HARVARD IP CONFERENCE PROBLEM

Summary of Characters/Patents

Patentee: Eric Simpson

Asserted Patent: '123 patent

Patentee's Product: Digital Doc

Accused device: Wi-FiHealthTech for Chronic Pain

Prior Art: '952 Patent; '104 Patent

Introduction

Eric Simpson is a prominent Harvard-trained physician, specializing in diabetic treatment. Dr. Simpson frequently travels across the country to attend conferences and give lectures.

Feeling out of touch with his patients because of his travel schedule, Dr. Simpson developed a new system of treatment in 2002. His wireless treatment system allows him to remotely monitor patients' blood sugar levels and insulin intake, and to make adjustments in their treatment, regardless of where he or the patient is located.

Dr. Simpson approached several medical device and technology companies about developing and refining the method and technology. However, none of the companies believed that the system could be profitable because no doctor would be willing to activate a treatment without being present to observe the patient. Physicians have traditionally believed that the risks (both medical and legal) of remote treatment were simply too great. Switzerland went so far as to institute a ban on physicians providing medical advice or prescribing medications for significant medical conditions (defined under Swiss law as "maladies beyond the common cold or flu or minor ailments") without consulting with the patient in person. Additionally, a recent National Institute of Health study found that 90% of patients preferred to meet with their doctor in person, rather than confer over the phone or via email.

Unable to find a partner, Dr. Simpson founded his own company, DigitalDoc, to develop the method and product in January of 2002. He filed a patent application for his idea in April of 2002 and obtained U.S. Patent No. 6,892,123 (the "'123 patent"), which he assigned to DigitalDoc, in 2004. Dr. Simpson also obtained identical patents in Japan, the United Kingdom, and Germany.

DigitalDoc's new product, DigitalDoc for Diabetes, met with immediate success upon entering the market. Diabetic patients appreciated the assistance in monitoring and responding to their blood sugar levels, and physicians felt more aware and in control of their patients' symptoms and needs. The average number of doctor visits declined, reducing healthcare costs. In recognition of these results, DigitalDoc for Diabetes was awarded the 2008 Medical Product of the Year award by the National Medical Device Manufacturers' Association.

DigitalDoc plans to release several additional wireless treatment systems, including a pain treatment system scheduled for release in six to nine months.

The '123 Patent[1]

The '123 patent outlines a system of treatment for diabetic patients, including a combination insulin pump and glucose monitor, which together collect and transmit the patient's personal health data to a remote location. A physician at the remote location is then able to remotely administer treatment (effect an increase or reduction in insulin delivery via the pump) to the diabetic patient in response to this health data.

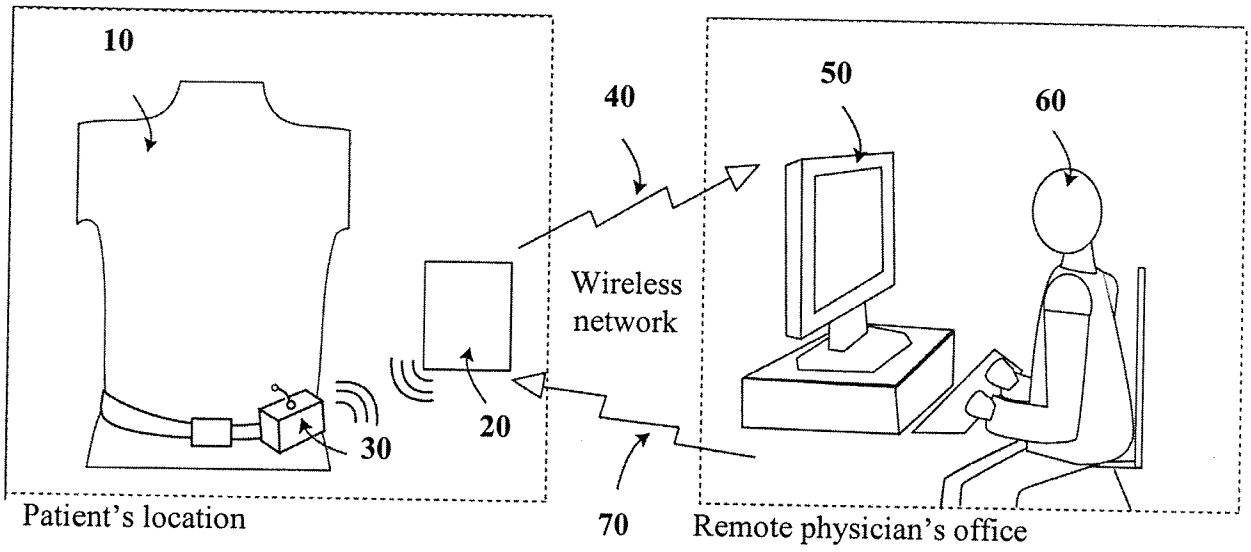
Figure 1 depicts one embodiment of a remotely controlled system of treatment for diabetics. First, a patient **10** uses a traditional glucose monitor **20** to measure his blood sugar level. He does this by pricking his finger and placing a drop of blood on a test strip. This test strip is then inserted into the glucose monitor which analyzes the blood on the strip to determine the patient's blood sugar level. Once the analysis is complete, the glucose monitor calculates the amount of insulin the patient needs based on an algorithm pre-programmed by the patient's physician. The monitor then wirelessly delivers this data to the insulin pump **30**.

Based on the data received from the glucose monitor, the insulin pump begins delivery. To use the insulin pump, the patient embeds an extremely thin needle into his or her body at an injection site, often in the abdomen area, and the pump delivers insulin through the site. Because the patient may keep the needle in the same site for several days before changing it, the insulin pump allows for a more even delivery of insulin than traditional insulin injections. The pump can deliver insulin continuously throughout the day (known as the basal dosage), and deliver additional doses of insulin to counteract spikes in blood sugar levels following meals (bolus dosage). The patient wears the pump (a small unit, approximately the size of a large beeper), on a belt.

The glucose monitor wirelessly communicates all collected data (including the glucose readings and insulin delivery data) **40** to a physician interface **50** at a remote physician's office. Using this interface, a physician **60** can review the data and can issue instructions **70** over the wireless network to the patient's insulin pump to adjust the pump's delivery of medication. The physician can either alter the more constant, basal dosage of insulin, or order a bolus dosage when a patient exhibits certain warning signs, such as a dangerously high glucose reading, without the patient taking corrective measures.

[1] Description and claims inspired by Bui et. Al, Medical Apparatus with Remote Control, Patent No. 6,689,091 B2, Feb. 10, 2004.

Figure 1



Claim 1 of the '123 patent reads as follows:

A remotely controlled medication delivery system comprising:

a medication delivery device to administer a treatment to a patient;

a measuring device configured to provide patient data;

a wireless transceiver to transmit the patient data to a physician's office and to receive treatment instructions from the physician's office based on the patient data;

wherein the medication delivery device adjusts the treatment administered to the patient according to the treatment instructions.

Claim 2 of the '123 patent reads as follows:

A method to provide medication to a patient remotely, comprising the steps of:

measuring patient data by analyzing a patient condition:

transmitting patient data to a remote controller;

receiving treatment instructions from the remote controller in response to the patient data;

adjusting the medication administered to the patient according to the treatment instructions received from the remote controller.

During prosecution of the patent, Dr. Simpson distinguished his invention from a prior art system involving the delivery of heat for medical purposes, on the ground that this system was not a "medication delivery device."

Prior Art

The '952 Patent[2]

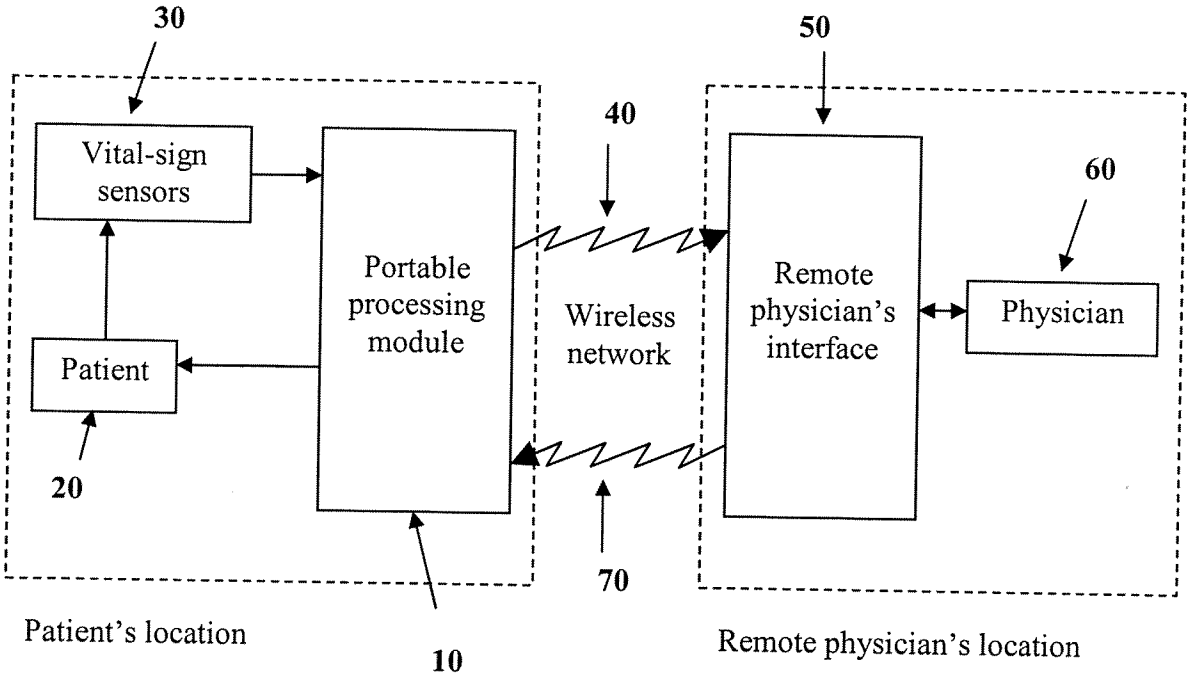
The '952 patent discloses a system for a physician to monitor a patient's vital signs from a remote location. Figure 2 depicts a functional block diagram of this remote-monitoring system, which includes a portable processing module **10** configured to be worn on the patient's body **20**. Various sensors **30** may be connected to this portable module. These sensors may include a finger-ring sensor that measures a patient's blood-pressure, heart-rate, and temperature, and which the patient may carry around and use to measure his or her blood sugar levels several times a day. The processing module processes input from its sensors and transmits the patient's vital sign information **40** over a standard wireless network, such as cell-phone networks provided by companies such as Sprint and Verizon. This vital sign information is received by a remote physician's interface **50**, which analyzes and then displays the information to a physician **60**. If the physician sees something which causes him concern, he can send a signal via means **70** to the portable processing module which is adapted to emit a buzzing sound on receipt of this signal, thereby alerting the patient to contact the physician for more information.

Further, the physician can incorporate the vital signs information into a diagnosis or medical treatment plan when the patient physically appears at the physician's office for an appointment.

This system allows one or more medical professionals located thousands of miles away to remotely monitor and analyze a large group of patients in real-time. The high frequency of data collection over an extended period of time ensures that medical conditions are detected earlier, and allows the physician to detect trends in a patient's data which may indicate a medical condition where those trends would not be ascertainable through a single office visit.

[2] Description loosely based on Banet et al., Wireless, Internet-based, Medical Diagnostic System, Patent Application No. US 2010/0168536 A1, Jul. 1, 2010.

Figure 2

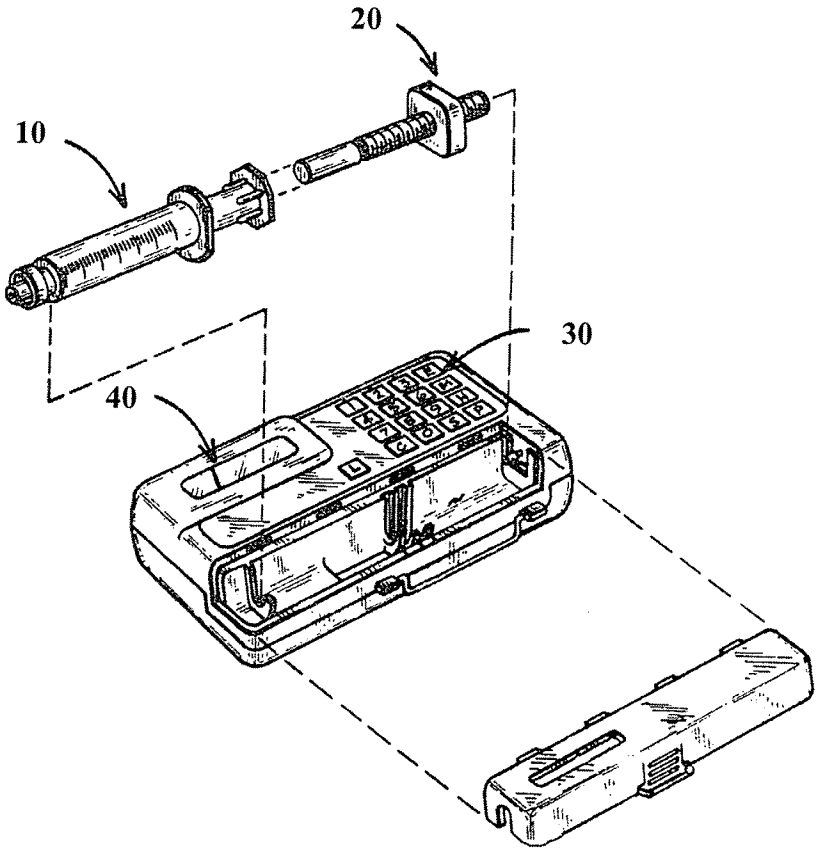

30
50
40
60
Vital-sign sensors
Portable processing module
Wireless network
Remote physician's interface
Physician
Patient
20
70
Patient's location
10
Remote physician's location

The '104 Patent[3]

The '104 patent discloses a portable, programmable drug pump that may be programmed to deliver a bolus of a medical agent or to deliver medication at a basal rate. Figure 3[4] depicts one embodiment of this device, which comprises a reservoir to hold a supply of liquid medicine **10**, a pump mechanism **20**, a data input device **30**, an LCD screen **40**, and a processor which controls the pump mechanism. The drug reservoir and pump mechanism are connected to a catheter and needle which is inserted into the patient's body to deliver the medication. Using the data input device, the user may program the processor to adjust the dosage amount and schedule. The LCD screen displays the device's current settings.

This device allows users to automate and regulate their daily dosage of drugs with minimal disruption to their daily activities.

Figure 3



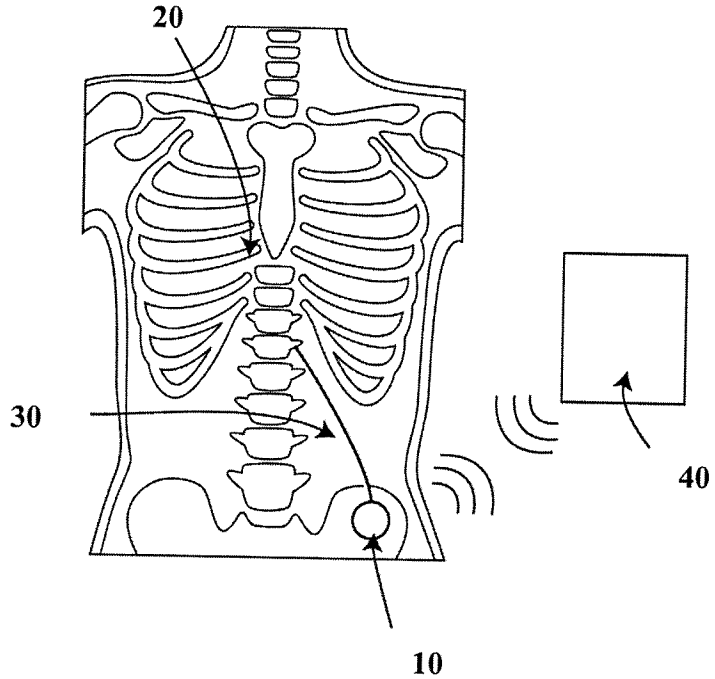
[3] Description loosely based on Leslie et. Al, Ambulatory Infusion Pump Having Programmable Parameters, Patent No. 4,529,401, Jul. 16, 1985.
[4] Figure adapted from Figure 1 in id.

The Accused Device

While attending the Physicians' Mobile Health Technology Conference 2009 at the Four Seasons Palo Alto, Dr. Simpson noted a product presentation that caused him concern. Wi-FiHealthTech, led by Dr. Louis Park, a specialist in chronic pain management, demonstrated a product it launched recently.

According to the promotional materials and Dr. Park's presentation, Wi-FiHealthTech for Chronic Pain involves an implanted stimulator designed to relieve chronic pain. Figure 4 shows a diagram of this device, which includes a programmable electric generator **10** capable of delivering small electric pulses to four to sixteen implanted electrical leads attached to areas of chronic pain **20** (usually the patient's spinal cord). The generator is connected to the leads by extremely thin electrical wiring **30**. The electric pulses generate a tingling sensation in the affected area and can reduce chronic pain by 50-70% by interfering with pain signals going to the patient's brain. The treating physician can program the device to meet the patient's needs by varying which area to stimulate, the frequency of the stimulation, and the size and intensity of the pulse width. The physician inputs multiple pre-set programs into a device and the patient then uses a handheld programmer **40** to turn the device on or off and select one of the pre-set programs.

Traditionally, reprogramming the device to reflect a change in the patient's needs required a visit to the doctor's office. Wi-FiHealthTech's device, however, can communicate with the doctor's office over a wireless network. The treating physician can monitor the patient's heart rate remotely. The physician can also monitor the patient's use of the device remotely, observing how often the device is used and which settings are used most commonly. Further, the device allows the doctor to adjust the stimulator's settings remotely.



The Lawsuit

In late 2009, DigitalDoc filed a lawsuit against Wi-FiHealthTech for infringement of the '123 patent in courts in the United States, England, Japan, and Germany. The complaint alleged that the Wi-FiHealthTech for Chronic Pain product infringed claim 1 of the patent, and that using the product infringed claim 2. Wi-FiHealthTech argued that its product was not infringing, that both claims were invalid because they were obvious from the prior art, and that claim 2 was not patentable in the United Kingdom, Japan, or Germany because it attempts to cover a method of treatment.

DigitalDoc's complaint also alleged that DigitalDoc plans to release a pain treatment device within six to nine months. It alleged that its device would be just as effective as the Wi-FiHealthTech device, and that the price of its device would be comparable to that of Wi-FiHealthTech's device. DigitalDoc also alleged that it will not be able to secure the necessary funding to launch its chronic pain management product if the Wi-FiHealthTech product remains on the market. DigitalDoc sought an injunction.

In the United States, both claims of the '123 patent were determined to be valid and infringed. In the United Kingdom, Germany, and Japan, claim 1 was determined to be valid and infringed, while claim 2 was determined to be a non-patentable method of treatment.

In the United Kingdom, Germany, and Japan, the courts awarded an injunction. In the United States, the court declined to issue an injunction on the grounds that it would violate public policy.

Both parties have appealed.