

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the *Inter Partes* Review of:
U.S. Patent No. 7,516,192
Filed: Jul. 14, 2006
Issued: Apr. 7, 2009

Trial Number: To Be Assigned

Inventor: Stephen J. Brown

Attorney Docket Nos.:
12771.106USR2
12771.106USR6

Assignee: Health Hero Network, Inc.

Title: Networked System For Interactive
Communication And Remote Monitoring
Of Individuals

**DECLARATION BY ROBERT T. STONE, PH.D. REGARDING U.S.
PATENT NO. 7,516,192 UNDER 37 C.F.R. § 42.63(a)**

I, Robert T. Stone, Ph.D., do declare and state as follows:

Background and Experience

1. I received my B.S. in Electrical Engineering from Virginia Polytechnic Institute and State University in 1977, my M.S. in Electrical Engineering from Virginia Polytechnic Institute and State University in 1979, and my Ph.D. in Electrical Engineering from Stanford University in 1981. My studies focused on electronics and signal processing.

2. I have over thirty years of academic and industry experience in the field of medical electronics systems and instrumentation. I have

extensive experience with remote health monitoring equipment and design, as well as computer programs for those systems.

3. While employed at Nellcor Puritan Bennett, Inc. (“Nellcor”), where I was Manager of Electronic Research from 1983 to 1989, I was the Lead Program Manager for the development of a patient monitoring system which allowed remote monitoring of in-hospital patients via a wireless network. That and virtually all of my work at Nellcor involved embedded systems level programming and application programming.

4. Virtually all of my work experience since that time has included application programming. In 2007 through 2009, I developed a home-based wireless patient monitoring system that would communicate with a central server i.e. a computer configured to service multiple clients or remote computers.

5. Attached to this declaration is a copy of my curriculum vitae.

6. I am presently the CEO and Founder of Medical Design Solutions, Inc., which is a consulting firm focusing on all aspects of medical device research and development.

7. I am not employed by, nor receiving grant support from, Cardiocom, LLC, the requester in this *inter partes* review. I am receiving

compensation for my involvement in this matter based on my standard hourly consulting fees.

8. I am competent to make this declaration based upon my personal knowledge and technical expertise in the area of remote patient monitoring as well as script programming.

9. In preparing this Declaration, I reviewed U.S. Patent No. 7,516,192 (hereinafter “the ‘192 Patent” or “Brown”), the file history of the ‘192 Patent, and the prior art cited as part of Cardiocom’s Request for *Inter Partes* Review of the ‘192 Patent. I have also reviewed portions of the Manual of Patent Examining Procedure, including Sections 2131, 2141-2145, as well as *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). That case, and the MPEP sections, explain the legal requirements of anticipation, obviousness and examining procedures relevant to obviousness. The documents I have reviewed are reflected in my analysis.

10. I was asked for my opinion as to the level of ordinary skill in the art, construction of claim terms at issue in the ‘192 Patent, and whether certain claimed inventions, as a whole, were obvious in view of the specific prior art I was shown.

11. I was asked for my opinion as to the level of ordinary skill in the art, construction of claim terms at issue in the ‘192 Patent, and whether

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Background of Art

12. Long before the time of the filing of the '192 Patent, there was pressure on the healthcare system to contain costs, increase quality of care, and provide greater access to healthcare. Since at least the early 1980s, the cost of healthcare increased faster than GDP. There has also been increased public awareness of geographical disparities in healthcare treatment, as well as the common occurrence of medical errors.

13. Long before the time of the filing of the '192 Patent, pressures to incorporate remote management of health existed. The era of house calls had ended. Further, the cost of facilities, maintenance overhead, transportation costs, and medical payment methodologies in the era prior to the '192 Patent led to higher costs for routine monitoring of health status, increased risks for facility based care including cross contamination by infectious patients, and increasingly costly services due to the ability to treat disease states in older or more fragile patients.

14. Systems and infrastructure enabling effective remote monitoring and diagnosis have, meanwhile, developed at an increasing rate.

15. Telephony has been a ubiquitous service in developed and

developing countries for several decades; and digital data interconnection has been available via telephone modems for several decades – since at least the 1970’s, at increasingly faster speeds.

16. Means of remote monitoring for health conditions and disease status and management of same has been practiced and reported upon to demonstrate the effectiveness of such practices. Table 1, attached hereto, is a survey result of literature in the public domain of such studies. These studies utilized remote monitoring and databases to determine the efficacy and cost savings of remote monitoring for the conditions listed.

17. In the 1980 and early to mid-1990s, all prior to the ‘192 Patent, computer based electronic devices and their utility increasingly appeared in everyday life. User interfaces were simplified, icons and symbols were incorporated for simplicity, voice synthesis, telephone auto-dialing, and e-mail universally were incorporated into our lifestyle. Home health monitors (blood pressure, blood glucose, smart scales, spirometers, etc.) were developed and adapted for early self-monitoring and reporting of chronic health conditions.

18. Also in the 1990s prior to the ‘192 Patent, hypertext mark-up language (“HTML”) was adapted into shared documents in research, internet browsers, and general document preparation, which allowed linking to other

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