

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

THE TRUSTEES OF
PURDUE UNIVERSITY,

Plaintiff,

v.

OMRON CORPORATION, OMRON
HEALTHCARE COMPANY, LIMITED, and
OMRON HEALTHCARE, INC.

Defendants.

Civil Action No. 1:20-cv-05443

Honorable Elaine E. Bucklo

PLAINTIFF'S SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Pursuant to the Court's Order (ECF No. 104), Plaintiff The Trustees of Purdue University ("Purdue") files this Second Amended Complaint for Patent Infringement against Defendants Omron Corporation, Omron Healthcare Company, Limited., and Omron Healthcare, Inc. (collectively "Defendants" and/or "Omron") and alleges as follows:

I. PARTIES

1. Purdue is a statutory body corporate that operates and conducts a state educational institution having its principal place of business at 610 Purdue Mall, West Lafayette, Indiana 47907.

2. Purdue is a public land-grant research university under the 1862 Morrill Act that was founded in 1869 and is consistently ranked among the top universities in the United States and the world. Purdue enrolls more than 40,000 students under the guidance of over 16,000 faculty and staff and has produced 24 National Academy of Engineering members. Purdue's professional and graduate programs include the well-ranked College of Engineering, Krannert School of

Management, College of Education, and College of Pharmacy. Purdue's esteemed School of Aeronautics and Astronautics within the College of Engineering has acquired the nickname "Cradle of Astronauts" for the twenty-five astronauts, including Neil Armstrong and Gus Grissom, it has produced. Other notable Purdue alumni are Nobel Prize winners Edward Mills Purcell, Ben Roy Mottelson, and Akira Suzuki.

3. Purdue is the State of Indiana's primary driver for economic growth in science and technology. For example, Purdue spent over \$435,185,000 on research during the 2019-2020 fiscal year, founded more than 80 technology startups, and raised more than \$96,000,000 in venture capital funding.

4. In 2019, Purdue ranked 13th globally for receiving U.S. utility patents according to a report published annually by the National Academy of Inventors and Intellectual Property Owners Association. This distinction marks the sixth straight year that Purdue has ranked in the top 20.

5. Purdue is an instrumentality of the State of Indiana, created and authorized by the Indiana General Assembly pursuant to Indiana Code § 21-23-2-1, *et seq.*, and thus enjoys sovereign immunity. *Kashani v. Purdue Univ.*, 813 F.2d 843, 845 (7th Cir. 1987); *Wasserman v. Purdue Univ.*, 431 F. Supp. 2d 911, 916 (N.D. Ind. 2006) ("[T]he Board of Trustees [of Purdue] is a political arm of the state which is immune to suit."); *Harris v. Trustees of Purdue Univ.*, 2017 WL 529598, at *2 (S.D. Ind. Feb. 8, 2017).

6. By filing this lawsuit or prosecuting this action, Purdue does not waive, either expressly or implicitly, its sovereign immunity or the sovereign immunity enjoyed by any arm of the State of Indiana under the laws of the United States or the State of Indiana, to any *inter partes* review, *ex parte* reexamination, or other post-grant proceeding at the United States Patent and

Trademark Office (“USPTO”) or its Patent Trial and Appeal Board, to any other administrative actions or proceedings, to any noncompulsory counterclaims, or to any other federal or state proceedings whatsoever, whether initiated by Omron or an entity other than defendant.

7. Defendant Omron Corporation (“OC”) is a Japanese company with a principal place of business at Shiokoji Horikawa, Shimogyo-ku, Kyoto 600-8530, Japan, and may be served through Japan’s Central Authority pursuant to Article 5 of the Hague Convention, to which Japan is a signatory.

8. Defendant Omron Healthcare Co., Ltd. (“OHCL”), a wholly owned subsidiary of OC, is a Japanese company with a principal place of business at 53, Kunotsubo, Terado-cho, Muko, Kyoto, 617-0002, Japan, and may be served through Japan’s Central Authority pursuant to Article 5 of the Hague Convention, to which Japan is a signatory.

9. Defendant Omron Healthcare, Inc. (“OHI”) is a Delaware corporation with a principal place of business at 1925 West Field Court, Suite 100, Lake Forest, Illinois 60045 and may be served through its registered agent, CT Corporation System, located at 208 South LaSalle Street, Suite 814, Chicago, Illinois 60604 or wherever else it may be found.

II. JURISDICTION AND VENUE

10. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over OC and OHCL because each Defendant admits it is subject to this Court’s personal jurisdiction at least for purposes of this action. ECF No. 105 ¶ 8; *see also* ECF No. 16 at 14 (“[OC] is subject to general jurisdiction in Illinois.... [“OHCL]’s United States contacts are with Illinois.”); *id.* at 18 (“In Illinois, there would be no jurisdictional battle.”).

12. This Court also has personal jurisdiction over each Defendant because Defendants are present in and transact and conduct business in and with residents of this District and the State of Illinois, including substantial marketing and sales of products within this District and the State of Illinois.

13. Purdue's causes of action arise, at least in part, from Defendants' infringing acts, business contacts, and other activities in this District and the State of Illinois. Defendants, directly and through their intermediaries, make, use, ship, import, distribute, offer for sale, sell, and/or advertise products, including the provision of blood pressure monitors and customer support, at least one of which infringes the patent-in-suit, throughout the United States and this State. Defendants solicit customers, including customers of infringing products in this State, have many customers who are residents of this State, including customers who use Defendants' products in this District, and/or derive substantial revenue from products and services provided to residents of this District and the State of Illinois.

14. Defendants' infringing products, which are manufactured exclusively for OHCL and are distributed in the United States by OHI, are clearly marked with OHCL's and OHI's names and addresses.

Manufactured for : OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo, Terado-cho, Muko, Kyoto, 617-0002 JAPAN
Distributed by : OMRON HEALTHCARE, INC.
1925 West Field Court Lake Forest, IL 60045 U.S.A.
www.omronhealthcare.com
© 2014 OMRON HEALTHCARE, INC.
Made in Vietnam



15. Venue is proper in this District as to OC and OHCL under 28 U.S.C. § 1391(c)(3) because each Defendant is a Japanese corporation and not a resident of the United States and may, therefore, be sued in any judicial district. *In re: HTC Corp.*, 889 F.3d 1349, 1357 (Fed. Cir. 2018) (reaffirming the long-established alien-venue rule); *see also Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 714 (1972); *TC Heartland LLC v. Kraft Food Group Brands LLC*, 137 S. Ct. 1514, 1520 n.2 (2017) (“The parties dispute the implications of petitioner’s argument for foreign corporations. We do not here address that question, nor do we express any opinion on this Court’s holding in *Brunette Machine*.”).

16. Further, OC and OHCL previously requested transfer to this District. *See* ECF No. 46; ECF. No. 16 at 16-19 (“This case belongs in the Northern District of Illinois.”). As OC admits, venue is proper as to OC because its “subsidiaries also maintain a large office in Hoffman Estates, IL where many employees of ...those subsidiaries are located.” ECF. No. 16 at 17.

17. Venue is proper in this District as to OHI pursuant to 28 U.S.C. § 1400(b) because OHI has committed acts of infringement in this District. *See, e.g.*, ECF No. 48 at 14 (admitting that OHI “is responsible for the United States marketing, sales and distribution of” the accused products.”); ECF No. 96 at 4 (declaring OHI “is the only entity that performs acts accused of infringement in the United States.”). And OHI has a regular and established place of business in this District. Specifically, OHI is headquartered at 1925 West Field Court, Suite 100, Lake Forest,

Illinois 60045. <https://www.omron.com/global/en/network/americas/> (last accessed April 20, 2021).

18. OHI is and has been registered to do business in the State of Illinois (File No. 54561709) since February 25, 1987.

19. Purdue does not waive its sovereign immunity as to any venue, including district courts and administrative tribunals, other than this Court, namely the United States District Court for the Northern District of Illinois, Eastern Division.

III. U.S. PATENT NO. 7,014,611

20. United States Patent No. 7,014,611 (“’611 patent”), filed on June 24, 2004 (“Filing Date”) and titled “Oscillometric Noninvasive Blood Pressure Monitor,” was duly and legally issued by the USPTO on March 21, 2006. A true and correct copy of the ’611 patent is attached as Exhibit A and is also available at <https://pdfpiw.uspto.gov/.piw?PageNum=0&docid=7014611>.

21. The inventors of the ’611 patent are the late Professor Leslie A. Geddes, Ph.D. (“Prof. Geddes”) and Rebecca A. Roeder, Ph.D. (“Dr. Roeder”).

22. Prof. Geddes was Purdue’s Showalter Distinguished Professor Emeritus of Bioengineering and former Director of Purdue’s Hillenbrand Biomedical Engineering Center. Prof. Geddes was born on May 24, 1921 in Port Gordon, Scotland. He moved to Canada at an early age and earned bachelor’s and master’s degrees in electrical engineering from McGill University in Montreal. In 1959, Prof. Geddes earned a doctorate in physiology and pharmacology from Baylor University College of Medicine where he developed physiological monitoring systems for the first astronauts.

23. Purdue recruited Prof. Geddes to establish the University’s biomedical engineering research center in 1974, which he grew and developed into the Purdue Department of Biomedical Engineering in 1998. Prof. Geddes is world-renowned for his pioneering work in defibrillators,

pacemakers, electrocardiographs, blood pressure monitoring, and regenerative tissue grafts for burn victims. Prof. Geddes' inventions have been used to treat hundreds of thousands of patients, are licensed to several Indiana companies such as Cook Biotech, DePuy, Eli Lilly, and Hillenbrand Industries, and have generated tens of millions of dollars of royalties for the benefit of Purdue and the State of Indiana.

24. In 2006, President George W. Bush awarded Prof. Geddes the National Medal of Technology, the United States' highest honor for technological innovation. Prof. Geddes was elected to the National Academy of Engineering and received the Institute of Electrical and Electronics Engineers ("IEEE") Edison Medal, the Engineering in Medicine and Biology Society Career Achievement Award, the Association for the Advancement of Medical Instrumentation Laufman-Greatbatch Award, and the Nelson Innovation Award. Prof. Geddes authored 13 books and more than 800 scientific papers, edited several scientific journals, and served as a consultant to the National Institute of Health, the Federal Drug Administration, and the National Science Foundation.

25. Dr. Roeder was a student of Dr. Geddes and received her doctorate in Bioengineering from Purdue under his guidance. She began working with Prof. Geddes on research and teaching projects in 1995 and continued working to do so until his death in 2009. The claimed invention of the '611 patent resulted from Drs. Geddes and Roeder's research conducted at Purdue.

26. The '611 patent's original patentee was Purdue Research Foundation, which acquired exclusive ownership of the patented invention by written assignments from Drs. Geddes and Roeder on June 18, 2004 which was recorded with the USPTO on June 24, 2004. Thereafter, on November 29, 2017, Purdue Research Foundation conveyed to Purdue all rights, title, and

interest in and to the '611 patent, including the right to sue and recover for past infringements, by written assignment recorded with the USPTO on November 30, 2017.

27. All requirements under 35 U.S.C. § 287 have been satisfied with respect to the '611 patent.

28. Every claim of the '611 patent is valid and enforceable and enjoys a statutory presumption pursuant to 35 U.S.C. § 282.

29. Defendants are not licensed to the '611 patent, either expressly or implicitly, nor do they enjoy or benefit from any rights in or to the '611 patent whatsoever.

A. The Field of Blood Pressure Measurement and Estimation.

30. Blood pressure when the heart is contracting is called systolic pressure, and when it is relaxing between beats is called diastolic pressure. Exhibit B, Declaration of Dr. Wolf von Maltzahn (“von Maltzahn Decl.”), ¶ 9.

31. Blood pressure can be directly measured by inserting a catheter into a blood vessel. However, direct measurements are invasive and can cause complications. So noninvasive techniques have been developed for indirectly estimating blood pressure. *Id.* ¶ 10.

32. One noninvasive technique uses a stethoscope to detect heart sounds that occur when an artery is compressed. These sounds can be used to estimate blood pressure when the heart is contracting (systolic pressure) and relaxing between beats (diastolic pressure). *Id.* ¶ 11.

33. Blood pressure can also be estimated by placing an ultrasonic transducer over a vein. *Id.* ¶ 12.

34. Tonometry estimates blood pressure by measuring the amount of pressure required to flatten a blood vessel. *Id.* ¶ 13.

35. Oscillometry is another type of noninvasive technique for estimating blood pressure. In oscillometry, an inflatable cuff is placed around a patient's appendage, the cuff is

inflated to apply pressure, and pressure readings are taken as the cuff deflates. Oscillometry estimates blood pressure by measuring changes in the amplitude of pulsatile pressure oscillations as an inflatable cuff is deflated. '611 patent, 1:14-21; von Maltzahn Decl. ¶ 14.

36. Several techniques for determining systolic and diastolic blood pressure through oscillometry are known. One oscillometric technique, pioneered by Prof. Geddes, estimates systolic and diastolic blood pressure based on the ratios of amplitudes of pressure oscillations. Prof. Geddes described this estimation technique in a 1982 article entitled “Characterization of the Oscillometric Method for Measuring Indirect Blood Pressure” (“Geddes 1982”), attached as Exhibit C, which the '611 patent incorporates by reference (1:30-32). This technique – sometimes called the “fixed ratio” or “characteristic ratio” technique – is described in U.S. Patent No. 6,801,798 (4:66 – 5:32), for which Prof. Geddes is the lead inventor, and which the '611 patent incorporates by reference (3:26-30). von Maltzahn Decl. ¶ 15.

B. At the Time of Invention There Existed A Need for A More Accurate Noninvasive Oscillometric Technique for Measuring Blood Pressure.

37. At the Filing Date, commercially available oscillometric devices were useful for noninvasive blood pressure measurement, but a need remained for improvement in accuracy, particularly with respect to identification of systolic and diastolic pressure.

38. Oscillometry literature confirms that there was a need for an oscillometric device capable of estimating systolic and diastolic pressures more accurately than the oscillometric technology available as of the time of invention.

39. The ratios for estimating systolic and diastolic blood pressure changed with changes in blood pressure. In particular, Prof. Geddes found that as systolic pressure increased from 100 mm Hg to 190 mm Hg the fixed ratio decreased from 0.57 to 0.45. Similarly, as diastolic pressure increased from 55 mm Hg to 115 mm Hg the fixed ratio decreased from 0.86 to 0.75. This meant

that the “fixed ratio” oscillometric technique was inaccurate over a range of blood pressures. von Maltzahn Decl. ¶ 16; Ex. C at 276-77.

40. A 2013 article by Raamat et al, entitled “A Model-Based Retrospective Analysis of the Fixed-Ratio Oscillometric Blood Pressure Measurement” (“Raamat”), attached as Exhibit D, compared the results of 10 studies that used the fixed ratio technique to determine systolic and diastolic blood pressure. Raamat identified a number of factors that influence these blood pressure estimates using the “fixed ratio” oscillometric technique and cause them to vary widely. For example, Raamat found systolic ratios (k_{syst}) ranging from 0.40 to 0.59 and diastolic ratios (k_{diast}) from 0.60 to 0.80, as depicted in Table I from the article. Raamat noted that “the accuracy of the fixed-ratio oscillometric BP [blood pressure] measurement can be influenced by a number of affecting factors.” von Maltzahn Decl. ¶ 17-18; Ex. D at 1.

TABLE I
AMPLITUDE-BASED CHARACTERISTIC RATIOS

| Source | k_{syst} | k_{diast} | $k_{\text{diast}} - k_{\text{syst}}$ |
|-------------------------------------|-------------------|--------------------|--------------------------------------|
| Geddes <i>et al.</i> (1982) [4] | 0.50 | 0.80 | 0.30 |
| Sapinski <i>et al.</i> (1986) [5] | 0.40 | 0.60 | 0.20 |
| Ramsey <i>et al.</i> (1988) [6] | 0.50 | 0.69 | 0.19 |
| Miyawaki (1988) [7] | 0.50 | 0.75 | 0.25 |
| Dinamap [8] | 0.50 | 0.63 | 0.13 |
| Drzewiecki <i>et al.</i> (1994) [9] | 0.59 | 0.72 | 0.13 |
| Ursino and Cristalli (1996) [10] | 0.52 | 0.70 | 0.13 |
| Moraes <i>et al.</i> (1999) [11] | 0.56 | 0.76 | 0.20 |
| Amoore <i>et al.</i> (2007) [12] | 0.49 | 0.72 | 0.23 |
| Zheng <i>et al.</i> (2009) [13] | 0.45 | 0.80 | 0.35 |
| min | 0.40 | 0.60 | 0.13 |
| max | 0.59 | 0.80 | 0.35 |

41. Oscillometric estimates can be especially unreliable among critically ill patients with low blood pressure and among diabetic patients who have stiff arteries.

42. A 1990 article by Runcie et al, entitled “Blood pressure measurement during transport,” attached as Exhibit E (“Runcie”) found that oscillometric devices underestimate systolic blood pressure and overestimate diastolic blood pressure in critically ill patients with low blood pressure. von Maltzahn Decl. ¶ 19; Ex. E at 660-662 and Figures 1-4. A 2000 article by Van Popele et al, entitled “Arterial Stiffness as Underlying Mechanism of Disagreement Between an Oscillometric Blood Pressure Monitor and a Sphygmomanometer” (“Van Popele”), attached as Exhibit F, found that oscillometric devices overestimate both systolic and diastolic blood pressure in diabetic patients suffering from arterial stiffness. von Maltzahn Decl. ¶ 19.

43. Prof. Geddes’ fixed ratio method is not the only oscillometric technique for estimating systolic and diastolic blood pressure. von Maltzahn Decl. ¶ 20.

44. A 1992 article by Sapinski entitled “Standard algorithm of blood-pressure measurement by the oscillometric method,” attached as Exhibit G, proposes that systolic pressure can be calculated as 40 percent of A_m .

45. Other oscillometric techniques estimate systolic and diastolic blood pressure based on the rate of changes in the oscillometric amplitudes over a range of cuff pressures. von Maltzahn Decl. ¶ 20.

46. A 1982 article by Borow et al entitled “Noninvasive estimation of central aortic pressure using the oscillometric method for analyzing systemic artery pulsatile blood flow” (“Borow”), attached as Exhibit H, identifies systolic blood pressure as the point during cuff deflation at which pulsation is first detected and identifies diastolic blood pressure as the lowest cuff pressure just before oscillations stop decreasing. Ex. H at 880; von Maltzahn Decl. ¶ 20.

47. A book chapter published in 2000 by Drzewiecki, entitled “Noninvasive arterial blood pressure mechanics” (“Drzewiecki”), attached as Exhibit I, used the change in the slope of oscillometric amplitude to estimate systolic and diastolic blood pressure. Ex. I at §71.2; von Maltzahn Decl. ¶ 20.

48. A 2005 article by Jilek et al, entitled “Oscillometric Blood Pressure Measurement: The Methodology, Some Observations, and Suggestions” (“Jilek”), , attached as Exhibit J, explains that, by 2005, accuracy had become “increasingly important” as more health care providers were relying on noninvasive blood pressure measurement devices. Ex. J at 240; von Maltzahn Decl. ¶ 21.

49. In fact, by 2005, accuracy had become increasingly important as more health care providers were relying on noninvasive blood pressure measurement devices.

50. Figures 1 and 2 of Jilek depict oscillometric measurements and identify several difficulties of using oscillometry to determine systolic and diastolic blood pressure: “Examination of oscillometric waveforms in Figures 1 and 2 reveals the challenge that designers of oscillometric BP [blood pressure] devices face in attempting to determine SBP [systolic blood pressure] and DBP [diastolic blood pressure] algorithmically. There are no easily identifiable SBP [systolic blood pressure] and DBP [diastolic blood pressure] points on the waveform envelope. Oscillometric BP [blood pressure] determination is complicated by other factors, such as movement artifacts, deep breathing, tremors, and arrhythmias.” Ex. J at 238; von Maltzahn Decl. ¶ 21.

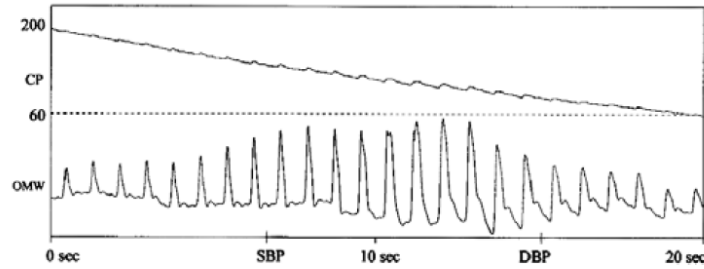


Figure 1. Oscillometric waveforms (OMW) derived from cuff pressure (CP) curve. Systolic (SBP) and diastolic (DBP) blood pressure reference points were determined by auscultation.

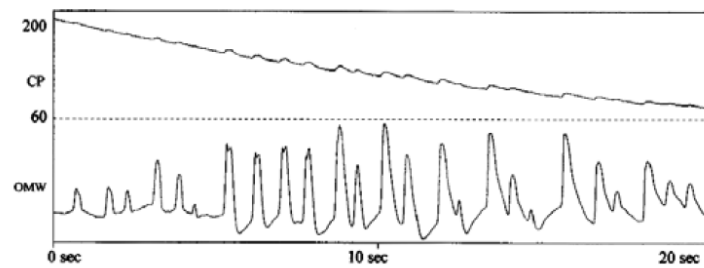


Figure 2. Oscillometric waveforms (OMW) contain irregular heart beats.

51. Geddes 1982, Ramaat, Runcie, Van Popele, Sapinski, Borow, Drzewiecki, and Jilek confirm that before the claimed invention of the '611 patent there had existed a long-felt need for an oscillometric device capable of estimating systolic pressure with improved accuracy.

C. The '611 Patent Claims Are Directed to An Improved Oscillometric Technique to More Accurately Estimate Systolic Blood Pressure.

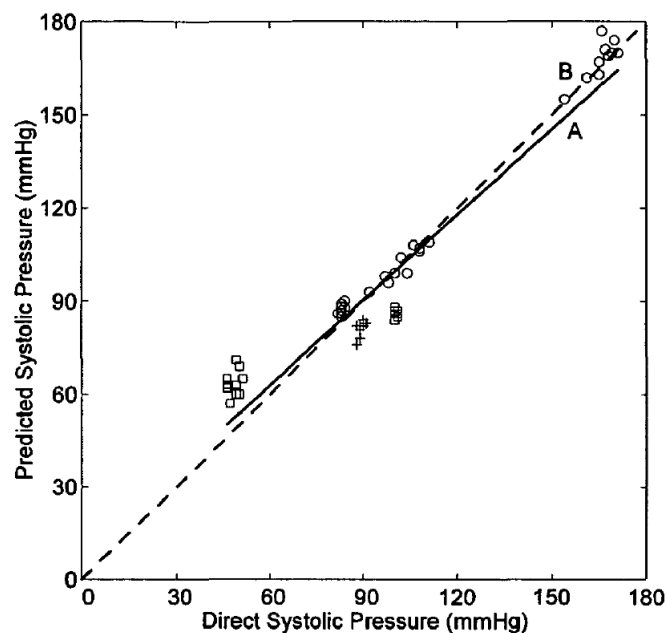
52. The '611 patent is directed to a novel device and method, which is practiced on a physical subject to more accurately estimate his/her systolic blood pressure (SBP) using the oscillometric method. von Maltzahn Decl. ¶ 22.

53. The '611 patent claims are directed to a novel device (and a method of measurement) that includes several physical components such as an inflatable cuff, pressure transducer, and a measurement circuit (microprocessor) to detect oscillations in cuff pressure and to measure mean cuff pressure (P_m) and the maximum amplitude (A_m) and to use both of these

parameters to reduce errors in estimating SBP over a large pressure range. These components are physical, not abstract notions, and arranged in a particular configuration to practice the claimed invention on a physical subject. *Id.* ¶ 23.

54. Before the '611 patent, no one had ever used mean cuff pressure (P_m) and the maximum amplitude (A_m) in the manner claimed in the '611 patent to estimate SBP. *Id.* ¶ 24.

55. In contrast to prior art oscillometric techniques, SBP estimated using the technique claimed in the '611 patent is virtually the same as directly measured systolic pressure. The accuracy of the claimed invention is illustrated by how closely the data points cluster about the dotted diagonal line in Figure 7 of the '611 patent.



56. The dotted diagonal line in Figure 7 identifies where the data points would lie if the SBP predicted by the claimed technique perfectly matched the SBP obtained by direct measurement. *Id.* ¶ 25.

57. Prior art oscillometric techniques struggled to accurately predict SBP at pressures that deviate from “normal pressure,” i.e., 120 mm Hg. Geddes 1982 identifies 120 mm HG as

“normal pressure.” By contrast, Figure 7 shows that the claimed technique provides an estimate of SBP that is virtually free of error in the range of normal blood pressures and provides reasonably accurate estimates even at pressures as low as 50 mm Hg and as high as 170 mm Hg. *Id.* ¶ 26.

58. The '611 patent's claimed technique detects certain oscillations in arterial pressure and measures P_m and A_m and uses those measurements in an unconventional equation to more accurately estimate systolic blood pressure across a wider range of pressures than was possible with conventional oscillometric devices. This novel technique reduces the errors in estimating systolic blood pressure that are common among noninvasive prior art techniques. *Id.* ¶ 27.

59. Claim 1 of the '611 patent requires:

An oscillometric, noninvasive blood pressure monitor, comprising:

an inflatable cuff;

a pump connected to said cuff;

a pressure transducer connected to said cuff, said pressure transducer producing a cuff-pressure signal;

means for detecting oscillations in arterial pressure occurring during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure; and

a blood pressure measurement circuit responsive to said oscillations, said circuit determining the maximum amplitude A_m of said oscillations, identifying mean cuff pressure P_m as the coincident value of said cuff-pressure signal, and determining systolic pressure as a function of both A_m and P_m .

60. The '611 patent claims a technique that reduces errors in estimating SBP with a noninvasive oscillometric device. In particular, SBP is estimated as a function of two parameters – P_m and A_m – that are tied to a specific device, i.e., an inflatable cuff having a sensor. Before the '611 patent, no one had ever calculated P_m and A_m using a device as claimed in the '611 patent and used those measurements to reduce errors in estimating SBP. *Id.* ¶¶ 34-36. In contrast to prior

art oscillometric techniques, SBP estimated as claimed in the '611 patent is virtually free of error. '611 Patent at 5:15-19; *see also* von Maltzahn Decl. ¶ 37.

61. The claims of the '611 patent are similar to claims in U.S. Patent No. 9,131,859 (“the '859 patent”), attached as Exhibit W, which is assigned to OHCL and directed to an oscillometric technique for measuring SBP and DBP using an algorithm. Ex. W. Portions of the '859 patent's file history are attached as Exhibit X.

62. During prosecution of the '859 patent, Omron overcame a rejection based on *Alice* by arguing that the claims are:

directed to a blood pressure measurement apparatus (i.e., a machine) that includes, at least, a cuff, a pressure detector, and a volume detector. As such, Applicant respectfully submits that amended independent claims 1 and 5 recite sufficient structure to qualify as patent-eligible subject matter under 35 U.S.C. § 101.

Ex. X, Response at 8.

63. The '611 patent claims require “an inflatable cuff” and “a pressure transducer,” which are nearly identical to components Omron successfully argued were sufficient to render patentable the '859 patent under *Alice*. von Maltzahn Decl. ¶ 74.

64. For the same reasons that the USPTO allowed the claims of the '859 patent to issue, the claims of the '611 patent are patentable under 35 U.S.C. § 101.

65. The claimed technique of the '611 patent is directed to a specific improvement in measurement capabilities of oscillometric devices.

66. The claims of the '611 patent do not preempt most methods of measuring SBP, such as direct measurement with a catheter or indirect estimation with a stethoscope, ultrasound, tonometry, or even oscillometric methods such as the fixed ratio technique. von Maltzahn Decl. ¶¶ 38-41.

67. The claims of the '611 patent are limited to methods that estimate SBP as a function of both P_m and A_m , two specific parameters that are tied to a particular noninvasive, cuff-based, oscillometric device. *Id.* ¶ 49.

68. The claimed technique of the '611 patent, when viewed as a whole, discloses an unconventional noninvasive technique for estimating systolic blood pressure. The use of P_m and A_m to estimate systolic blood pressure was not well-understood, routine, or conventional at the time that Drs. Geddes and Roeder invented the claimed technique. *Id.* ¶ 43.

69. The '611 patent's error-reducing technique more accurately estimates SBP based on noninvasive oscillometric measurements. The '611 patent claims are directed to a novel device (and a method of measurement) with an inflatable cuff and pressure transducer that detects certain oscillations in arterial pressure and measures P_m and A_m and uses both of those measurements to reduce errors in estimating SBP. Before the '611 patent, no one had ever used P_m and A_m in the manner claimed in the '611 patent to estimate SBP. *Id.* ¶ 23-24. Thus, even if the claims of the '611 patent are directed to a natural law or abstract idea (they are not as explained above), they are patentable under *Alice* Step Two because they are directed to a specific technological improvement over the prior art.

70. OHCL has overcome *Alice* rejections to obtain at least five patents that analyze various cardiovascular and/or bodily conditions by explaining to the USPTO that the patents improve the accuracy of prior art techniques. *Id.* ¶ 42.

71. OHCL overcame several of these *Alice* rejections by explaining that: (1) the claimed technique does not preempt others from determining blood pressure; (2) the claimed techniques are patentable technological improvements that improve the accuracy or reliability of

estimating various blood pressure parameters or diagnosing vascular conditions; and/or (3) the claims are sufficiently tied to physical components. *Id.* ¶ 45.

72. OHCL's patents are analogous to the claims of the '611 patent which provide similar technological improvements. *Id.* ¶ 46.

73. The claims of the '611 patent are not invalid under *Alice* for at least the types of reasons that OHCL articulated to the USPTO when it obtained patents directed to improved measurements and calculations using oscillometric techniques.

1. U.S. Patent No. 9,271,655

74. The claims of the '611 patent are similar to claims in U.S. Patent No. 9,271,655 ("the '655 patent"), attached as Exhibit K, which is assigned to OHCL and directed to a technique for calculating blood pressure. Portions of the '655 patent's file history are attached as Exhibit L.

75. During prosecution of the '655 patent, Omron overcame a rejection based on *Alice* by arguing that "there is no risk that the claims will 'tie-up' the excepted subject matter and preempt others" because the claims require (1) a cuff with a pressure sensor and (2) determining blood pressure based on the amplitude of a pulse wave that has been corrected to account for changes in cuff pressure and pulse rate. Ex. L, Response at 13-14. Thereafter, the claims of the '655 patent were allowed. *Id.* at 17.

76. Both the '611 patent and the '655 patent are directed to a cuff-based oscillometric technique for estimating blood pressure parameters. von Maltzahn Decl. ¶ 49.

77. Both the '611 patent and the '655 patent contain limitations that avoid preempting most methods of estimating systolic blood pressure. *Id.*

78. The claimed technique of the '611 patent does not preempt any techniques for directly measuring systolic blood pressure using a catheter. Nor does it preempt indirect estimation techniques that use a stethoscope, ultrasound, or tonometry. The claims of the '611 patent are

limited to methods that estimate systolic blood pressure as a function of two parameters, P_m and A_m . These two parameters that are tied to a particular noninvasive, cuff-based, oscillometric device. The claimed technique of the '611 patent does not preempt the fixed ratio method or any other method that does not estimate systolic blood pressure as a function of P_m and A_m . *Id.*

79. The claims of the '611 patent are not invalid under *Alice* for at least the types of reasons that OHCL articulated to the USPTO when it obtained the '655 patent.

2. U.S. Patent No. 9,668,658

80. U.S. Patent No. 9,668,658 (“the '658 patent”), attached as Exhibit M, is assigned to OHCL and directed to a technique for detecting arterial aneurysms based on pulse wave measurements.

81. The '658 patent originated from U.S. Patent Application No. 13/718,413 (“the '413 application”), which was filed on December 18, 2012. Ex. M. Portions of the '658 patent’s file history are attached as Exhibit N.

82. On December 6, 2016, the examiner rejected all pending claims of the '413 application under 35 U.S.C. § 101 and concluded that the claims were “directed to calculating pulse wave velocity using two different mathematical correlations, which is an abstract idea.” Ex. N, Response at 9.

83. OHCL responded to the § 101 rejection on February 24, 2017, stating: “In *McRO*, the Federal Circuit expanded on its holding in *Enfish* by explaining that a claim is not an abstract idea under the first step of the *Alice* analysis if, when viewed as a whole, it recites rules that limit the claimed process in such a manner that does not preempt other approaches for achieving the result using different rules or different techniques. ... When viewed as a whole, independent claims 1 and 5 recite the same type of ‘rules’ that were at issue in *McRO*. ... The claimed ‘rules’ provide a particular and improved way for evaluating the likelihood of a predetermined pathologic change

in a vascular pathway from the heart to a first measurement area and a second measurement area. Importantly, by virtue of these recitations, claims 1 and 5 do not preempt all other approaches for evaluating a likelihood of a pathologic change in a vascular pathway from the heart to a first measurement area and a second measurement area. Thus, for the same reasons identified by the Federal Circuit in *McRO*, claims 1 and 5 are not directed to an abstract idea under the first step of the *Alice* analysis.” *Id.* at 10-12.

84. OHCL further stated: “the Supreme Court unequivocally identified the claims at issue in the Supreme Court’s decision in *Diamond v. Diehr*, 450 U.S. 175 (1981) (*Diehr*) as claims that resulted in improvements a technological field and an existing technological process, and thus satisfied the second step of the *Alice* analysis. ... Similar to the patent eligible claims in *Diehr*, independent claims 1 and 5 provide an improvement to the technological field of evaluating a pathologic change in a vascular pathway because the claimed features provide a more accurate, quicker, and simpler evaluation than was previously possible, as clearly shown by the improvements over the art of record.” *Id.* at 12-13.

85. On March 10, 2017, the Examiner issued a Notice of Allowance stating that all pending claims would be allowed to issue. In her Reasons for Allowance, the Examiner stated: “Applicant details the differences between the prior art and invention to show the improvement to another technology or technical field. Applicant argues the claimed features provide a technical solution to the identified problems with a simpler evaluation of a predetermined pathologic change in a vascular pathway. This was considered persuasive and thus, the previous rejection is withdrawn.” *Id.* at 18.

86. Similar to OHCL’s argument with respect to its ’658 patent, the claims of the ’611 patent recite measurement techniques similar to the rules that were at issue in *McRO*. The claimed

noninvasive oscillometric measurement techniques provide a particular and improved way to estimate SBP as a function of both A_m and P_m , which is more accurate than prior art techniques that determined SBP based on cuff pressure associated with an amplitude at a fixed percentage of A_m . The claimed noninvasive oscillometric techniques do not preempt all other approaches for determining systolic pressure. von Maltzahn Decl. ¶ 53.

87. Similar to OHCL's argument with respect to its '658 patent, the claims of the '611 patent provide an improvement to the technological field of using a noninvasive oscillometric blood pressure monitor to determine systolic pressure because the claimed features provide a more accurate determination of systolic pressure than was previously possible, as clearly shown by the improvements over the art of record. von Maltzahn Decl. ¶ 53.

88. The claims of the '611 patent are not invalid under *Alice* for at least the types of reasons that OHCL articulated to the USPTO when it obtained the '658 patent.

3. U.S. Patent No. 9,532,720

89. U.S. Patent No. 9,532,720 ("the '720 patent"), attached as Exhibit O, is assigned to OHCL and directed to an improved technique for diagnosing arteriosclerosis. The claimed technique performs mathematical functions on waveforms detected in a patient's arteries to identify the degree of arteriosclerosis in a patient.

90. The '720 patent originated from U.S. Patent Application No. 13/852,132 ("the '132 application"), which was filed on March 28, 2013. *Id.* Portions of the '720 patent's file history are attached as Exhibit P.

91. On March 23, 2016, the examiner rejected all pending claims of the '132 application under 35 U.S.C. § 101 and concluded that the claims were "directed to generating a waveform; decomposing the pulse waveform; and calculating the index of degree of

arteriosclerosis which are all abstract ideas similar to mathematical relationships/formulas and organizing information through mathematical correlations.” Ex. P, Office Action at 2.

92. OHCL responded to the § 101 rejection on June 22, 2016, explaining that the claimed technique “has improved accuracy over the prior art” by providing “a better indicator of how much a measurement subject’s arteries have hardened (i.e., how much a measurement subject’s arteriosclerosis has progressed).” *Id.*, Response at 12.

93. Omron’s arguments overcame the *Alice* rejection because “the arguments have laid out a specific improvement for the accuracy of the degree of arteriosclerosis in comparison with the prior art.” *Id.*

94. The claims of the ’611 patent are not invalid under *Alice* for at least the reason the Examiner found when allowing the claims of OHCL’s ’720 patent to issue, i.e., because the claimed technique of Purdue’s ’611 patent provide a specific improvement to estimating SBP based on A_m and P_m . von Maltzahn Decl. ¶ 58.

4. U.S. Patent No. 9,044,145

95. U.S. Patent No. 9,044,145 (“the ’145 patent”), attached as Exhibit Q, is assigned to OHCL and directed to noninvasive technique that provides a more accurate calculation of a vascular metric based on heartbeat measurements.

96. The ’145 patent originated from U.S. Patent Application No. 13/310,421 (“the ’421 application”), which was filed on December 2, 2011. Ex. Q. Portions of the ’145 patent’s file history are attached as Exhibit R.

97. On October 23, 2014, the examiner rejected all pending claims of the ’421 application under 35 U.S.C. § 101. Ex. R.

98. When responding to the § 101 rejection, OHCL likened its claims to those at issue in *Diamond v. Diehr*, 450 U.S. 175 (1981) because they are directed to improvements that “allow a more accurate determination of a key aspect of the problem to be solved”:

“While the claims in *Diehr* allowed a more accurate determination of the cure time for synthetic rubber than was previously possible, the present claims allow a more accurate calculation of a pulse wave analysis index and a degree of stability (indicating reliability of the pulse wave analysis index), which is outputted (e.g., displayed) and used in “medical practice as an index for noninvasively evaluating vein hardness.” Ex. R, Response at 8-9.

99. On March 2, 2015, the Examiner issued a Notice of Allowance stating that all pending claims would be allowed to issue. In his Reasons for Allowance, the examiner stated: “viewing the claim elements as an ordered combination, the processing steps recited permit a healthcare professional such as a physician to more accurately diagnose whether there is the suspicion of arterial sclerosis (pg. 22, line 24 - pg. 23, line 4). These are improvements in the technology of medical diagnostics. Unlike the invention in *Alice*, the instant claims are not merely limiting the abstract idea to a computer environment by simply performing the idea via a computer (i.e., not merely performing routine storage, output, or mathematical operations on a computer), but rather reflect an improvement in medical diagnostic technology, namely diagnostic reliability of arteriosclerosis based on pulse wave analysis, which in this case reflects an improvement in medical diagnostic technology. Taking all the additional claim elements, both individually and in combination, the claims as a whole amount to significantly more than the abstract idea of a mathematical operation/formula.” Ex. R, Notice of Allowance at 5.

100. The claims of the ’611 patent are not invalid under *Alice* for at least the reason the Examiner found when allowing the claims of OHCL’s ’145 patent to issue: the claimed technique

of the '611 patent provides a technological improvement, i.e., a more accurate estimate of systolic blood pressure using noninvasive measurements. von Maltzahn Decl. ¶ 62.

5. U.S. Patent No. 9,474,485

101. U.S. Patent No. 9,474,485 (“the ’485 patent”), attached as Exhibit S, is assigned to OHCL and directed to a technique to more accurately measure blood pressure based on oscillometric measurements of pulse waves.

102. The ’485 patent originated from U.S. Patent Application No. 13/790,026 (“the ’026 application”), which was filed with the USPTO on March 8, 2013. Ex. S. Portions of the ’485 patent’s file history are attached as Exhibit T.

103. On March 11, 2016, the examiner rejected all pending claims of the ’026 application under 35 U.S.C. § 101 and concluded that these claims were “directed to determining the blood pressure and calculating a positional relationship of the device to the patient, which are no more than an abstract idea.” Ex. T, Office Action at 2.

104. OHCL responded to the § 101 rejection on June 13, 2016, stating: “[D]etermining the angle of inclination and the distance to the head as recited in the pending claims adds significantly more because the calculations are directly tied to, at least, improving the *accuracy* and *precision* of the blood pressure calculation.” Ex. T, Response at 4-5.

105. On July 5, 2016, the Examiner issued a Notice of Allowance stating that all pending claims would be allowed to issue. In his Reasons for Allowance, the examiner stated: “Applicant’s arguments, see pg. 5, filed 6/13/16, with respect to the 35 U.S.C. § 101 rejection have been fully considered and are persuasive. It is clear from the arguments and the specification that the distance sensor and angle determination are critical to determining if the device is in the most accurate position to take a blood pressure reading, either allowing the device to take a reading or telling the user to reposition as needed. Thus, the addition of the distance sensor and determination of the

angle of inclination improve the functionality of the device and processor and provide a more accurate result than that demonstrated by prior art. The rejection of claims 1-3 and 5-7 have been withdrawn.” *Id.*

106. Similar to OHCL’s argument with respect to its ’485 patent, the claims of the ’611 patent improve the accuracy of blood pressure estimates. Determining the P_m and A_m as recited in the claims adds significantly more because the calculations are directly tied to improving the accuracy of the blood pressure calculation. The ability of the claimed device and method to make these measurements are critical to reducing the error in the estimate. von Maltzahn Decl. ¶ 67.

6. U.S. Patent No. 9,766,090

107. U.S. Patent No. 9,766,090 (“the ’090 patent”), attached as Exhibit U, is assigned to OHCL and directed to a body movement detection device.

108. The ’090 patent originated from U.S. Patent Application No. 13/351,887 (“the ’887 application”), which was filed on January 17, 2012. Ex. U. Portions of the ’090 patent’s file history are attached as Exhibit V.

109. After the examiner rejected OHCL’s claims under *Alice*, OHCL likened its claims to those in *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017), because the pending claims recited a “sensor-based improvement” that “is exactly like the sensor-based improvement in *Thales*.” Ex. V, Response at 10.

110. OHCL explained that, in *Thales*,

The Federal Circuit recognized: (i) that a new and useful technique of using particular sensor data in an equation in a way that improves a prior technique is not an abstract idea; and (ii) the fact that the improvement relies on an equation does not by itself render a claim ‘abstract’ under step one of the *Alice* analysis.

Id. at 9.

111. OHCL further explained that “the claim[ed] invention showed improvement over the current technology such as sharing activity information between users, providing more accuracy in calculating activity intensity and providing stimulating information.” Ex. V, Interview Summary.

112. The Examiner found OHCL’s arguments persuasive and allowed the claims to issue. Ex. V, Notice of Allowance at 2-3.

113. Like OHCL’s ’090 patent and the patent in *Thales*, the ’611 patent claims a sensor-based improvement that is more accurate in estimating information that comports with *Alice*. von Maltzahn Decl. ¶ 71.

IV. INFRINGEMENT OF THE ’611 PATENT

114. Defendants have and continue to directly, indirectly, and willfully infringe one or more claims of the ’611 patent in violation of 35 U.S.C. § 271, including but not limited to claims 1 and 10.

115. Each Defendant, acting alone and/or in concert with and/or at the direction and subject to the control of other Defendants, imports into the United States, offers to sell in the United States, sells in the United States and directs, encourages, and instructs downstream customers’ use in the United States, each of the Accused Products.

A. Count One: Direct Infringement

116. All previous paragraphs are incorporated herein as if fully set forth.

117. Defendants have directly infringed, literally and/or under the doctrine of equivalents, and will continue to directly infringe the ’611 patent by, making, using, offering for sale, selling, distributing, and/or importing in or into the United States, products that embody the apparatuses and practice the methods covered by at least claim 1 of the ’611 patent, including but not limited to the following blood pressure monitors and product families thereof: Omron 3 Series

Wrist Blood Pressure Monitor, exemplified by Model BP629; Omron 3 Series Upper Arm Blood Pressure Monitor, exemplified by Model BP710N and BP7100; Omron 5 Series Upper Arm Blood Pressure Monitor, exemplified by Model BP742N and BP7200; Omron 5 Series Wireless Upper Arm Blood Pressure Monitor, exemplified by Model BP7250; Omron 7 Series Wrist Blood Pressure Monitor, exemplified by Model BP652; Omron 7 Series Upper Arm Blood Pressure Monitor, exemplified by Model BP760N; Omron 7 Series Wireless Upper Arm Blood Pressure Monitor, exemplified by Model BP761N and BP7350; Omron 10 Series Wireless Wrist Blood Pressure Monitor, exemplified by Model BP653; Omron 10 Series Upper Arm Blood Pressure Monitor, exemplified by Model BP785N; Omron 10 Series Wireless Upper Arm Blood Pressure Monitor, exemplified by Model BP786N; Omron Evolv Wireless Upper Arm Blood Pressure Monitor, exemplified by Model BP7000; and any other blood pressure monitors that use the same or similar algorithm for measuring systolic pressure as these devices (collectively, the “Accused Products”) in violation of 35 U.S.C. § 271(a), as shown in Purdue Initial Infringement Contentions served on February 19, 2021, and any amendments thereto, which are incorporated herein by reference.

118. Defendants’ direct infringement of the ’611 patent has caused, and will continue to cause, substantial and irreparable damage to Purdue. Purdue is, therefore, entitled to an award of damages adequate to compensate for Defendants’ infringement of the ’611 patent, but in no event less than a reasonable royalty for Defendants’ use and/or sale of Purdue’s invention, together with interest and costs as fixed by the Court under 35 U.S.C. § 284.

1. Omron 3 Series Wrist Blood Pressure Monitor: BP629 (BP629N)

119. BP629 is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

120. BP629 is capable of measuring blood pressure noninvasively.

121. BP629 includes an inflatable cuff.
122. BP629 is capable of inflating the inflatable cuff.
123. BP629 includes a pump connected to the cuff.
124. BP629 includes a pressure transducer connected to the cuff.
125. BP629's pressure transducer is capable of producing a cuff-pressure signal.
126. BP629 is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

127. BP629 includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

128. BP629's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

129. BP629's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

130. BP629's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

2. Omron 3 Series Upper Arm Blood Pressure Monitor: BP710N

131. BP710N is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

132. BP710N is capable of measuring blood pressure noninvasively.

133. BP710N includes an inflatable cuff.

134. BP710N is capable of inflating the inflatable cuff.

135. BP710N includes a pump connected to the cuff.

136. BP710N includes a pressure transducer connected to the cuff.

137. BP710N's pressure transducer is capable of producing a cuff-pressure signal.

138. BP710N is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

139. BP710N includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

140. BP710N's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

141. BP710N's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

142. BP710N's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

3. Omron 3 Series Upper Arm Blood Pressure Monitor: BP7100

143. BP7100 is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

144. BP7100 is capable of measuring blood pressure noninvasively.

145. BP7100 includes an inflatable cuff.

146. BP7100 is capable of inflating the inflatable cuff.

147. BP7100 includes a pump connected to the cuff.

148. BP7100 includes a pressure transducer connected to the cuff.

149. BP7100's pressure transducer is capable of producing a cuff-pressure signal.

150. BP7100 is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

151. BP7100 includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

152. BP7100's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

153. BP7100's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

154. BP7100's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

4. Omron 5 Series Upper Arm Blood Pressure Monitor: BP742N

155. BP742N is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

156. BP742N is capable of measuring blood pressure noninvasively.

157. BP742N includes an inflatable cuff.

158. BP742N is capable of inflating the inflatable cuff.

159. BP742N includes a pump connected to the cuff.

160. BP742N includes a pressure transducer connected to the cuff.

161. BP742N's pressure transducer is capable of producing a cuff-pressure signal.

162. BP742N is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

163. BP742N includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

164. BP742N's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

165. BP742N's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

166. BP742N's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

5. Omron 5 Series Upper Arm Blood Pressure Monitor: BP7200

167. BP7200 is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

168. BP7200 is capable of measuring blood pressure noninvasively.

169. BP7200 includes an inflatable cuff.

170. BP7200 is capable of inflating the inflatable cuff.

171. BP7200 includes a pump connected to the cuff.

172. BP7200 includes a pressure transducer connected to the cuff.

173. BP7200's pressure transducer is capable of producing a cuff-pressure signal.

174. BP7200 is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

175. BP7200 includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

176. BP7200's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

177. BP7200's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

178. BP7200's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

6. Omron 5 Series Wireless Upper Arm Blood Pressure Monitor: BP7250

179. BP7250 is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

180. BP7250 is capable of measuring blood pressure noninvasively.

181. BP7250 includes an inflatable cuff.

182. BP7250 is capable of inflating the inflatable cuff.

183. BP7250 includes a pump connected to the cuff.

184. BP7250 includes a pressure transducer connected to the cuff.

185. BP7250's pressure transducer is capable of producing a cuff-pressure signal.

186. BP7250 is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

187. BP7250 includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

188. BP7250's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

189. BP7250's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

190. BP7250's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

7. Omron 7 Series Wrist Blood Pressure Monitor: BP652

191. BP652 is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

192. BP652 is capable of measuring blood pressure noninvasively.

193. BP652 includes an inflatable cuff.

194. BP652 is capable of inflating the inflatable cuff.

195. BP652 includes a pump connected to the cuff.

196. BP652 includes a pressure transducer connected to the cuff.

197. BP652's pressure transducer is capable of producing a cuff-pressure signal.

198. BP652 is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

199. BP652 includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

200. BP652's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

201. BP652's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

202. BP652's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

8. Omron 7 Series Upper Arm Blood Pressure Monitor: BP760N

203. BP760N is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

204. BP760N is capable of measuring blood pressure noninvasively.

205. BP760N includes an inflatable cuff.

206. BP760N is capable of inflating the inflatable cuff.

207. BP760N includes a pump connected to the cuff.

208. BP760N includes a pressure transducer connected to the cuff.

209. BP760N's pressure transducer is capable of producing a cuff-pressure signal.

210. BP760N is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

211. BP760N includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

212. BP760N's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

213. BP760N's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

214. BP760N's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

9. Omron 7 Series Wireless Upper Arm Blood Pressure Monitor: BP761N

215. BP761 is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

216. BP761 is capable of measuring blood pressure noninvasively.

217. BP761 includes an inflatable cuff.

218. BP761 is capable of inflating the inflatable cuff.

219. BP761 includes a pump connected to the cuff.

220. BP761 includes a pressure transducer connected to the cuff.

221. BP761's pressure transducer is capable of producing a cuff-pressure signal.

222. BP761 is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

223. BP761 includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

224. BP761's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

225. BP761's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

226. BP761's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

10. Omron 7 Series Wireless Upper Arm Blood Pressure Monitor: BP7350

227. BP7350 is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

228. BP7350 is capable of measuring blood pressure noninvasively.

229. BP7350 includes an inflatable cuff.

230. BP7350 is capable of inflating the inflatable cuff.

231. BP7350 includes a pump connected to the cuff.

232. BP7350 includes a pressure transducer connected to the cuff.

233. BP7350's pressure transducer is capable of producing a cuff-pressure signal.

234. BP7350 is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

235. BP7350 includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

236. BP7350's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

237. BP7350's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

238. BP7350's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

11. Omron 10 Series Wireless Wrist Blood Pressure Monitor: BP653

239. BP653 is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

240. BP653 is capable of measuring blood pressure noninvasively.

241. BP653 includes an inflatable cuff.

242. BP653 is capable of inflating the inflatable cuff.

243. BP653 includes a pump connected to the cuff.

244. BP653 includes a pressure transducer connected to the cuff.

245. BP653's pressure transducer is capable of producing a cuff-pressure signal.

246. BP653 is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

247. BP653 includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

248. BP653's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

249. BP653's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

250. BP653's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

12. Omron 10 Series Upper Arm Blood Pressure Monitor: BP785N

251. BP785N is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

252. BP785N is capable of measuring blood pressure noninvasively.

253. BP785N includes an inflatable cuff.

254. BP785N is capable of inflating the inflatable cuff.

255. BP785N includes a pump connected to the cuff.

256. BP785N includes a pressure transducer connected to the cuff.

257. BP785N's pressure transducer is capable of producing a cuff-pressure signal.

258. BP785N is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

259. BP785N includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

260. BP785N's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

261. BP785N's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

262. BP785N's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

13. Omron 10 Series Wireless Upper Arm Blood Pressure Monitor: BP786N

263. BP786 is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

264. BP786 is capable of measuring blood pressure noninvasively.

265. BP786 includes an inflatable cuff.

266. BP786 is capable of inflating the inflatable cuff.

267. BP786 includes a pump connected to the cuff.

268. BP786 includes a pressure transducer connected to the cuff.

269. BP786's pressure transducer is capable of producing a cuff-pressure signal.

270. BP786 is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

271. BP786 includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

272. BP786's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

273. BP786's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

274. BP786's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

14. Omron Evolv Wireless Upper Arm Blood Pressure Monitor: BP7000

275. BP7000 is a blood pressure monitor, and more specifically, an oscillometric blood pressure monitor capable of detecting oscillations in arterial pressure.

276. BP7000 is capable of measuring blood pressure noninvasively.

277. BP7000 includes an inflatable cuff.

278. BP7000 is capable of inflating the inflatable cuff.

279. BP7000 includes a pump connected to the cuff.

280. BP7000 includes a pressure transducer connected to the cuff.

281. BP7000's pressure transducer is capable of producing a cuff-pressure signal.

282. BP7000 is capable of detecting arterial pressure oscillations that occur during a transition in cuff pressure between a pressure greater than normal systolic pressure and a pressure less than normal diastolic pressure.

283. BP7000 includes a blood pressure measurement circuit responsive to arterial pressure oscillations.

284. BP7000's blood pressure measurement circuit is capable of determining the maximum amplitude of the arterial pressure oscillations.

285. BP7000's blood pressure measurement circuit is capable of identifying a mean cuff pressure as the value of the cuff pressure signal coinciding in time with the maximum amplitude of the arterial pressure oscillations.

286. BP7000's blood pressure measurement circuit is capable of determining systolic pressure as a function of both the maximum amplitude of the arterial pressure oscillations and the mean cuff pressure.

B. Count Two: Indirect Infringement

287. All previous paragraphs are incorporated herein as if fully set forth.

288. Defendants indirectly infringe at least claim 10 of the '611 patent under 35 U.S.C. § 271(b) by inducing others (e.g., its retailers and customers) to use the patented method through making, using, selling, offering for sale, distributing, and/or importing the Accused Products.

289. Defendants were and have been aware of the '611 patent and its coverage of blood pressure monitors since as early as August 22, 2007, when the U.S. Patent and Trademark Office expressly notified Defendant OC of the '611 patent in connection with U.S. Patent Application Serial No. 11/374,989, and potentially earlier, and were aware that their actions as to importers, distributors, resellers, wholesalers, retailers, and/or end users of the Accused Instrumentalities would induce infringement. Despite such awareness, Defendants continue to take active steps (e.g.,

creating and disseminating the Accused Products and product manuals, instructions, promotional and marketing materials, and/or technical materials to distributors, resellers, wholesalers, retailers, and end users) to encourage others to infringe at least claim 10 of the '611 patent with the specific intent to induce such infringement.

290. Defendants' indirect infringement of the '611 patent has caused, and will continue to cause, substantial and irreparable damage to Purdue. Purdue is, therefore, entitled to an award of damages adequate to compensate for Defendants' infringement of the '611 patent, but in no event less than a reasonable royalty for Defendants' use and/or sale of Purdue's invention, together with interest and costs as fixed by the Court under 35 U.S.C. § 284.

C. Count Three: Willful Infringement

291. All previous paragraphs are incorporated herein as if fully set forth.

292. Defendants have been willfully infringing the '611 patent since as early as August 22, 2007 when the U.S. Patent and Trademark Office expressly notified Defendant OC of the '611 patent in connection with U.S. Patent Application Serial No. 11/374,989.

293. Therefore, Plaintiff are entitled to receive enhanced damages up to three times the amount of actual damages for Defendants' willful infringement under 35 U.S.C. § 284.

V. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby demands a trial by jury on all issues triable to a jury.

VI. PRAYER

WHEREFORE, Plaintiff requests the following relief:

- A. A judgment that the '611 patent is valid and enforceable;

B. A judgment that Defendants have directly (literally and/or under the doctrine of equivalents), indirectly, and willfully infringed and continue to infringe the '611 patent as alleged herein;

C. A judgment and order requiring Defendants to pay Plaintiff damages under 35 U.S.C. § 284, including treble damages for willful infringement as provided by 35 U.S.C. § 284, and supplemental damages for any continuing post-verdict infringement through entry of the final judgment with an accounting as needed;

D. A judgment that this is an exceptional case within the meaning of 35 U.S.C. § 285 and Plaintiff is therefore entitled to reasonable attorneys' fees;

E. A judgment and order requiring Defendants to pay Plaintiff pre-judgment and post-judgment interest on the damages awarded;

F. A judgment and order awarding Plaintiff costs associated with bringing this action; and

G. Such other and further relief as the Court deems just and equitable.

Respectfully submitted,

/s/ Michael W. Shore

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CERTIFICATE OF SERVICE

Pursuant to the Federal Rules of Civil Procedure, I hereby certify that on April 28, 2021, the foregoing document was electronically filed with the Clerk of the Court using the Court's CM/ECF system which will send notification of the filing to all counsel of record for the parties.

/s/ Michael W. Shore