UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

CANFIELD SCIENTIFIC, INC., Petitioner

v.

MELANOSCAN LLC, Patent Owner

Case No. IPR2017-02125

Patent No.: 7,359,748

DECLARATION OF DR. DANIEL VAN DER WEIDE

Melanoscan LLC Exhibit 2019 Canfield Scientific, Inc. v. Melanoscan LLC IPR 2017-02125

ENGAGEMENT AND COMPENSATION

1. I have been retained by counsel for Melanoscan to provide analyses and opinions in the IPR matter brought by Canfield Scientific ("Canfield"). I am being compensated for my work on this case at my customary rate of \$500 per hour, plus reimbursement of expenses. I have no financial interest in the outcome of this matter.

2. I have been asked to render opinions regarding U.S. Patent No. 7,359,748.

3. I make the following statements based on my own personal knowledge and, if called as a witness, I could and would testify to the following.

BACKGROUND AND QUALIFICATIONS

4. I received a Ph.D. in Electrical Engineering in 1993 from Stanford University. I also received a Bachelor of Science in Electrical and Computer Engineering from the University of Iowa in 1987.

5. I was appointed a Full Professor in the Department of Electrical and Computer Engineering Department of the University of Wisconsin-Madison in 2004. I also have courtesy appointments in the Departments of Radiology, Biomedical Engineering, and Materials Science at the University of Wisconsin-Madison, and I have advised Ph.D. students in Physics. I previously served as an Associate Professor in the University of Wisconsin-Madison's Department of

Electrical and Computer Engineering from 1999 to 2004. Before that, I served as both an Associate Professor and an Assistant Professor in the Department of Electrical and Computer Engineering at the University of Delaware from 1995-1999. And, from 1993 to 1995, I was a Post-Doctoral Researcher at the Max Planck Institut für Festkörperforschung in the group of Nobel laureate Klaus von Klitzing.

I also have extensive professional experience. I am the Founder and 6. President of vdW Design, LLC, which specializes in design and consulting services for electrical measurements at high frequencies. I also have professional experience with medical devices. For example, I have been Co-Founder, Board Member and Advisor for NeuWave Medical, Inc. (now owned by Johnson & Johnson), which develops and sells microwave-based systems for percutaneous tissue ablation. Additionally, I am the Founder and President of NFI, LLC, which develops devices relating to near-field imaging for skin cancer. Most recently I have been co-founder of Elucent Medical, a startup to build an implantable tag to aid in surgical navigation for resection of breast cancer tumors. I am also a cofounder of Accure Medical together with a board-certified dermatologist. I have also been involved with numerous other professional companies, including companies in the areas of ultrawideband antennas, coherent lightwave signal

analyzers, microwave devices, cellular telephones, speech and handwriting recognition devices, dye laser systems, and automatic testing equipment.

7. I have also received extensive recognition for my work. I received the Vilas Associate Award, the Alexander Von Humboldt Fellowship, and the PECASE Award from the National Science Foundation. I also received the Young Investigator Program Award from the Office of Naval Research. The DARPA ULTRA Program also awarded me with the Innovation/Technical Achievement Award. I also received the University Research Award from the Ford Motor Company. Additionally, I received the Dean's Merit Increase and the Provost's Special Merit Increase from the University of Delaware. I was also a Fellow at both the National Science Foundation and the University of Delaware. I am a member of the Optical Society of America, and Senior Member of the IEEE, with elevation to Fellow grade pending.

8. I have also performed extensive research, receiving over forty research grants. I have also supervised numerous post-doctoral researchers and doctoral candidates and graduates. Through my academic placements, I also have extensive teaching experience, including in courses such as Applied Communication Systems, Advanced Communications Circuit Designs, Electromagnetic Wave Transmission, and many others.

9. My work has also led to over ninety journal publications, numerous book sections, over one hundred conference presentations, and over forty patents in the United States and abroad. I have prosecuted at least one of these U.S. patents *pro se*.

10. I have also published work on 3D imaging with Song Zhang (listed in the Materials Considered section) that has been cited at least 184 times as of the date of my signature on this declaration. This work used structured illumination similar to that used by many of the references cited by Petitioner and Dr. Muller against the eligibility of the '748 patent discussed herein.

11. I have performed research on skin imaging using a wide range of electromagnetic wavelengths, culminating in an issued US patent (7,725,151 "Apparatus and method for near-field imaging of tissue") that teaches, among other things, the use of both visible light and millimeter-wave reflection to assist a physician in determining the nature and margins of a skin carcinoma. I continue to direct two students in my research group as they pursue similar techniques for skin imaging. Furthermore, I have a courtesy appointment in the Department of Radiology at the University of Wisconsin Hospitals and Clinics, and as such have co-advised Ph.D. students with faculty in that department, namely Dr. Fred T. Lee, Jr. and Dr. Thomas Grist. Finally, I am both an investor in and advisor to a startup company ImageMover MD, which manages medical images.

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12. In the previous four years, I have testified as an expert at trial or by

deposition in the cases listed below (client represented in **boldface**):

Civil testimony (patent litigation)

Atlas IP, LLC v. Medtronic, Inc. et al. (**St Jude Medical**), Case No. 1:13-cv-23309-CMA (S.D. Fla.) (written and deposition testimony; summary judgment in client's favor) Lead attorneys Wayne Barsky & Neema Jalali, Gibson Dunn

In the Matter of Certain Activity Tracking Devices, Systems, and Components Thereof (**Fitbit, Inc.**), Inv. No. 337-TA-963 (U.S.I.T.C.) (written and deposition and trial testimony; ITC ruling in client's favor) Lead attorneys Fred Chung & Neema Jalali, Gibson Dunn

13. Further information regarding my background, education, training,

experience and qualifications can be found in my CV (Exhibit 2020).

14. A complete listing of the materials I reviewed in preparing this declaration is below.

- Ex. 1001 U.S. Patent No. 7,359,748 (Drugge)
 Ex. 1002 File History for U.S. Patent No. 7,359,748
 Ex. 1003 Holger Voigt M.D. and Richarda Classen M.D., "Topodermatographic Image Analysis for Melanoma Screening and the Quantitative Assessment of Tumor Dimension Parameters of the Skin," Cancer 1995 Fed; 75(4):981-988
 Ex. 1004 Jeffrey D. Hurly, Michelle H. Demers, Richard C. Wulpern, John R.
- Ex. 1004 Jeffrey D. Hurly, Michelle H. Demers, Richard C. Wulpern, John R. Grindon, "Body Measurement System Using White Light Projected Patterns for Made-to-Measure Apparel," SPIE Vol. 3131, July 7, 1997, 212-223
- Ex. 1005 Heim A.M. Daanen and Jeroen van de Water, "Whole Body Scanners," Displays 19 (1998) 111-120.
- Ex. 1006 PCT published application WO 98/28908

Ex. 1007	PCT published application WO 99/56249
Ex. 1008	H.A.M. Daanen, 3-D Surface Anthropometry: accurate determination of body dimensions, NATO Panel 8 RSG 24 Workshop on Emerging Technologies in Human Engineering and Testing & Evaluation, June 24-26, 1997
Ex. 1009	Atkinson, Whittles Publishing, "Close Range Photogrammetry and Machine Vision" Ch. 11 "Medical photogrammetry," 303-327 (1996)
Ex. 1010	Curriculum Vitae of Dr. Jan-Peter Muller
Ex. 1011	Deacon, Bhatia, and Jan-Peter Muller, "Evaluation of a CCD based Facial Measurement System," Medical Informatics 16, 213-228 (1991).
Ex. 1012	Comer, R.P. et al., Talking Digital, Photogrammetric Engineering & Remote Sensing, 1139 (December 1998)
Ex. 1013	Manual of Photogrammetry (4th Ed. 1980), published by the American Society of Photogrammetry at p. 801-809.
Ex. 1014	"USB powers up for market thrust," Office World News, September 1, 1998
Ex. 1015	"What's the big deal about USB," Info-Tech Advisor Newsletter, January 12, 1999
Ex. 1016	Declaration of Dr. Jan-Peter Muller
Ex. 1027	Declaration of Eric Pepper
Ex. 1028	Jeffrey D. Hurly, Michelle H. Demers, Richard C. Wulpern, John R. Grindon, "Body Measurement System Using White Light Projected Patterns for Made-to-Measure Apparel," SPIE Vol. 3131, July 27, 1997, 212-223 ("Hurley")
Ex. 1029	Cover and copyright page of SPIE Vol. 3131
Ex. 1030	Book Receiving Report for Vol. 3131
Ex. 1031R	Redacted Second Declaration of Dr. Jan-Peter Muller

- Ex. 1032 Printout of https://spie.org/Publications/Proceedings/Paper/10.1117/12.277751, captured on April 27, 2018 Ex. 1035 Defendant Melanoscan, LLC and Dr. Rhett Drugge's Preliminary Proposed Constructions served on April 6, 2018 in Canfield, Inc. v. Melanoscan, LLC et al, Case No. 2:16-cv-4636 Ex. 2001 Complaint, C.A. 2:16-cv-04636 (JMV) (D.N.J.) Ex. 2002 Answer, C.A. 2:16-cv-04636 (JMV) (D.N.J.) Ex. 2003 Counterclaim-in-Reply, C.A. 2:16-cv-04636 (JMV) (D.N.J.) Ex. 2004 *Counterclaim*, Barron's Law Dictionary 106 (3d ed. 1991) Ex. 2005 *Counterclaim*, People's Law Dictionary 118 (2002) Ex. 2006 *Counterclaim*, Black's Law Dictionary 376 (8th ed. 2004) Ex. 2007 157 Cong. Rec. S1375 (daily ed. Mar. 8, 2011) Ex. 2008 153 Cong. Rec. E774 (daily ed. Apr. 18, 2007) Ex. 2009 H.R. Rep. 112-98 (June 1, 2011) Ex. 2010 Declaration of Dr. Rhett Drugge Ex. 2011 Curriculum Vitae of Dr. Rhett Drugge Ex. 2012 Definition of "specify," Dictionary.com, http://www.dictionary.com/browse/specify?s=t (Dec. 26, 2017) Ex. 2013 Predetermined, Webster's New College Dictionary 891(3d ed. 2008) Ex. 2014 Predetermined, Webster's Ninth New Collegiate Dictionary 926
- Ex. 2014 *Predetermined*, Webster's Ninth New Collegiate Dictionary 926 (1990)
- Ex. 2015 *Receive*, Webster's Ninth New Collegiate Dictionary 982 (1990)
- Ex. 2016 Heath v. Audatex N. Am., Inc., 2012 WL 177413 (E.D. Pa. 2012)
- Ex. 2017 Baker v. Borg Warner Morse Tec, Inc., 2012 WL 195011 (S.D.W. Va. 2012)

Ex. 2018	<i>Fujitsu, Ltd. v. Nanya Tech. Corp.</i> , 2007 WL 1660694 (N.D. Cal.2007)
Ex. 2021	<i>Joint Claim Construction and Pre-Hearing Statement</i> , Canfield, Inc. v. Melanoscan, LLC <i>et al.</i> , C.A. no. 2:16-cv-04636 (D.N.J.), Doc. No. 73
Ex. 2022	Definition of "registration," merriamwebster.com, https://www.merriamwebster.com/dictionary/registration (June 20, 2018)
Ex. 2023	Definition of "register," merriamwebster.com, https://www.merriamwebster.com/dictionary/registering (June 20, 2018)
Ex. 2024	Definition of "register," oxforddictionaries.com, hhttps://en.oxforddictionaries.com/definition/us/register (June 20, 2018)
Ex. 2025	Definition of "register," ahdictionary.com, https://www.ahdictionary.com/word/search.html?q=register (June 20, 2018)
Ex. 2026	Slue W, Kopf AW, Rivers JK. Total-Body Photographs of Dysplastic Nevi. <i>Arch Dermatol.</i> 1988;124(8):1239–1243 ("Slue")
Ex. 2027	Kodak, The Magic of Black and White, 1985 ("Kodak")
Ex. 2028	Song Zhang, Daniel van der Weide, and James Oliver. Superfast phase-shifting method for 3-D shape measurement. Optics Express 26 April 2010 / Vol. 18, No. 9 ("Zhang")
Ex. 2029	Locate, The New Oxford American Dictionary 1001(2001)
Ex. 2030	Locate, Merriam-Webster's Collegiate Dictionary 684 (10th ed. 1993)

RELEVANT LEGAL PRINCIPLES

Person of Ordinary Skill in the Art

15. I am informed and understand that the content of a patent or other printed publication should be interpreted the way a person of ordinary skill in the art ("POSA") would have interpreted the reference at the time the application for the '748 patent was filed in the United States.

16. I have been asked to assume that the person of ordinary skill is a hypothetical person who is assumed to be aware of all the pertinent information that qualifies as prior art.

17. Although at the time of the '748 invention I was one of more than ordinary skill in the art, I have based my opinions on my understanding of the capabilities of one having ordinary skill in this field prior to July 2000.

Standard for Claim Construction

18. I have been informed that claim construction is a matter of law and that the final claim construction will ultimately be determined by the Board. I am informed and understand that a claim in *inter partes* review is given the "broadest reasonable construction in light of the specification." 35 C.F.R. §42.100(b). I am informed and understand that any claim term that lacks a clear definition in the specification is given its plain meaning, which is the ordinary and customary meaning the term would have to one of ordinary skill in the art at the time of the invention. I am further informed and understand that limitations from the specification are not to be read into the claims.

19. For the purposes of my validity analysis in this proceeding and with respect to the prior art, I have construed each claim term in accordance with its customary and ordinary meaning under the required broadest reasonable interpretation standard as it would be understood by one of ordinary skill in the art.

20. I understand that certain claim limitations are described using the word "means," which are referred to as "means-plus-function" claim elements. These elements must be construed according to 35 U.S.C. §112(6). I understand that when claim language uses the word "means" and recites a function, the language is presumed to be a means-plus-function element under§ 112(6). I understand that the presumption is overcome if the language recites sufficient structure to perform the function. To construe a means-plus-function element, I understand that the board will first define the function of the element and then look to the specification and identify the structure, material and acts corresponding to that function. The broadest reasonable interpretation is the corresponding structure, materials, and acts and their equivalents.

Obviousness

21. It is my understanding that a claim is "obvious," and therefore unpatentable, if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made.

22. I am informed and understand that a determination of whether a claim would have been obvious should be based on several factors, including, among others, the level of ordinary skill in the art at the time of the invention; the scope and content of the prior art; and what differences exist between the claimed invention and the prior art.

23. I have been informed and understand that the teachings of two or more references may be combined in the same way as disclosed in the claims, if such a combination would have been obvious to one having ordinary skill in the art. However, an invention is not obvious merely because all the limitations are found in separate pieces of prior art, the references can be combined or modified, or the combination is within the technical capabilities of one of ordinary skill to make. There must be some objective reason or rationale why one of ordinary skill would modify or combine the references.

24. It is my further understanding that the law recognizes several rationales for combining references or modifying a reference. Some of these rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; use of a known technique to improve similar devices, methods or products in the same way; applying a known technique to a known device, method or product ready for improvement to yield predictable results;

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choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; work in one field of endeavor would prompt variations of it in the field of the invention based on design incentives or other market forces if the variations are predictable to one of ordinary skill, and some teaching, suggestion, or motivation in the prior art would have led one of ordinary skill to modify the prior art to arrive at the claimed invention.

25. I further understand, though, that an invention is not obvious if the alleged modification would render the prior art unsatisfactory for its intended purpose or change its principle of operation, or when one of ordinary skill would not have a reasonable expectation of success. I yet further understand that an obviousness analysis must consider the teachings of the prior art must be considered in their entirety, including disclosures that teach away from the invention.

26. I also understand that an obviousness analysis must consider whether there are additional factors that would indicate that the invention would not have been obvious. These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) a teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; (vii) failure of others and (viii) copying by others. In view of the

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above, below I provide evidence that the claims of the '748 patent would have been non-obvious to a POSA.

27. In particular, I understand that, in considering whether the claims of a patent would be obvious to a POSA in view of a combination of prior art, it is impermissible to employ the benefit of hindsight derived from the patent being considered. It is impermissible to use the claimed invention as a roadmap or template to find its components in the prior art, and pick and choose some disclosures in the prior art but not others to fit the parameters of the invention.

ONE OF ORDINARY SKILL IN THE ART

28. In my opinion, a person of ordinary skill in the art at the time of the invention ("POSA") would have at least an associate's degree (2-year) in photography or related disciplines with two years' experience in digital photography and use of computers for collecting, manipulating and viewing images.

29. The '748 patent teaches "Total Immersion Photography" ("TIP" '748 Title and Abstract). Photography is defined as "the art or process of producing images on a sensitized surface (as film in a camera) by the action of light" (The Merriam-Webster Dictionary © 1977 ISBN 0-87779-911-3). Thus, in my opinion, a POSA in the photographic arts understands the range of cameras that can be used, and further understands the wide variety of illumination types available for

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lighting a subject (See, e.g. definitions for "Available light", "Backlighting", "Bottom lighting", "Diffused light", "Fill-in light", "Frontlighting", "Hard light", "Photolamp", "Rimlighting", "Sidelighting", "Soft light", and "Tungsten light" (Kodak, 100-102)). One of skill would also understand from the photographic arts what instrumentation or sensor can be used for monitoring or measuring illumination. Finally, a POSA would understand how to collect, manipulate and view images from cameras using computers.

30. I understand that Dr. Muller opines that a POSA "would have possessed at the time the patent application was filed at least: (a) a university degree in physics, electrical engineering, photogrammetry, surveying, or optics; and (b) at least about two years of post-degree experience in the field of imaging." (Ex. 1016 ¶ 35) The education and experience levels I have defined above are consistent with the technical scope of the '748 specifications and claims. In my opinion, the '748 patent neither requires nor suggests Dr. Muller's proposed higher level of education and experience for a POSA, and indeed the '748 specification never contemplates that one be skilled in the fields of "physics, electrical engineering, photogrammetry, surveying, or optics." Rather, the '748 patent indicates that the persons in the field of body photography before the invention were photographers. (Ex. 1001 1:42-43, 1:1:51-53, 1:59-61, 3:10-23). At the time of the invention, a photographer, even an "expert" or "medical" photographer,

would not need, and ordinarily would not have, the degrees and experience Dr. Muller contends. Thus, in my opinion, Dr. Muller attributes to a POSA reading the '748 patent education and experience levels far exceeding what the teachings of the '748 specifications and claims require to practice its invention.

31. Although I am someone of more than ordinary skill in the art and am an expert in the field and subject matter of the '748--both now and at the time of its invention--my opinions are based on what was known and would be understood by one of ordinary skill in the art at that time. Furthermore, my opinions set forth below on the non-obviousness of claims 1-8, 11, 30, 32-34, 46, and 51 of the '748 patent are the same whether the board adopts my definition of a POSA or that of Dr. Muller.

32. In my opinion, as set forth in more detail below, a person having ordinary skill in the art prior to the filing of the application for the '748 patent would have considered claims 1-8, 11, 30, 32-34, 46, and 51 of the '748 patent to be non-obvious in view of the prior art.

'748 PATENT AND BACKGROUND OF THE TECHNOLOGY

33. As I mention above, the invention of the '748 patent teaches TIP for rapid, precise and reproducible imaging of skin. Despite different methods of imaging skin to identify and track suspicious lesions being practiced before the time of the invention, "[t]hus far, the reproducibility of positioning skin-surface

areas for digitized videographic imaging has been a major technical obstacle that has not yet been mastered successfully." (e.g. Voigt Ex. 1003 p. 981) As I explain more fully below, Voigt teaches an occlusive "position framework" for both the subject and the (single repositionable video) camera to overcome the obstacle of reproducibility. The '748 patent teaches a completely different solution: an array of fixed still cameras and light sources positioned relative to a specified imaging position, obviating the need for any occluding scale artifact or position framework, and enabling rapid, aligned and complete imaging of the subject's body.

34. The '748 (e.g. Cl. 1) teaches using a plurality of imaging devices vertically and laterally spaced from each other on opposite sides of a centerline from each other, where the imaging devices are each located a predetermined distance relative to a specified imaging position. This creates a coordinate space that allows precise measurements of people or objects located in the space.

35. While the '748 patent does not use the precise phrase "total body photography," a POSA would understand the distinction between TIP of the '748 and the prior art of total body photography (e.g. Slue *passim*), which the '748 criticizes: the prior art is limited by "point and shoot techniques" that require "a trained operator" ('748 2:51-53); "this approach requires multiple posings by the photographer and the subject that may exceed 30 views in total." ('748 2:59-61) Accordingly, the '748 does not, as Canfield and Dr. Muller contend, recognize or

otherwise make any statement about use total body photography outside of dermatology. Instead, the '748 invention overcomes the deficiencies of total body photography with total immersion photography (TIP), which, among other advantages, "eliminat[es] the barrier of an available expert photographer" ('748 3:11-15) and "may reduce patient time spent in a health care...facility." ('748 6:6-10) The '748 lists some prospective applications of TIP as well as its intended application to screening skin abnormalities. ('748 5:60-8:13)

CLAIM CONSTRUCTION

Specified Imaging Position

36. One of skill reading the '748 patent would understand the phrase "specified imaging position" to mean an imaging position that is defined by the enclosure "specifically and definitely." ('748 5:3-5; 18:36-44; 19:43-48; 20:37-44; Figs. 1, 3, 5)

"Each Imaging Device/Means Is Located a Predetermined Distance Relative To The Specified Imaging Position

37. "Each imaging device/means is located a predetermined distance relative to the specified imaging position/second means," according to the ordinary and customary meaning, means that each imaging device/means is located (*i.e.*, is situated in a particular place or set in a particular spot) a predetermined distance (*i.e.*, a distance that is determined or established in advance) relative to the specified imaging position. *See* Exs. 1001 4:42-43 ("With subject placement, the

camera array coordinates and distances are known in relation to the subject.), FIGS. 1, 3, 5; 2010 ¶ 32; 2013; 2014; 2028 ("locate" means "situate in a particular place"); 2029 ("locate" means "2: to set or establish in a particular spot or position")

Centerline

38. "Centerline" should be construed according to its ordinary and customary meaning. Canfield and Dr. Muller's contention that the centerline is defined by the center of the person is incorrect and not supported by the '748. The claims clearly state that the centerline is a feature of the device, not of the person being imaged. Claims 1, 51.

The Wherein Clause

39. A clause in both Cl. 1 and 51 states:

(a) wherein each...[imaging device/means] defines respective coordinates and said respective predetermined distance relative to the [specified imaging position/second means], and defines a respective focal length and resolution information, allowing precise measurement of imaged features of the person or portion thereof located at the [specified imaging position/second means].

40. In my opinion, this clause should be construed according to its ordinary and customary meaning.

First Means for Receiving and Enclosing a Person or Portion Thereof

41. One of skill would understand that this means an enclosed structure and equivalents thereof and can include an optional doorway and equivalents thereof. ('748 18:47, 19:5-8, 19:52-54, 20:9-13, 20:48-49, 21:14-16; Figs. 1, 3, 5).

Second Means for Specifying an Imaging Position

42. One of skill would understand that the second means is construed according to its ordinary and customary meaning, the markings at center points 108, 308 of the respective device/system 100, 300 shown in FIGS. 1, 3, 5 and equivalents. ('748 5:3-5; 18:36-44; 19:43-48; 20:37-44; 21:40-44 (subject is imaged "within system 100, and preferably, at center 108"); FIGS. 1, 3, 5).

SUMMARY OF OPINIONS ON PATENTABILITY

43. In my opinion, claims 1-8, 11, 30, 32-34, 46, and 51 are valid because they would not have been obvious to a person having ordinary skill in the art prior to the filing of the application for the '748 Patent.

44. It is my understanding that Pet. Canfield and their technical expert Dr. Muller argue that a POSA reading Voigt in light of certain 3D body measurement art would find it obvious to combine certain elements of that art, such as arrays of fixed cameras, with certain elements of Voigt, such as computer image acquisition, processing and storage. Below I argue in detail that the prior art provides no reason for a POSA to combine these elements and thus render claims 1-8, 11, 30, 32-34,

46, and 51 of the '748 obvious; these claims of the '748 are valid, in my opinion. Furthermore, the 3D body measurement art relies on highly non-uniform, even monochromatic light, which is incompatible with the diffuse, broad-spectrum illumination used and necessary for imaging skin, a disincentive for one of skill to look to this art or believe it would be useful for skin imaging systems.

General State of the Art

At or around July 26, 2000 — the time of filing the application that 45. would mature into the '748 patent — digital photography was considerably less advanced and less used than it is today. Much like the development of computers, still digital cameras offered far fewer features than equivalently-priced cameras today; in my opinion it would not have been obvious for a POSA at the time of the '748 invention to connect many cameras together via USB as is taught by the '748. Although with the benefit of hindsight, it is tempting for Canfield to argue that the disputed claims of the '748 patent would have been obvious to one of ordinary skill in the art, the sole assertion of Voigt as prior art in the field of dermatology proves otherwise, both because Voigt provides no motivation to one of skill to add still cameras or to image the entire subject, and because Canfield could not cite any other useful references in the field of use of dermatology, instead citing art in the very different field of body measurement that does not image skin, but rather uses 3D measurement data to construct a model of the body. In my opinion, the paucity

of dermatological references alone bolsters the patentability of the '748 TIP invention at a time when digital cameras were relatively expensive, usable USB connectivity was barely emerging, and computer operating systems and hardware were only beginning to support USB.

Overall the promise of faster standard connections is promising technology. The increased speed for storage devices and multimedia data alone makes USB technology attractive. Windows 95 (running Service Release 2.1) and Windows 98 both support USB devices. Although Windows NT 4.0 does not support USB, it will definitely be a feature of Windows 2000 (NT 5).

The bottom line is that the number of USB devices will continue to proliferate with USB well positioned to become the next standard interface. What should be your USB strategy for the time being? Just this: "When you buy a new PC make sure it has at least one USB port. And when you add peripherals, think USB first."

(Ex 1015, 1)

PATENTABILITY OF CLAIMS 1-5, 8, 11, 33, 34, 46 AND 51 OVER VOIGT IN VIEW OF HURLEY

In my opinion, claims 1-5, 8, 11, 33, 34, 46 and 51 are patentable over Voigt in view of Hurley.

Voigt

46. In the world of July 26, 2000, one of skill reading Voigt would learn about "topodermatological" imaging for recording, identifying and longitudinal tracking of nevi (Ex. 1003). Voigt surveys but deprecates several prior-art techniques to screen for skin abnormalities: Cutaneous tumor manifestations can be detected and evaluated directly by visual perception versus those that are hidden internally. However, besides subjective inspection, quantitative assessment of multiple skin surface alterations and their dynamic changes over time is nearly impracticable because of inadequate objective registration modalities...attempts to improve assessment scrutiny and thus to extend the quantity and quality of skin-surface information have led to a variety of technical procedures including extensive manual body charting, photographic documentation (total body photography), epiluminescence microscopy (nevoscopy), ultrasonography, and, finally, introducing the computer as a technical tool assisting the clinician in diagnosing selected skin manifestations... (Ex. 1003, 981, emphasis added).

47. Among other deprecated "technical procedures," Voigt mentions "total body photography," which is cited by both Canfield (Pet., 29-30) and Dr. Muller, e.g., "Voigt itself acknowledges the usefulness of total body photography for melanoma screenings." (Muller Decl. ¶¶ 116, 133) In fact, one of skill would find nowhere in Voigt that "acknowledges the usefulness of total body photography." Thus, I disagree with Dr. Muller's assertion as contrafactual. (Muller Decl. ¶ 116, 133).

48. Contrary to praising total body photography, a known practice at the time of the invention which involves (preferably a medical photographer) taking many individual images of a patient using a 35 mm film camera with "[a] millimeter paper ruler...placed next to this nevus so that it is included in the close-up photograph" (Slue p. 1239) Voigt <u>criticizes</u> this technique along with others (including "the computer as a technical tool assisting the clinician in diagnosing selected skin manifestations") as deficient: "Thus far, the reproducibility of positioning skin-surface areas for digitized videographic imaging has been a major technical obstacle that has not yet been mastered successfully." (p. 981).

49. It would be clear to one of skill reading Voigt (or Slue cited therein) that "total body photography" is not the invention of the '748, at least because it uses a single hand-held film camera, human operator repositioned around a subject, strobe lights, and takes about 3 minutes. (Slue p. 1239) Total body photography lacks the claimed features of the '748 invention, including arrays of multiple cameras and light sources, a specified imaging position, and associated scaling, which obviates the need for a "millimeter paper ruler." (Slue p. 1239) Voigt criticizes total body photography for its lack of reproducibility, so—contrary to the representations of Canfield and Dr. Muller—one of skill would <u>not</u> understand that "Voigt itself acknowledges the usefulness of total body photography..." (Muller Decl. ¶ 116, 133).

50. Contrary to Canfield's petition and Dr. Muller's declaration, one of skill is taught by both Voigt and the '748 that total body photography has deficiencies. As described below, Voigt teaches one solution to the irreproducibility of total body photography (a vertically-adjustable video camera and a "position framework" that occludes or shadows significant portions of the body), while the '748 teaches a completely different solution: Photographing the body with multiple cameras (and light sources) located at different positions relative to the subject, located at a "specified imaging position." Unlike in the '748, Voigt's camera is not located a predetermined distance from a specified imaging position because its camera is adjustable, and not situated in a particular place or spot realtive to a specified imaging position.

51. In my opinion, at least because Voigt teaches a solution to overcome the deficiencies of total body photography that uses a single video camera but adds an occlusive position framework, while the '748 teaches a solution that employs multiple fixed still cameras at different locations relative to a specified imaging position, one of skill would not look to combine or modify Voigt with any of the other references cited by Dr. Muller to render obvious claims 1-8, 11, 30, 32-34, 46, and 51 of the '748 patent. As I explain below, far from motivating a POSA to add more cameras to Voigt to image the entire body, or alternatively, eliminate the position framework, which would be necessary to image the entire body, Voigt

touts the advantages, indeed the necessity, of this position framework. Furthermore, Voigt's criticism of total body photography for lack of necessary reproducibility of imaging conditions would dissuade a POSA from seeking to "improve" Voigt (e.g. by adding more cameras and light sources), to achieve total body imaging as Canfield contends: <u>Voigt teaches away from total body</u> <u>photography or any system that otherwise allows the entire body to be imaged at</u> <u>one time.</u>

52. To address "...the reproducibility of positioning skin-surface areas [that] has been a major technical obstacle that has not yet been mastered successfully," Voigt describes a system that uses a "position framework" to align the patient against a wall, then also repositions a video camera to record skin images that can be used with a computer to track nevi over time. Voigt's motivation for using a position framework is provided in the first two paragraphs:

Using the computer as a diagnostic tool for the image analysis of sequentially captured skin surface images has resulted in the technical problem of insufficient registration reproducibility. [...] Digitized measurements of skin-surface image parameters were performed using a high-speed processor with an on-board coprocessor, a high-resolution video camera...and a position framework for the adjustment of the patient's standing position.

(Exhibit 1003, p. 981).

Voigt teaches that "reliable registration reproducibility" is the crucial 53. ability to reliably and reproducibly register the adjustable scaled sliders and the scaled-camera slider of the position framework *i.e.*, adjust them so that they correspond exactly in position or are in proper alignment. Exs. 1003, 982; 2022 ("Registration" means "1 : the act of registering"); 2023 ("Register" means "2 : to make or adjust so as to correspond exactly"); 2024 ("Register" means "Printing Photography - Correspond or cause to correspond exactly in position"); 2025 ("Register" means "7. To adjust so as to be properly aligned. ... 8. To be in proper alignment"). Voigt teaches one of skill that the solution to "insufficient registration reproducibility" lies in the use of a "position framework for the adjustment of the patient's standing position", further illustrated on the left side of Voigt Fig. 1, which shows a wall on which four "Scaled Sliders" are mounted, and further on the right depicts a "Camera Slider" with "Halogen Lights" arrayed on (only) the right wall, opposite the subject, with a scanned sector field (middle) between the camera and the preset skin surface:

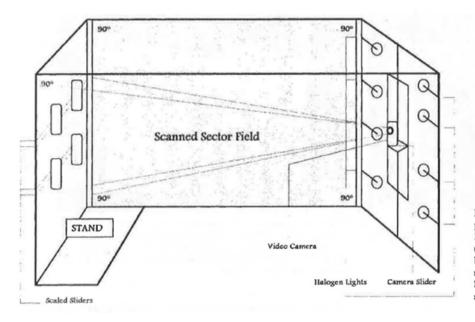


Figure 1. Topodermatographic position framework (schematic). Patient's median standing level (left), median video camera/ bilateral lighting level (right), and scanned sector field (middle) between camera and preset skinsurface area.

54. One of skill is also taught by Voigt (p. 982) that

[t]o avoid axial and transversal spinal flexion and thus to provide reliable registration reproducibility, the patient's standing position was fixed at the thoracic and iliac level by symmetrically fitting the lateral extent of the trunk shape into horizontally adjustable scaled sliders of the position framework, the positions of which were recorded and identically readjusted for serial follow-up measurements. In addition, the vertical height of the video camera was adjusted on a scaledcamera slider, and its framework position was recorded. Calibration for camera setting and position reproducibility was considered adequate if the image boundaries, the framework slider position settings, and the depicted anatomic match points were identical. Images were captured three times sequentially under identical illumination conditions provided by halogen lights fixed laterally at the position framework. A POSA would understand that patients are of different heights, and the adjustability of the camera is necessary to scan the desired area of a particular patient. Further, though typically the camera is later adjusted to the same position, in some case, such as when the patient is a child and grows, a different camera position would be used to scan the same area of skin.

55. Voigt thus teaches one of skill that "to provide reliable registration reproducibility," both the patient position framework and the position framework for the vertically-adjustable video camera are necessary. Voigt further teaches one of skill how to evaluate the calibration of the patient and camera adjustable position frameworks.

56. Although the position framework blocks the view of significant portions of the body (only a dorsal or a ventral view can be taken at one time) requiring repositioning of the patient to image additional views, Voigt never admits this as a shortcoming. Rather, Voigt touts the improvement afforded by the position framework. Voigt mentions established computer-based image processing to consistently locate nevi but adds, "[i]n the present study, reproducibility of image registration was, in contrast, provided by <u>additionally using a specifically designed position framework for the patient's positioning</u>. Consequently, any axial or transversal spinal flexion was effectively prevented." (p. 987 emphasis added) The position framework (along with the positionally adjustable video camera) is

thus an advantageous, central and distinguishing feature of Voigt, and there are no teachings or suggestions to eliminate it. Since Voigt's position framework occludes or shadows at least half of the subject's body, total immersion photography as taught or suggested by the '748 patent, e.g., multiple cameras at multiple locations to image different views of the body, is not contemplated--much less taught or motivated--by Voigt. One of ordinary skill would have understood that the occlusion would shadow if not prevent imaging additional parts of the body, and certainly the entire body, even if more cameras were added, because parts of the position framework would be located between the cameras and the patient's skin. In my opinion, therefore, one of skill would have had no motivation or reason to alter or improve upon the Voigt system disclosed to one of skill as Canfield contends (e.g., add more cameras).

57. Furthermore, by touting the advantages of the patient position framework, Voigt effectively teaches away from eliminating it, which would be necessary to image additional parts or views of the body without occlusion. Since the patient position framework is touted by Voigt as an improvement necessary to obtain the needed reproducibility, one of skill would understand that Voigt would not work without it, and thus would not be motivated or have any reason to remove it to enable simultaneous imaging of both sides (dorsal and ventral) of a subject: the wall against which the subject is positioned occludes or shadows one side of

the body, especially cameras placed behind the patient. Additional cameras would not overcome the problems of lack of reproducibility and patient movement, even if a person stood at a particular location. a so-modified Voigt would have to function in a different, undisclosed way, in order to achieve the precise imaging and reproducibility Voigt achieves. Furthermore, the "horizontally adjustable scaled sliders of the position framework" (p. 982 and Fig. 1) would be understood to one of skill to partially occlude or shadow each side of the subject. The structure holding the sliders would also occlude or shadow parts of the subject. With the substantial occlusion of the subject due to Voigt's touted position framework, one of skill would have no motivation to add more cameras to the apparatus other than the one video camera is taught. Without clear visual access to the entirety of the subject, adding cameras to image partially or completely occluded portions of the subject would not accomplish what Canfield contends one of ordinary skill would seek – imaging of the whole body at once. Nor would it accomplish what the '748 patent describes as a goal of the invention, "...a TIP device that provides nonoccluded images by employing an array of imaging devices and thereafter combining individual images to form a continuous image." ('748 18:21-24). Dr. Muller contends that one could modify Voigt's position framework to remove the rear wall and attach the horizontal sliders to the stand or the "existing outer framework." (¶ 125) The art cited by Canfield does not suggest such a

modification (I note that Voigt does not teach an "existing outer framework"), but regardless such would not permit imaging the whole body at once. The horizontal sliders would block and/or shadow parts of the body, as would whatever structure that supported the sliders.

58. Lacking any motivation or teaching for adding cameras to make images of occluded portions of a subject, a POSA would not be motivated or have any other reason to add cameras in addition to Voigt's existing single video camera. Thus, there is no teaching or motivation for a POSA to modify Voigt to achieve "...a plurality of...imaging devices/means...located on opposite sides of the centerline of the specified imaging position relative to each other..." ('748 Cl. 1 22:7-9, Cl. 50 25:28-33).

59. Likewise, a POSA would lack any a reason to illuminate occluded portions of a subject, which occlusions, in addition to outright blocking such illumination, would cast shadows onto further portions of the body. Thus, a POSA would not be motivated to add light sources to Voigt. Thus, there is no teaching or motivation for a POSA to modify Voigt to achieve "…a plurality of light sources spaced relative to each other and peripheral to the plurality of imaging devices…" ('748 Cl. 1 22:12-13).

60. Just as the position framework for the patient is touted as an improvement, Voigt also teaches one of skill that the position framework for the

video camera is likewise necessarily adjusted for each patient: "In addition, the vertical height of the video camera was adjusted on a scaled-camera slider, and its framework position was recorded." (p. 982) That is, the position of camera is adjusted before imaging begins and is in that position during imaging and again during subsequent imaging. One of skill thus understands that the advantages accruing to a position framework are important both for the subject and for the camera, e.g. enabling registered images over time: "[u]sing a position framework for better registration reproducibility, the results of the monitoring study presented here indicate that topodermatographic image analysis provides a comprehensive, reproducible, and quantifiable diagnostic access to any skin lesion distribution relative to time changes. (Voigt 987). A POSA would understand that one could not provide "reproducible registration conditions" without the adjustability of the camera.

61. There is no teaching or motivation to replace the single, repositionable video camera of Voigt with several fixed still cameras, whose added cost, necessary alignment, and overall increased maintenance and reduced durability due to an increase in parts would be a disincentive having no commensurate benefit for the reasons discussed above. Voigt does not suggest that its system has any deficiencies so that one of skill would seek to modify it. Even if one wished for additional resolution in the images (pixels), one would use a single camera with

higher resolution rather than adding the cost and complexity of multiple cameras. One of skill understands reading Voigt that a video camera is collecting many sequential frames of a scene. In the likely case of even slight subject movement, a portion of the images aligning with previous ones can be selected, stored, processed and compared without the need for alignment of multiple fixed still cameras. Voight would not work without the camera being repositionable. Thus, a POSA would not be motivated to replace the single, position-adjustable video camera of Voigt with one or more fixed still cameras.

Hurley

62. In addition to my analysis and opinions on Hurley here, I further discuss Hurley below regarding Canfield's allegation that certain claims are unpatentable over Hurley alone. My discussion of Hurley below equally applies to this context of the contended combination of Voigt and Hurley.

63. Hurley (Ex. 1004) teaches a body measurement system (BMS) under development for made-to-measure apparel. (Ex. 1004 p. 212) As depicted below, the BMS of Hurley takes three views of a subject using two viewing angles of the front and one view of the rear. (Ex. 1004 p. 212-13).

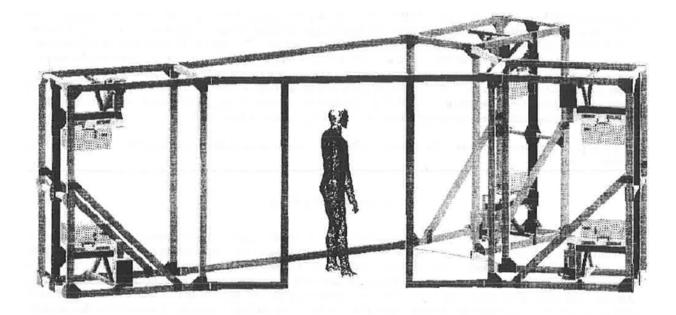


Figure 2.1 Overview of Body Measurement System for made-to-measure apparel.

64. The BMS of Hurley is not photography, nor does it produce a photographic image; in fact, nowhere in Hurley is the word "photography" used. Unlike the process of photographing a subject to reveal accurate details of a skin condition, Hurley employs highly non-uniform illumination from a projector: "The camera and projector are positioned to achieve the desired total sensing area necessary for mapping points onto the surface of the body. The projector contains a two-dimensional grating which is projected onto the body using a white light source." (Ex. 1004 p. 213 ¶3) As I explain above, a POSA at the time of the invention would have at least an associate's degree (2-year) in photography or related disciplines with two years' experience in digital photography and use of computers for collecting, manipulating and viewing *images*. The teaching and ultimate goal of Hurley (which is not even achieved at the time of Hurley's writing

as I explain below) is to provide a *quantitative model of body measurements* "for use in making made-to-measure apparel" (p. 212), not making photographic images. Hurley is not producing images but rather "[c]ontour plots of test subjects." (p. 212) For this reason alone, in my opinion a POSA would not even consult the non-photographic arts, including Hurley, to combine with Voigt to render obvious claims 1-8, 11, 30, 32-34, 46, and 51 of the '748 patent. Were I to view Hurley as Dr. Muller's more educated and experienced POSA, I would reach the same conclusion, since that POSA would reject Hurley at least for its highly non-uniform illumination, which, as I explain below, Voigt teaches away from as unsuitable for skin surface imaging, as well as for the other reasons as I explain below.

65. Hurley is not photographing the subject, and the BMS does not produce photographs of the subject; Hurley is taking measurements to create a model of the subject's outline, a numerical description of the subject's surface geometry or shape. Hurley teaches, "[t]he area segments from each of the sensors are combined to form an integrated surface model...for extracting measurements used in making apparel." (Ex. 1004 p. 213 ¶2) To enable this, Hurley has "a highly non-uniform light projector" (Ex. 1004 p. 213 ¶3), which superimposes stripes onto the subject to facilitate geometrical measurement, in a manner similar to work I have done (Zhang). One of skill in the photographic arts understands the wide

variety of illumination types available for lighting a subject. See, e.g. definitions for "Available light", "Backlighting", "Bottom lighting", "Diffused light", "Fill-in light", "Frontlighting", "Hard light", "Photolamp", "Rimlighting", "Sidelighting", "Soft light", and "Tungsten light" (Kodak, 100-102). As one of skill would understand, Hurley's highly non-uniform light inhibits use of high (grey level) resolution needed for accurate diagnostics of skin conditions, as taught, e.g., by Voigt: "[t]otal in-depth object illumination was given special attention to prevent any artificial shadowing possibly leading to incorrect gray-level discrimination." (Voigt Ex. 1003 p. 983 ¶1) Rather, the highly non-uniform light of Hurleycommon to most 3D imaging techniques-enables measurement of contours using a 2D imager via phase measurement profilometry (PMP). (Hurley p. 212) The result of imaging with highly non-uniform light is a model of the subject's external outline and body shape, but the model is not photographic; it does not detect much less preserve skin conditions. Thus, in my opinion, a POSA would understand that Hurley's disclosures are not useful for imaging skin conditions. Furthermore, Hurley neither teaches nor suggests that additional camera sensors will overcome any shadowing, since Hurley is not concerned with creating an image of the subject. Accordingly, just as adding more cameras to Voigt would not allow imaging of the whole body due to the occlusion by Voigt's position framework (which would be unsuitable for clothing measurements because it would block

parts of the body or cause large inaccuracies because the outline generated by Hurley's edge detection function would include portions of the framework), Canfield's alleged additional reason to add more cameras to Voigt, to avoid "shadowing or shading effects," does not derive from Hurley. Thus in my opinion, a POSA would not, for these reasons, combine the teachings of Hurley with Voigt to render obvious claims 1-8, 11, 30, 32-34, 46, and 51 of the '748 patent.

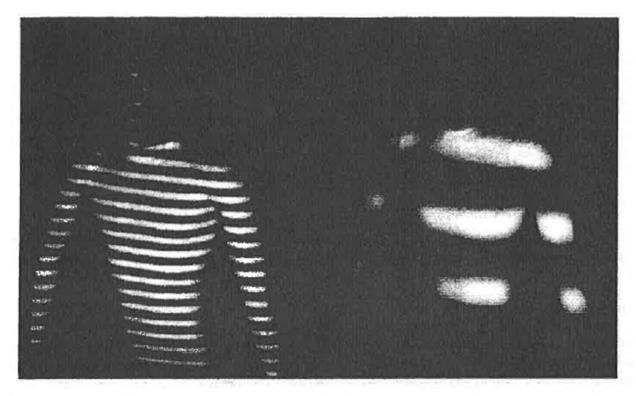


Figure 2.2 Projected sinusoidal patterns from fine and coarse grating.

66. As shown in Fig. 2.2 above, Hurley acquires measurements in succession (p. 214), i.e. not simultaneously, from the subject in a "round robin" fashion, using two different gratings and additional algorithms "to help resolve the ambiguous surface discontinuities." (p. 212, 214) The acquisition of 24 images

with the 1 mm grating occurs within 2 seconds; (p. 214) another 24 images with the 5 mm grating take more time. One of skill would understand that the "round robin" acquisition was required with multiple cameras as in Hurley; Hurley states that this "minimize[s] the capture time." (p. 214). One of skill would further understand that, especially for the fine grating (left side Fig 2.2 above), any movement of the subject could hide a skin lesion in artificial shadow, were it located on the edge of a bright and dark band, particularly if measurements are acquired in succession. Such movement would vary the image registration among the images taken – the relative positioning of the camera and patient. At the scale and precision required for assessing skin lesions, a POSA would understand that an inaccurate assessment could result. This would also lead to non-reproducibility of later scans, which Voigt also teaches away from: "Thus far, the reproducibility of positioning skin-surface areas for digitized videographic imaging has been a major technical obstacle that has not yet been mastered successfully." (Voigt p. 981) The same issues are not implied for Hurley's clothing measurement due to the differences in required scale and precision discussed above, and the one-time nature of the measurements; Hurley, though, has not even proven it works for clothing, as I also discuss above. For these additional reasons a POSA would not combine the teachings of Hurley with Voigt to render obvious claims 1-8, 11, 30, 32-34, 46, and 51 of the '748 patent.

67. To enable accurate measurement of a subject's outline, Hurley requires "a calibration object of known size and orientation." (Ex. 1004 p. 221 ¶3) The result of this calibration is that the subject in Hurley stands in no particular position; the calibration object is to "assure correct coverage" of the subject wherever the subject happens to stand. (Ex. 2004 p. 221) In fact, Hurley does not state that the subject stands in any particular location or show any particular location to stand in the figures. Furthermore, Hurley does not teach or require an alignment framework since one skilled in the art would understand that-unlike taught by Voigt—there is no need to re-position a given subject in exactly the same place were a later measurement to be conducted: Hurley's disclosed calibration procedure teaches one of skill that the subject need not and does not stand in any particular or specific location. For example, as shown in Fig. 2.1 (p. 212), Hurley has a subject facing somewhere between two viewing angles of the front, but there is no teaching or restriction about how precise the subject's stance relative to these angles should be. Nor does Hurley teach or suggest that fewer sensor cameras would economize or save cost, or that additional sensor cameras around the subject would improve the BMS (in fact, these would unnecessarily add cost and complexity.) Hurley says only that one sensor head is needed behind the person because less detail is needed than the front, and does not suggest additional sensors, and an POSA would not add any due to added cost and complexity. (Exs.

1004, 212) Nor does Hurley suggest that fixed cameras are more durable than the adjustable camera in Voigt; as discussed above additional cameras would increase maintenance and decrease durability. By contrast, Voigt is very concerned with reproducibility of the subject's position, and teaches only one adjustable video camera in combination with positioning frameworks for the subject and for the camera. (Voigt 981-82) A POSA would understand that substituting fixed position cameras as taught in Hurley for Voigt's adjustable camera would eliminate this feature from Voigt and not provide "reproducible registration conditions" that "crucially" influence the ability to accurately detect and measure skin-surface changes over time. Hurley does not suggest that its fixed or any other fixed cameras would provide registration reproducibility. Such change would prevent the vertical adjustment of the camera and thus prevent registering the camera and its scanned sector field with the target registration area of the patient, e.g., the area of the patient to be imaged. Instead, the sector field with be fixed, targeting the same vertical location regardless of the where the target registration area of the patient was located. As discussed, Hurley does not require registration reproducibility because it does not involve measurement comparisons over time. One of skill understands that Hurley is making one-time measurements for made-to-measure apparel; there is no teaching in Hurley to achieve repeatable registration for any purpose, much less for skin lesions, from one session to the next. As a practical

matter, Canfield's proposed change would require substantial reconstruction and redesign of the elements shown in Voigt. It would also require a substantial change in the procedures used to accurately and reproducibly image patients over time, for the reasons discussed above. The prior art, though, does not suggest how that would be accomplished with fixed cameras. Regardless, such would be a fundamental change in how Voigt operates; it would be the exact opposite of Voigt's camera adjustment protocols. The above are reasons enough not to modify Voigt, but this is especially so considering Hurley does not discuss single camera imaging systems (such as Voigt or otherwise), suggest that such are deficient, or that adding additional cameras that are fixed would address deficiencies. Because there is no teaching by Hurley to place the subject in a repeatable position, much less a position framework to precisely position the subject and adjust camera position, a POSA would understand that Hurley's disclosure would not be beneficial for imaging skin abnormalities and thus would not combine the teachings of Hurley with Voigt to render obvious claims 1-8, 11, 30, 32-34, 46, and 51 of the '748 patent.

68. As I have argued above, although Hurley describes a BMS, in fact Hurley provides no quantitative results from the system, saying only that the BMS is "under development" (p. 212) and "work is also progressing to extract measurements from the body data sets..." (p. 223) A POSA would expect that if

Hurley's authors had successfully extracted measurements from the data sets, they would have included such quantitative results in the article, which would be normal practice. One of skill would not understand from Hurley that the BMS at the time it was disclosed in fact *worked*, that it could perform quantitative measurements, much less achieved the necessary millimeter-scale measurements of skin lesions taught by Voigt. (p. 981) Thus a POSA would not have a reasonable expectation of success, and in my opinion, would not combine the teachings of Hurley with Voigt to render obvious claims 1-8, 11, 30, 32-34, 46, and 51 of the '748 patent.

PATENTABILITY OF CLAIMS 1-5, 8, 11, 33, 34, 46 AND 51 OVER VOIGT IN VIEW OF CRAMPTON

69. In my opinion, claims 1-5, 8, 11, 33, 34, 46 and 51 are patentable over Voigt in view of Crampton.

70. Crampton teaches a kiosk that houses one or more cameras to produce an avatar of a person. (Exs. 1006, 1, 4) Similar to the BMS of Hurley, Crampton uses sensors to map the surface of a subject to realize "[a] closed, texture mapped, 3D polygonal mesh Avatar..." (Exs. 1006, 8) Also, like Hurley, Crampton is not tracking a subject over time, but rather acquiring an instant set of data for generating a model of the outline of the body; there is no teaching in Crampton that contemplates capture—much less alignment—of a subject's skin features (such as millimeter-scale lesions), and certainly not across multiple imaging sessions, as is taught by Voigt. Because Crampton's teachings are so distinct from those of Voigt they offer no expected benefits in combination with Voigt, and a POSA would thus have no reason to combine the two to render obvious claims 1-4, 8, 11, 30, 33-34 and 51 of the '748.

71. Like Hurley, Crampton teaches "3D cameras" that "use fringe or other types of structured light." (Exs. 1006, 7) As I have stated above, this alone would preclude a POSA from combining Crampton with the teachings of Voigt. Crampton's first embodiment employs a "laser stripe" structured illumination data capture method, calling it "[t]the main data capture method." (Exs. 1006, 7) This embodiment superimposes stripes onto the subject to facilitate geometrical measurement, in a manner similar to work I have done (Zhang). Sensors of Crampton's first embodiment contain lasers and cameras that capture data from the subject as they are scanned vertically along two motor-driven axes; there is no teaching by Crampton of fixed sensors in the first embodiment, and Crampton's mention of "static" cameras refers to still vs. video cameras. (Exs. 1006, 7-8).

72. As one of skill would understand, such highly non-uniform light inhibits use of high (grey level) resolution needed for accurate diagnostics of skin conditions, as taught, e.g., by Voigt: "[t]otal in-depth object illumination was given special attention to prevent any artificial shadowing possibly leading to incorrect gray-level discrimination." (Voigt Ex. 1003 p. 983 ¶1) Rather, the highly non-

uniform light of Crampton's first embodiment—common to most 3D imaging techniques—enables measurement of contours using a 2D imager. As I have stated above, imaging with highly non-uniform light can be used to generate a model of the subject's external outline and body shape, but the model is not and cannot be photographic; it does not detect much less preserve skin conditions. Thus, in my opinion, a POSA would understand that the disclosures of Crampton's first embodiment are not useful for imaging skin conditions.

73. Furthermore, Crampton's first embodiment teaches laser illumination, which is monochromatic. This would inhibit imaging of a skin lesion since only one color would be reflected; laser light is coherent and monochromatic, while the illumination of Voigt using halogen lamps is white and relatively diffuse. Voigt (Exs. 1003 p. 985) teaches digitization of the luminance information from the reflected (white) light to aid in diagnosis and tracking of lesion growth: "As is known from professional photographic procedures, brightness variations of viewed objects under illumination are critical in discriminating object contours." (Voigt 985) As one of skill understands, different colors (e.g. within a skin lesion) are the result of white light reflecting from e.g. different surfaces or pigments. Even when interpreted in the greyscale camera of Voigt to give shading, much more detail is available under broad spectrum (white) illumination than from monochromatic illumination, which is reflected by only one color of surface or pigment. Kodak,

1010 (defining "panchromatic" as "A term applied to sensitized materials . . . that respond to all the visible colors of the spectrum" Thus, as a POSA understands, broad spectrum illumination reveals much more about skin conditions, allowing color to be used as a diagnostic tool to identify and assess skin features (including borders) and determine changes over time, but this is neither taught nor suggested by Crampton, at least indicating that Crampton's first embodiment with laser illumination would offer far less information about skin lesions than, e.g. the halogen illumination taught by Voigt, making it effectively impossible to see and assess skin features of interest. Thus, one of skill would not seek to replace the illumination and single video camera of Voigt with the multiple lasers and cameras of Crampton.

74. For the first embodiment, Crampton teaches that "a capture time of less than 5 seconds is achievable." (Exs. 1006, 7-8) For the same reasons I argue above that a POSA would not use Hurley in combination with Voigt due to subject movement over such a relatively long capture time, likewise a POSA would not combine Crampton's first embodiment with Voigt.

75. Although in its laser stripe sensors Crampton contemplates additional "[c]olour cameras and flashlights...to capture the colours of the person" (Exs. 1006, 7 \P 4), there is no teaching or enablement of these "cameras and flashlights" to "...define[] respective coordinates and said respective predetermined distance

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relative to the specified imaging position, and define[] a respective focal length and resolution information, allowing precise measurement of imaged features of the person or portion thereof located at the specified imaging position." ('748 22:19-25). They are mounted on the moving sensors 57. (1006, 8, Fig. 5) Furthermore, a POSA would understand that "the colours of the person" is directed to coarse features, such as clothing color or even racial features, but not to millimeter-scale skin lesions, since Crampton's sensors already capture data used to derive the subject's superficial geometry. (See 1006, 8, 9) Color is captured only at three points during the scan – the top, middle and bottom of travel. (1006, 8). A POSA would understand that such limited capture provides only generalized color information to add to the avatar, not color detail of the skin surface and features, and certainly not at the level that one could assess skin lesions.

76. Crampton teaches a second embodiment that uses sources of incoherent light such a LEDs instead of lasers, and data captured by the sensors is used to generate the avatar. As I have argued above, this alone would preclude a POSA from combining Crampton with the teachings of Voigt. Crampton's second embodiment illuminates the subject with "fringe or other types of structured light." (Exs. 1006, 10, 13) This embodiment superimposes stripes onto the subject to facilitate geometrical measurement, in a manner similar to work I have done (Zhang).

77. As one of skill would understand, such highly non-uniform light inhibits use of high (grey level) resolution needed for accurate diagnostics of skin conditions, as taught, e.g., by Voigt: "[t]otal in-depth object illumination was given special attention to prevent any artificial shadowing possibly leading to incorrect gray-level discrimination." (Voigt Ex. 1003 p. 983 ¶1) Rather, the highly nonuniform light of Crampton's second embodiment—common to most 3D imaging techniques—enables measurement of contours using a 2D imager. As I have argued above, the result of imaging with highly non-uniform light is a model of the subject's external outline and body shape, but the model is not photographic; it does not detect much less preserve skin conditions. Thus, in my opinion, a POSA would understand that the disclosures of Crampton's second embodiment are not useful for imaging skin conditions.

78. Crampton teaches a preferred embodiment with a kiosk 62 that has only one camera with "the lowest...costs as well as a higher degree of reliability." (Exs. 1006, 9-10) This is reinforced by Crampton's discussion of Fig. 7, which states, "[k]iosk [62] is the preferred layout requiring cameras [63] on one side and four postures of the person [3]." (Exs. 1006, 13) There is no indication to a POSA that the embodiments in Fig. 7 have more cameras than those expressly depicted. Thus a POSA would understand from Crampton's rationale that fewer, not more,

cameras are preferred, and would follow Crampton's guidance. For this reason, a POSA would not modify Voigt by adding more cameras in view of Crampton.

79 Likewise Crampton also teaches an alternative second embodiment with four cameras (Exs. 1006 Fig. 9), and—consistent with Crampton's teaching (above) about the "preferred layout" — Fig. 9 depicts to a POSA that only one side of a subject is captured at a time, requiring a reposing or repositioning ("four postures") of the subject to capture the entire body. This is true whether the cameras move or not. The number of poses depend on how many sides the cameras are on, not whether they move. When the camera(s) are on one side as in Fig. 9, multiple poses are needed. There is no teaching or depiction that the first two embodiments in Fig. 9 have a plurality of cameras "located on opposite sides of a centerline." ('748 Claims. 1, 51) The front views make this clear. Thus, even the multiple-camera embodiment of Crampton Fig. 9 requires repositioning of the person to capture the whole body, and would not provide a POSA reason to combine Crampton with Voigt to render obvious claims 1-4, 8, 11, 30, 33-34 and 51 of the '748 patent.

80. One of skill is also taught by Voigt (p. 982 emphasis added) that [t]o avoid axial and transversal spinal flexion and thus to provide reliable registration reproducibility, the patient's standing position was fixed at the thoracic and iliac level by symmetrically fitting the lateral

extent of the trunk shape into horizontally adjustable scaled sliders of the position framework, the positions of which were recorded and identically readjusted for serial follow-up measurements. In addition, the vertical height of the video camera was adjusted on a scaledcamera slider, and its framework position was recorded. Calibration for camera setting and position reproducibility was considered adequate if the image boundaries, the framework slider position settings, and the depicted anatomic match points were identical. Images were captured three times sequentially under identical illumination conditions provided by halogen lights fixed laterally at the position framework.

81. Therefore, to address "...the reproducibility of positioning skinsurface areas [that] has been a major technical obstacle that has not yet been mastered successfully," Voigt describes a system that uses a "position framework" to align the patient against a wall, then also repositions a video camera to record skin images that can be used with a computer to track nevi over time. Unlike Voigt, Crampton's four cameras on one wall (Exs. 1006 Fig. 9) are not vertically adjustable or positioned with a framework that is set for each subject. As Voigt teaches, the camera position is recorded, and "[c]alibration for camera setting and position reproducibility was considered adequate if the image boundaries, the

framework slider position settings, and the depicted anatomic match points were identical." Thus, a POSA would understand that vertical adjustability for the camera is essential to Voigt's requirement to achieve adequate position reproducibility, and would not have a reason from Crampton to add more cameras yet remove the camera positioning framework.

82. All the reasons as to why a POSA would not modify Voigt with the multiple cameras of Hurley apply to Crampton. As with Hurley, a POSA would understand that, if cameras were placed on more than one side of the person, the position framework of Voigt would occlude and/or cause shadowing of parts of the body. A POSA would thus understand that imaging of the whole body could not be achieved by adding more cameras. Also as with Hurley, a POSA would understand that the Crampton kiosks would process the position framework as part of the subject and include it in the avatar, rendering the avatar quite inaccurate. Canfield further contends that a POSA would add additional cameras to increase resolution. Crampton does not teach this. The discussion of Fig. 9 does not even mention resolution. A POSA would not add multiple cameras to Voigt in view of Crampton for these reasons also.

83. On the other hand, as I discuss above, a POSA would understand from Voigt that the position framework, including both the patient position framework and the camera position framework, is critical to obtaining adequate imaging and

imaging reproducibility for skin lesions. A POSA would thus understand that, because Crampton does not have a position framework as in Voigt, Crampton does not and cannot achieve the accuracy and reproducibility necessary for screening cancers and skin lesions. This is so even through Crampton has foot positioning guidance means 4, 104 on the floor. As a POSA would understand, foot positioning guidance means-even with "head positioning guidance" (Exs. 1006 5)—do not prevent movement of the rest of the body, e.g., fix the person "at the thoracic and iliac level" to prevent axial and transversal spinal flexion, which Voigt teaches is necessary for accurate imaging. (Ex. 1003 982, 987) Similarly as with Hurley's fixed cameras, modifying Voigt's adjustable camera to include Crampton's fixed cameras would be understood by a POSA to render Voigt not to work, i.e., not achieve accurate imaging and reproducibility over time. A POSA would understand, though, that such accuracy is not necessary for Crampton's kiosks. A POSA would understand that the proposed uses of the kiosk, which include, similar to Hurley, "clothing size specifications," do not require anything close to the millimeter-scale precision that skin cancer screening and tracking requires. Also, similar as to discussed above regarding the combination with Hurley, substituting Voigt's single adjustable camera with multiple fixed cameras would fundamentally change how Voigt operates. For these further reasons, a POSA's understanding would be that Crampton's teachings are not useful for

cancer screening and tracking, and the POSA would not combine Crampton with Voigt, e.g., to add more cameras to Voigt.

PATENTABILITY OF CLAIMS 1-5, 8, 11, 33, 34, 46 AND 51 OVER HURLEY

84. In my opinion, claims 1-5, 8, 11, 33, 34, 46 and 51 are patentable over Hurley.

85. As I opine above, the BMS of Hurley is not producing images but rather "[c]ontour plots of test subjects" (p. 212) and if Hurley is not producing images, then a POSA would understand that at least there is no "specified imaging position." For this reason alone, in my opinion a POSA would not even consult Hurley to render obvious claims 1-5, 8, 11, 33, 34, 46, and 51 of the '748 patent.

86. As I have opined above, to enable accurate measurement of a subject's outline, Hurley requires "a calibration object of known size and orientation." (Ex. 1004 p. 221 ¶3) The result of this calibration is that the subject in Hurley stands in no particular position; the calibration object is to "assure correct coverage" of the subject wherever the subject happens to stand. (Ex. 2004 p. 221) As shown in Fig. 3.1, (Hurley 216) a given data point (x,y,z) on the subject is determined through a form of triangulation among the structured light projector, the data point, and the camera, so there is no "specified imaging position," "centerline," or "second means," at least because the data point may be located

anywhere within the coverage of the BMS. If Hurley had a "specified imaging" position" and the further resultant features of the claims, the calibration procedure would not be required. For example, Hurley neither teaches nor uses a "centerline" because the BMS has no need for a defined "centerline" inasmuch as the subject could stand anywhere within the zone of correct coverage and the triangulation procedure would map the subject's surface geometry. As I note above, collecting spatial data points to model the dimensions of a subject would not be understood by a POSA as imaging the subject. In fact, Hurley does not state that the subject stands in any particular location or show any particular location to stand in the figures; Hurley teaches no "specified imaging position" or "second means" of '748 Claims 1 and 51. For example, as shown in Fig. 2.1 (p. 212), Hurley has a subject facing somewhere between two viewing angles of the front, but there is no teaching or restriction about how precise the subject's stance relative to these angles should be. Nor does Hurley teach or suggest that fewer sensor cameras would save cost, or that additional sensor cameras around the subject would improve the BMS (in fact, these would unnecessarily add cost and complexity.) Hurley says only that one sensor head is needed behind the person because less detail is needed than the front. (Exs. 1004, 212) One of skill understands that Hurley is making measurements for made-to-measure apparel; there is no teaching in Hurley to achieve repeatable registration of e.g. skin lesions from one session to

the next. At least because there is no teaching by Hurley of a "specified imaging position," "centerline," or "second means," a POSA would understand that Hurley does not render unpatentable claims 1-5, 8, 11, 33, 34, 46, and 51 of the '748 patent.

87. As I opine above, Hurley neither teaches nor suggests to a POSA that fewer sensor cameras would economize or save cost, or that additional sensor cameras around the subject would improve the BMS (in fact, these would unnecessarily add cost and complexity.) Hurley says only that one sensor head is needed behind the person because less detail is needed than the front. (Exs. 1004, 212)

88. As I have argued above, although Hurley describes a BMS, in fact Hurley provides no quantitative results from the system, saying only that the BMS is "under development" (p. 212) and "work is also progressing to extract measurements from the body data sets…" (p. 223) A POSA would expect that if Hurley's authors had successfully extracted measurements from the data sets, they would have included such quantitative results in the article, which would be normal practice. One of skill would not understand from Hurley that the BMS at the time it was disclosed in fact *worked*, that it could perform quantitative measurements, even for clothing, and for this reason, a POSA would not have had an understanding or expectation that Hurley "allows precise measurement …" as in

the claims of the '748 Patent, and Hurley does not render unpatentable claims 1-5, 8, 11, 33, 34, 46, and 51 of the '748 patent.

PATENTABILITY OF CLAIMS 6 AND 7 OVER VOIGT IN VIEW OF HURLEY AND DAANEN

89. In my opinion, claims 6 and 7 are patentable over Voigt in view of Hurley and Daanen.

90. Daanen surveys scanning systems that create geometric models or representations of the body. Like Hurley and Crampton, these systems do not perform photography, as I have stated previously; they do not and cannot capture images of the skin surface for study of skin lesions, much less reproducible images to enable longitudinal study of lesion changes. Voigt teaches one of skill that "[u]sing a position framework for better registration reproducibility, the results of the monitoring study presented here indicate that topodermatographic image analysis provides a comprehensive, reproducible, and quantifiable diagnostic access to any skin lesion distribution relative to time changes." (Voigt 987) None of the systems in Daanen have a positioning system that can achieve this. Moreover, the position framework in the alleged combination, as with the Hurley and Crampton combinations, would still occlude or shadow parts of the person. Complete imaging of the body is not achieved, even with additional cameras. In view of the added cost and complexity, one would add more cameras.

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91. One 3D scanner discussed by Daanen, the TC^2 system, appears to be related to that described by Hurley, but in a different publication. (Exs. 1005, 115, 120) A POSA would understand that the TC^2 system is not yet available, since Daanen comments, "[1]ater, the system will be commercialized for a price of about US\$100 000." (Exs. 1005, 115) Daanen notes that the disclosed fixed camera systems are more durable than the other systems with cameras that move during imaging. A POSA would understand that Daanen was not referring to cameras as in Voigt that are adjusted into position and remain there for imaging, or suggesting that such cameras have durability or maintenance issues.

92. Like Hurley and Crampton, the systems in Daanen all use a form of structured or patterned illumination using "light sources that project a line or other pattern on the human body" (Exs. 1005, 112), and for all the reasons I have provided above that a POSA would not look to or use teachings with such illumination to combine with Voigt, it is my opinion likewise that a POSA would not combine the teachings of Voigt in view of Daanen with Hurley to render obvious claims 6 and 7 of the '748.

93. Daanen describes the Vitronic VIRO 3D-2400 ("Vitronic") system, which uses a scanned laser line on a moving frame to acquire dimensional data from a subject. (Exs. 1005, 112-13, 115) According to '748 Cl. 6, the system has at least eight imaging devices; while in my opinion a POSA would understand that

none of the 3D measurement systems performs photographic imaging, even if the Board decides otherwise, only two of the eight systems in Daanen have at least eight cameras, the Vitronic and the Hamamatsu; both use only moving cameras. (Exs. 1005, 117-118) As I have stated above, the Vitronic system, like the rest of those taught by Daanen, does not perform photography: "The data is exported in voxels (3D-coordinates)...[the] output can be converted to a format that can be used to control milling machines." (Exs. 1005 115) A POSA would understand that the Vitronic system acquires and outputs, not an image suitable for tracking skin lesions, but rather a set of coordinates for describing the geometry of the subject. As taught by Daanen, "[t]he Vitronic has the best resolution of the mentioned systems: the resolution is 1-2 mm in every direction...mainly caused by the large number of cameras that is used." (Exs. 1005 115) Thus a POSA would understand that the "large number of cameras" of Daanen/Vitronic is not for imaging a larger portion of the body (or the whole body at once, which is not done by the Vitronic since it has moving cameras that scan), but rather to increase (3D) resolution, which is a different parameter than the resolution in an image of the skin as used in Voigt, at least because it is resolution in 3-dimensional space, not on a 2dimensional surface.

94. As I have opined above, a POSA would also understand that a monochromatic laser is not a white light source such as the halogen illumination

taught by Voigt for imaging skin lesions (Voigt Fig. 1) and is not usable for imaging skin lesions, and thus would not combine such laser scanning technology with Voigt. As I discuss above, laser light would inhibit imaging of a skin lesion since only one color would be reflected; laser light is coherent and monochromatic, while the illumination of Voigt using halogen lamps is white and relatively diffuse. As I discuss above, accurate and complete imaging skin tissue coloration is an important tool for detecting and assessing skin lesions. Voigt (Exs. 1003 p. 985) teaches digitization of the luminance information from the reflected (white) light to aid in diagnosis and tracking of lesion growth, which is neither taught nor suggested by Daanen and Hurley. Thus, one of skill would not seek to replace the imaging system of Voigt with the teachings of Daanen and Hurley.

95. One of skill would not add, in view of the multiple *moving* cameras of the Vitronic system taught by Daanen, additional cameras to the system of Voigt for at least the reasons of added complexity with no added benefit, since the occlusive position framework of Voigt remains, and multiple moving cameras would not circumvent the detrimental effect of the framework. Nowhere in Daanen is a stationary (non-moving) camera taught or suggested for the Vitronic system. Moreover, nothing in the prior art suggests Hurley's coverage is inadequate or that additional sensors would add further benefit. Nothing in Daanen suggests that its arrangement would be a further improvement. Furthermore, with moving cameras,

there is no "predetermined distance" to a "specified imaging position" as taught by '748 Claim 1 (from which Cl. 6 depends; I understand Cl. 7 depends from Cl. 6). Thus, a POSA would not combine teachings of Voigt in view of Daanen with Hurley to render obvious claims 6 and 7 of the '748.

CONCLUSIONS

96. For all of the foregoing reasons, it is my opinion that claims 1-8, 11, 30, 32-34, 46, and 51 would not have been obvious to one of ordinary skill in the art at the time of the invention.

97. I understand that my declaration will be filed as evidence in this matter before the Patent Trial and Appeal Board and constitutes testimony. I understand that I may be subject to cross examination in this matter, and I will appear for cross examination as required by the laws of the United States and the rules and regulations application to this matter.

98. I reserve the right to supplement my opinions in the future, including but not limited to, to address new information that becomes available to me, to respond to any further arguments raised or evidence brought forth by Canfield or Dr. Muller in this matter, to address any rulings or decisions by the Board. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

June 20, 2018

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Dr. Daniel Van Der Weide