

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Poeze et al.
U.S. Patent No.: 10,258,265 Attorney Docket No.: 50095-00006IP1
Issue Date: April 16, 2019
Appl. Serial No.: 16/212,440
Filing Date: December 6, 2018
Title: MULTI-STREAM DATA COLLECTION SYSTEM FOR
NONINVASIVE MEASUREMENT OF BLOOD
CONSTITUENTS

SECOND DECLARATION OF DR. THOMAS W. KENNY

Declaration

I declare that all statements made herein on 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 under Section 1001 of Title 18 of the United States Code.

Dated: August 20, 2021.

By:  _____

Thomas W. Kenny, Ph.D.

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1. This Declaration further expands the conclusions that I have formed based on my analysis, in addition to those provided in my first declaration (APPLE-1003, which is incorporated herein by reference in its entirety; “Original Declaration”). Consistent with my findings provided in my Original Declaration, and based upon my knowledge and experience and my review of the prior art publications listed above, a POSITA would have found that claims 1-4, 6-14, and 16-30 (“the Challenged Claims”) of the ’265 patent are rendered obvious by at least the combination of as set forth in my Original Declaration.

I. GROUNDS 1A-1E RENDER OBVIOUS THE CHALLENGED CLAIMS

2. As I further clarify below in response to Patent Owner’s arguments, claims 1-4, 6-14, 17, 19-23, and 26-29 are rendered obvious by the combination of Aizawa and Inokawa (Ground 1A). For additional reasons as explained below, those same claims are further rendered obvious by the combination of Aizawa, Inokawa, and Ohsaki (Ground 1B).

A. Inokawa’s lens enhances the light-gathering ability of Aizawa

3. As I previously explained in the Original Declaration, Inokawa *very generally* describes a “lens [that] makes it possible to increase the light-gathering ability” of a reflectance type pulse sensor, APPLE-1008, [0015], [0058], FIG. 2,

and, based on this disclosure, a POSITA would have been motivated to incorporate “an Inokawa-like lens into the cover of Aizawa to increase the light collection efficiency...” APPLE-1003, ¶¶94-99. In a significant extrapolation from the very simple and purely illustrative description in Inokawa, Patent Owner provides two incorrect arguments. First, Patent Owner claims that Inokawa’s disclosure is narrowly-limited to a particular lens that somehow is only capable of operation with peripheral emitters and a central detector. Second, the Patent Owner claims that the lens of Inokawa directs all incoming light rays “to the center of the sensor” and would “direct light *away* from the *periphery*-located detectors as in Aizawa”, regardless of the direction of light propagation of each ray, which is a violation of elementary laws of light propagation that would be familiar to a POSITA. POR, 15, 18. Based on these two incorrect claims, the Patent Owner insists that there would be no motivation to combine.

4. Patent Owner’s misinformed understanding of Inokawa’s lens as well as lenses in general is demonstrated by their description of Inokawa’s lens 27 as “focus[ing] light from LEDs (21, 23)...*to a single detector (25) in the center*” and “direct[ing] incoming light *to the centrally located detector.*” POR, 13; *see also* APPLE-1042, 170:12-20 (“To be precise, my opinion is that...Inokawa’s convex lens 27...would redirect light from the...measurement site towards the center.”).

5. A correct understanding of Inokawa's lens as well as of reflectance type pulse sensors in general (like those disclosed by each of Aizawa, Inokawa, and Mendelson-1988) readily exposes Patent Owner's flawed rationale. Indeed, as I noted during deposition, a POSITA would understand that Inokawa's lens improves "light concentration at pretty much all of the locations under the curvature of the lens," as opposed to only at a single point at the center as asserted by Patent Owner. Ex. 2006, 164:8-16.

6. Among other things, because Inokawa is a reflectance-type pulse detector that receives diffuse, backscattered light from the measurement site, its lens cannot focus all incoming light at a single point. Ex. 2006, 163:12-164:2 ("A lens in general, when placed in the view of a diffuse optical source, doesn't produce a single focal point."). Indeed, as I previously explained, "light entering and returning from the tissue will follow many different random paths," and there are "variations in the path associated with the randomness of the scattering." APPLE-1003, ¶128. Reflectance type pulse detectors and oximeters, as in each of Aizawa, Inokawa, and Mendelson-1988, work in this manner, by detecting light that has been "partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector." Ex. 2012, 86. That is, as a POSITA would have clearly understood, light that backscatters from the measurement site after diffusing through tissue reaches the active detection area

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