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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BOZIDAR FEREK-PETRIC

Appeal 2011-000649
Application 10/695,848
Technology Center 3700

Before ERIC GRIMES, JEFFREY N. FREDMAN, and
ULRIKE W. JENKS, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for treating a cancerous tumor. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

Statement of the Case

Background

"Electroporation is a process wherein electrical fields are applied across target cells, usually through the application of multiple electrical pulses. These pulses create transient pores through the cell membrane, yet do not result in permanent cell damage" (Spec. 1, l. 32 to 2, l. 1). According to the Specification, "[m]olecules of chemotherapeutic drugs delivered during the electroporation process may then more easily enter the cell through these temporary pores" (Spec. 2, ll. 1-3).

The Claims

Claims 46-48, 50-52, 54-59, and 61-67 are on appeal. Claim 46 is representative and reads as follows:

> 46. A method for treating a cancerous tumor, comprising:
> implanting a wholly-implantable electroporation device wholly within a body, wherein said wholly-implantable electroporation device includes a drug reservoir and operative control circuitry both disposed within a housing for said wholly-implantable electroporation device;
> delivering a drug to the body and proximate the cancerous tumor via a fluid conduit coupled to the drug reservoir;
> delivering from the wholly-implantable electroporation device, at least one electrical pulse across at least a portion of the cancerous tumor, wherein said at least one electrical pulse produces an electrical field strength of from about 700 V/cm to about 1500 V/cm and said at least one electrical pulse has a pulse width of from about 50 microseconds to about 200 microseconds; and
> detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of the at least one electrical pulse with the qRs complex.

The issues

A. The Examiner rejected claims 46-48, 50-52, 56, and 57 under 35 U.S.C. § 103(a) as obvious over Whitehurst[1] and Houben[2] (Ans. 4-5).

B. The Examiner rejected claims 54 and 55 under 35 U.S.C. § 103(a) as obvious over Whitehurst, Houben, and Sterzer[3] (Ans. 6).

C. The Examiner rejected claims 58, 59, 63-65, and 67 under 35 U.S.C. § 103(a) as obvious over Weaver,[4] Sterzer, and Houben (Ans. 6-9).

D. The Examiner rejected claims 61, 62, and 66 under 35 U.S.C. § 103(a) as obvious over Weaver, Sterzer, Houben and Whitehurst (Ans. 9-10).

Since all of these rejections rely upon the teaching of Houben regarding the qRs complex, the same issue is dispositive for all of these rejections, so we will consider the rejections together.

The Examiner finds that "Whitehurst et al disclose a method of treating a cancerous tumor via a wholly-implantable medical device comprising a wholly-implantable electroporation device (150) which includes a drug reservoir (140) and operative control circuitry (145) both disposed within a housing (150)" (Ans. 4). The Examiner finds that Whitehurst teaches "delivering a drug to the body and proximate the tumor via a fluid conduit (141) coupled to the drug reservoir" (Ans. 4). The Examiner finds that Whitehurst teaches "delivering from the wholly-implantable electroporation device at least one electrical pulse across at least a portion of the cancerous tumor where the electric pulse produces an

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[1] Whitehurst et al., US 6,733,485 B1, issued May 11, 2004.
[2] Houben et al., US 6,261,280 B1, issued Jul. 17, 2001.
[3] Sterzer, F., US 5,386,837, issued Feb. 7, 1995.
[4] Weaver, J., US 5,389,069, issued Feb. 14, 1995.

electric field from about 700 V/cm to about 1500 V/cm and has a pulse width of from about 50 ms to about 200 ms" (Ans. 4).

The Examiner finds that Whitehurst does not teach "the step of detecting a qRs complex from an electrocardiogram and synchronizing the delivering of the electrical pulses with the qRs complex" (Ans. 5).

The Examiner finds that Houben teaches "a method for delivering stimulus or electrical pulses to generate an electric field and further teach[es] detecting a qRs complex from an electrocardiogram during the delivery of the electrical pulses . . . Houben et al also teach synchronizing the delivery of the electrical pulses with the qRs complex" (Ans. 5).

The Examiner finds it obvious to combine since "Houben et al teach that it is well known to monitor a patient's heart such that the delivery of the electrical pulses can be synchronized with the qRs complex to reduce cardiac interference" (Ans. 5).

The issue with respect to the rejection is: Does the evidence of record support the Examiner's conclusion that Whitehurst and Houben provide a reason for "synchronizing the delivering of the at least one electrical pulse with the qRs complex" as required by claim 46?

Findings of Fact

The following findings of fact ("FF") are supported by a preponderance of the evidence of record.

1. Whitehurst teaches that

> chemotherapy is a common therapy for cancer. Electrical stimulation, e.g., using low-level direct current (DC) stimulation, has also been investigated as a means of therapy for neoplasms. While these two methods are each effective in fighting cancer alone, the combination of the two, known

> as electrochemotherapy, electropermeabilization, or electroporation, may prove to be a more powerful weapon against cancer and other neoplastic diseases.

(Whitehurst, col. 6, ll. 28-36).

2. Whitehurst teaches that "configurations of implantable microstimulator **150** are sufficiently small to permit placement entirely within or near neoplasm **108**" (Whitehurst, col. 11, ll. 43-45).

3. Whitehurst teaches that "microstimulator **150** further includes a fluid mixer **136** for mixing fluids that are contained within multiple isolated reservoirs **140'**, **140"**" (Whitehurst, col. 14, ll. 1-4).

4. Whitehurst teaches a "hermetically-sealed case in which a control circuit **138**, a power/data receiving circuit **142**, electrical stimulation circuit **145** such as pulse or current generator circuitry, memory **160**, and power source/storage **162** are housed" (Whitehurst, col. 15, ll. 2-6).

5. Whitehurst teaches that the microstimulator may include "a pump or other driver **130**, a reservoir **140** for holding fluid **139** (e.g., a drug), tubing **141** (if necessary) connecting reservoir **140** with driver **130** . . . and outlets **112**A, **112**B free from occlusions" (Whitehurst, col. 15, ll. 16-22).

6. Whitehurst teaches that "Heller, et al. combined bleomycin with six to eight cycles of a 1 Hz square wave with a pulse width of 100 msecond and an electric field of 1300 V/cm to treat cutaneous and subcutaneous tumors in 34 patients" (Whitehurst, col. 8, ll. 12-14).

7. Whitehurst teaches that the "microstimulator may continue to provide electrical stimulation for a predetermined period following the administration of the chemotherapy agent(s), e.g., 2 hours. This may provide benefits for patients, such as continuing to cause selective uptake of

chemotherapy agents even after administration has ceased" (Whitehurst, col. 16, ll. 55-60).

8. Houben teaches "a system and method for improved insulin delivery for an NIDDM patient" in which the "system monitors cardiac activity, and controls the delivery of stimulus pulses so that the onset of each beta cell burst is relatively free of interference of the heart's QRS complex" (Houben, col. 2, ll. 42-44, 52-55).

9. Houben teaches that:

> Amplifier **32** has suitable timing control and filters for isolating, as well as possible, the beta cell electrical activity from other interference signals. The sense signals are processed further with correction circuit **34**, such as an adaptive filter, which subtracts out a QRS template as generated by block **46** whenever a QRS is detected. . . . correction circuit **34** may also suitably correct for artifacts originating from some other source, i.e., heart, respiration, stomach, duodemun [sic] and uterus. This is done to cancel out the interference effect of a QRS complex whenever it occurs during sensing of the beta cell burst. The output of correction circuit **34** is further processed at **50**, where the time duration of the burst, TB is determined. Block **50** may also derive a measure of the mean spike frequency of the burst duration. This information [is] transferred to memory associated with microprocessor **48**, and also is stored at diagnostics block **52**.

(Houben, col. 4, ll. 26-44).

Principles of Law

To establish a prima facie case of obviousness, the Examiner must find "a reason that would have prompted a person of ordinary skill in the

relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l. Co. v. Teleflex Inc*., 550 U.S. 398, 418 (2007).

Analysis

While Whitehurst clearly teaches treatment of cancer using an electroporation device (FF 1-7), we agree with Appellant that "synchronization in Houben is for a purpose completely inapplicable to the device of Whitehurst" (Reply Br. 2). Whitehurst's stimulation is intended to treat cancer cells and enhance chemotherapeutic agent uptake into the cancer cells (FF 7). Houben, however, teaches that its insulin delivery "system monitors cardiac activity, and controls the delivery of stimulus pulses so that the onset of each beta cell burst is relatively free of interference of the heart's QRS complex" (Houben, col. 2, ll. 52-55; FF 8). Houben teaches that this "is done to cancel out the interference effect of a QRS complex whenever it occurs during sensing of the beta cell burst" (Houben, col. 4, ll. 35-37; FF 9).

Therefore, we find that there is no reason to combine Houben and Whitehurst. The Examiner's stated reason, to reduce cardiac interference (Ans. 5), has no relevance to Whitehurst who lacks any concern for cardiac interference, and in fact, provides up to two hours of electrical stimulation which is not synchronized or otherwise coordinated with qRS signals or any other electrical activity (FF 7). Even Houben's concern for cardiac interference relates to an ability to monitor beta cells, not to a concern that the electrical stimulation will have any impact on the patient, and no specific teaching of synchronization is identified by the Examiner (FF 8). Therefore,

there is no apparent reason to combine the teachings of Whitehurst and Houben to render the claim obvious.

The Examiner acknowledges that both Sterzer, who is concerned with the use of high frequency wave energy for enhancing chemotherapy, and Weaver, who is concerned with electroporation in vivo, are "silent to the step of detecting a qRs complex from an electrocardiogram and synchronizing the delivery of the electrical pulses with the qRs complex" (Ans. 8). Therefore, Sterzer and Weaver do not provide any reason for synchronizing the electrical pulses with the qRs complex.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that Whitehurst and Houben provide a reason for "synchronizing the delivering of the at least one electrical pulse with the qRs complex" as required by claim 46.

SUMMARY

In summary, we reverse the rejection of claims 46-48, 50-52, 56, and 57 under 35 U.S.C. § 103(a) as obvious over Whitehurst and Houben.

We reverse the rejection of claims 54 and 55 under 35 U.S.C. § 103(a) as obvious over Whitehurst, Houben, and Sterzer.

We reverse the rejection of claims 58, 59, 63-65, and 67 under 35 U.S.C. § 103(a) as obvious over Weaver, Sterzer, and Houben.

We reverse the rejection of claims 61, 62, and 66 under 35 U.S.C. § 103(a) as obvious over Weaver, Sterzer, Houben and Whitehurst.

<u>REVERSED</u>

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