. Swanson teaches waveforms >15msec total duration (col. 6, line 43). Therefore the teaching of Swanson could not be easily adapted to be used in an external defibrillator capable of delivering a waveform shorter than 15msec.

13. Pless measures the capacitor voltage until it reaches a threshold value. Once the threshold value is set, phase one is ended. Thus, Pless does not use a timer to control the duration of phase one.

14. I would not be able to design and build a high voltage, high energy biphasic external defibrillator based on the teachings of Swanson, or Swanson in combination with Pless without overcoming the design challenges described above.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements

may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dated: 5/27/99

By: _____
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