Federal Court  Cour fédérale

Date: 20180212

Docket: T-300-16

Citation: 2018 FC 164

Ottawa, Ontario, February 12, 2018

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA AND TEARLAB CORPORATION

Plaintiffs
(Defendants by Counterclaim)

and

I-MED PHARMA INC.

Defendant
(Plaintiff by Counterclaim)

JUDGMENT AND REASONS

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I. Pleadings

[1] This action concerns the validity and enforcement of Canadian Patent No. 2,494,540 entitled “Tear Film Osmometry” (the “‘540 Patent”). The ‘540 Patent was filed on March 25, 2003, issued on June 3, 2014, and expires on March 25, 2023. It grants the patentee the exclusive right in Canada to make, use, import and sell the invention claimed.

[2] The Plaintiffs are the Regents of the University of California (the “University”) and TearLab Corp. (“TearLab”). The Defendant is I-MED Pharma Inc. (“I-MED”).

[3] The University owns the ‘540 Patent. TearLab holds a sub-license from its wholly-owned subsidiary TearLab Research Inc., who holds an exclusive license from the University to, among other things, make, have made, use, sell, offer for sale and import products into Canada that are covered by the claims of the ‘540 Patent.

[4] The Plaintiffs assert that the Defendant’s i-Pen Osmolarity System (the “i-Pen”) infringes claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 of the ‘540 Patent.

[5] The Defendant asserts non-infringement (including the Gillette Defence) and invalidity of each of the claims asserted by the Plaintiffs under the ‘540 Patent, on the basis of anticipation, obviousness, inutility, insufficient disclosure and overbroad and ambiguous claims.

[6] The issues are as follows:

1. Preliminary issue:
    A. Does TearLab have standing?
2. Patent infringement and validity
    A. Infringement:
        i. Does the i-Pen infringe any of claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 of the ‘540 Patent?
3. Validity:
    A. Anticipation:
        i. Does the subject-matter of any of claims 1, 2, 5, 8, 13 and 14 lack novelty?
    B. Obviousness:
        i. Was the subject-matter of any of claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 obvious at the claim date?
    C. Utility:
        i. Do any of claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 fail to demonstrate the utility of the invention?
        ii. Did claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 fail to soundly predict the utility of the invention as of the filing date?
    D. Sufficiency:
        i. Does the specification fail to correctly and fully describe the invention and its operation?
        ii. Does the specification fail to set out the invention in such full, clear and concise and exact terms as to enable any person skilled in the art of science to which it pertains?
        iii. Does the specification fail to explain the principle of the invention and the best mode in which the inventor has contemplated the application of that principle?
    E. Ambiguous claims:
        i. Do claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 fail to define distinctly and in explicit terms the subject-matter of the alleged invention for which an exclusive privilege or property is claimed?
        ii. Are claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 directed to a desired result rather than to any invention directed to how to achieve that result?
    F. Overbroad claims:
        i. Are claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 broader than any invention made or disclosed in the ‘540 Patent?

II. Summary of Results

1. Preliminary issue:
    A. TearLab has standing.
2. Patent infringement and validity
    A. Infringement

i. The i-Pen infringes claims 1, 2, 5, 8, 13, 14, 16, 25 and 26 of the ‘540 Patent; it does not infringe claim 6.

B. Validity:

i. Anticipation:
   a) Claims 1, 2, 5, 8, 13 and 14 are anticipated.

ii. Obviousness:
   a) Claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 are obvious.

iii. Utility:
   a) Claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 demonstrate utility.

iv. Sufficiency:
   a) Claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 are sufficient.

v. Ambiguous claims:
   a) This issue was abandoned at trial.

vi. Overbroad claims:
   a) This issue was abandoned at trial.

III. Background

A. *The Parties*

[7] The University is the owner of the ‘540 Patent.

[8] TearLab is a sub-licensee under the ‘540 Patent. It is incorporated in Delaware and is based in California. TearLab manufactures diagnostic products for eye-care professionals. In particular, it manufactures the TearLab Osmolarity System (the “TearLab System”).

[9] I-MED is a Québec-based company that focuses on human and animal eye care. Among other things, it distributes medical devices, including importing and selling the i-Pen through a distributor in Canada.

B. *Technological Background*

(1) Scientific Primer

[10] The parties jointly prepared a scientific primer with respect to relevant technology and principles that they agree upon. The primer contains sections on osmolarity, eye and tear film anatomy, dry eye disease and principles of electricity.

[11] Osmolarity refers to the concentration of all dissolved particles, or solutes, in a solution. It can be estimated by the measurement of physical properties that are affected by solute concentration. In 2002, analyses used to estimate osmolarity included freezing point depression, boiling point elevation, vapour pressure depression, osmotic pressure and electrical impedance. The freezing point and vapour pressure of a solution decrease as osmolarity increases, whereas its boiling point increases. Osmotic pressure will differ between solutions that have different osmolarities and are separated by a semi-permeable membrane. Electrical impedance of a solution decreases as its osmolarity increases.

[12] The inner surfaces of the eye are composed of the cornea (the transparent window to our vision), the sclera (the white portion) and the inner sides of the eyelids. The conjunctiva, a mucous membrane, lines the sclera and eyelids. A layer of tear film also covers the inner surfaces of the eye and is composed of three layers. The inner mucin layer is a mixture of proteins that spreads the tear film and holds it to the ocular surface. The intermediate aqueous layer accounts for most of the volume of the tear film, keeps the eye moist, washes away debris and helps with oxygen supply to the cornea. It has a specific level of dissolved nutrients and

salts; fresh production by the lacrimal gland and drainage through nasal canals prevents increases in osmolarity that result from evaporation. The outer lipid layer helps spread the tear film and reduce evaporation of the aqueous layer. The primary solutes in tear fluid are ions; therefore, a conductance measurement of tear fluid is closely related to its osmolarity.

[13] Dry Eye Disease ("DED"), also known as keratoconjuctivitis sicca, is a disease of the tears and ocular surface that results in discomfort, visual disturbance and tear film instability, with potential damage to the ocular surface. There are two forms of DED, which both lead to a tear fluid with increased osmolarity: aqueous-deficient dry eye, which refers to reduced tear film secretion from the lacrimal gland; and evaporative dry eye, which refers to excessive evaporation of the tear film. In 2002, four main tools were used to diagnose DED in the clinical setting: (1) Schirmer's test, a correlation of tear volume with the length of wetting on paper or string; (2) tests of tear film stability, such as the time taken for tear film to break on the ocular surface; (3) ocular surface staining with dyes to assess ocular surface damage; and (4) patient symptoms. The link between tear osmolarity and DED was explored between the 1970s and 1990s; however, measurement of tear osmolarity at that time relied on freezing point and vapour pressure analyses, which were complicated, expensive or required large sample volumes. Those challenges restricted the use of osmolarity as a diagnostic tool in a clinical setting.

[14] Conductivity is an intrinsic property of a material that indicates how well it conducts electricity; the dimensions of the material do not affect conductivity. In contrast, conductance is a holistic property of a system that indicates how well it conducts electricity and is dependent on properties of the system such as mass, size, shape and components. Other relevant principles of

electricity include: resistivity (how well a material hinders current); resistance (how well a system hinders current); capacitance (the ability of a system to store an electric charge); reactance (a measure of the opposition of a circuit element in a given system to a change in current or voltage, due to that element's inductance or capacitance); and impedance (a measure of the opposition that a circuit presents to a current when a voltage is applied). Finally, Ohm's Law, which is V=IR, describes the relationship between voltage (V), current (I) and resistance (R). In a system with negligible capacitive and inductive effects, an impedance measurement can be treated as the resistance and Ohm's Law can be applied.

(2) The '540 Patent

[15] The '540 Patent discloses an invention related to measuring the osmolarity of a sample of a bodily fluid, including particularly tear film, whereby the sample fluid is deposited on a chip. The chip has a substrate and a sample region. The sample fluid is deposited such that it operatively covers the sample region, so that energy imparted to the sample fluid is detected from the sample region to produce an output signal that indicates osmolarity of the sample fluid. As described at page 4, lines 12 to 17 of the '540 Patent:

> Osmolarity measurement of a sample fluid, such as tear film, is achieved by depositing an aliquot volume of the sample fluid on a microchip having a substrate and a sample region of the substrate, wherein the volume of the sample fluid operatively covers a sufficient portion of the sample region such that energy imparted to the sample fluid is detected from the sample region to produce an output signal that indicates osmolarity of the sample fluid.

[16] The requisite volume of sample fluid can be as low as 1 nl, which can be easily obtained from patients.

[17] Energy transferred to the sample fluid can be electrical, optical or thermal. Electrodes can be installed on the substrate such that the sample fluid bridges the electrodes, and electrical energy passing through the electrodes measures conductivity and is correlated to osmolarity. Alternatively, nanometre-sized spheres can be coated with luminescent ion-sensitive chemicals and then exposed to a sample fluid and excited with light energy, such that the spheres luminesce and emitted light is correlated to osmolarity of the sample fluid. As a further alternative, continuously cooling the sample fluid results in reduced conductivity upon freezing, which allows for correlation of the determined freezing point with the osmolarity of the sample.

[18] The ‘540 Patent also discloses an osmolarity measuring system comprising a sample fluid reception device as well as a platform for data communication. The reception device can be as simple as a set of electrodes on a chip, or as complex as a logic-enabled microprocessor capable of enacting measurement dynamics, and may also be used to control and measure temperature. The platform for data communication receives output from the reception device and interprets and displays osmolarity to the user. In this way, an accurate osmolarity measurement can be obtained with minimum inconvenience, little skill and a high degree of repeatability. As described at page 7, lines 11 to 21 of the ‘540 Patent:

> Exemplary embodiments are described for measuring the osmolarity of an aliquot volume of a sample fluid (e.g., tear film, sweat, blood or other fluids). The exemplary embodiments are configured to be relatively fast, non-invasive, inexpensive, and easy to use, with minimal injury of risk to the patient. Accurate measurements can be provided with as little as nanolitre volumes of a sample fluid. For example, a measuring device configured in accordance with the invention enables osmolarity measurement with no more than 20µL of sample fluid, and typically much smaller volumes can be successfully measured. In one embodiment described further below, osmolarity measurement accuracy is not compromised by variations in the volume of sample fluid

> collected, so that osmolarity measurement is substantially independent of collected volume.

[19] The ‘540 Patent contains four independent claims, only two of which, claims 1 and 16, are being asserted by the Plaintiffs:

> Claim 1: a sample receiving chip comprising:
>
> > a substrate that receives an aliquot volume of a sample fluid; and
> >
> > a sample region of the substrate, sized such that the volume of the sample fluid is sufficient to operatively cover a portion of the sample region, whereupon energy properties of the sample fluid can be detected from the sample region to produce an electrical signal comprising a sample fluid reading, wherein the sample fluid reading is related to the sample fluid energy properties and indicates osmolarity of the sample fluid.
>
> Claim 16: an osmolarity measuring system for measuring osmolarity of a sample fluid, the system comprising:
>
> > a measurement device comprising a sample receiving chip that includes a substrate having a sample region configured to contact the sample fluid to produce an electrical signal that is related to energy properties of the sample fluid, wherein the region is sized to be substantially covered by an aliquot volume of the sample fluid; and
> >
> > a processing device coupled to the measurement device, the processing device configured to receive the measured energy properties and to process and estimate the osmolarity of the sample fluid from the processed energy properties.

[20] The following asserted claims are dependent on claim 1:

> Claim 2: a chip as defined in claim 1, wherein the sample region includes a plurality of electrodes disposed to contact the sample.
>
> Claim 5: a chip as defined in claim 2, further comprising a plurality of conductive connection lines coupled to the plurality of electrodes, wherein the conductive connection lines provide means for transferring energy to and from the sample fluid.

Claim 6: a chip as defined in claim 5, further comprising:

> a processing unit configured to receive energy properties of the sample fluid from the plurality of conductive connection lines, wherein the processing unit processes the received energy properties and outputs the osmolarity of the sample fluid.

Claim 8: a chip as defined in claim 1, wherein area of the sample region on the substrate is less than one centimeter square.

Claim 13: a chip as defined in claim 1, wherein the sample fluid includes bodily fluid.

Claim 14: a chip as defined in claim 13, wherein the bodily fluid is a tear film.

[21] The following asserted claims are dependent on claim 16:

Claim 25: a system as defined in claim 16, wherein the substrate includes an electrical conductivity measurement circuit.

Claim 26: a system as defined in claim 16, wherein the measurement device includes a plurality of electrodes.

(3) The i-Pen

[22] The i-Pen measures the conductivity of the moisture in the eyelid conjunctiva and tear film thereon, and that measurement can be correlated to osmolarity. The measurement is provided by a single use sensor ("SUS"), consisting of a pair of electrodes installed on a non-conducting substrate, which is placed against the moist tissue on the inner surface of an eyelid. When stimulated with electrical current, the moisture completes a circuit between the electrodes and its conductivity is measured by a microprocessor located within the i-Pen. A different SUS is inserted into the i-Pen for each measurement and disposed thereafter.

[23] The i-Pen was approved in Canada as a Class II Medical Device in January 2015; the license was suspended on September 23, 2015, and was reinstated on May 13, 2016.

IV. Plaintiffs' Fact Witnesses

A. *Mr. Paul Smith*

[24] Mr. Paul Smith ("Mr. Smith") is TearLab's Vice President of Global Sales. Previously, he was Vice President of International Markets. He joined TearLab in April, 2014, after working at another eye-care corporation for 12 years. He stated that TearLab has 75 employees, including 49 in his sales team.

[25] Mr. Smith briefly described the TearLab System. There is a reader base-station, handheld pen and single-use test card. The user attaches the card to the top of the pen and brings the pen in contact with the corner of the eye, at which point the card wicks-up and analyzes a 50 nl sample of tear film. The raw data is stored inside the pen, which is returned to the reader and an osmolarity measurement is reported.

[26] Mr. Smith stated that the TearLab System is primarily used by technicians under the supervision of eye care professionals. It obtained regulatory approval in Europe in 2008 and Canada and the United States in 2009. Sales in Canada began "in earnest" in 2012, but there may have been some sales prior to that year. Currently, the TearLab System is sold in over 50 countries. Since January 2016, TearLab has used an independent distributor in Canada named

Labtician Ophthalmics Inc. Worldwide sales total approximately 5,600 systems, of which 4,600 have been in the USA and 100 in Canada.

[27] Mr. Smith explained the corporate structure of TearLab. OcuSense Inc. ("OcuSense") was a corporation started by Dr. Ben Sullivan in 2008. OcuSense became a wholly-owned subsidiary of OccuLogix Inc. ("OccuLogix") in 2008. OccuLogix changed its name to TearLab Corp. in 2010. OcuSense has since changed its name to TearLab Inc. and then again to TearLab Research Inc. The result is that TearLab Research Inc. is a wholly owned subsidiary of TearLab Corp. Both corporations are incorporated in Delaware and based in California and Texas.

[28] Moreover, Mr. Smith explained that OcuSense, now TearLab Research Inc., obtained an exclusive license under the '540 Patent from the University in 2003. Currently, it makes quarterly royalty payments to the University. As well, TearLab Corp. currently holds an exclusive sub-license from TearLab Research Inc.

[29] Finally, Mr. Smith discussed a clinical study entitled "Randomized Comparison of In Vivo Performance of two Point-of-Care Tear Film Osmometers", which was published in Clinical Opthalmology, a well-known peer review journal, in May 2017 (the "Nolfi Study"). This study was sponsored by TearLab and was meant to compare the TearLab System and the i-Pen. The two authors are practicing optometrists in Toronto: Dr. Barbara Caffery ("Dr. Caffery") is president of the American Academy of Optometry; Dr. Jerry Nolfi ("Dr. Nolfi") was previously a consultant on TearLab's clinical advisory board and was the principal in a company called Science with Vision Inc., which distributed the TearLab System in the Canadian market

for a period of approximately 12-18 months. Dr. Nolfi also owned shares in TearLab at the time the study protocol was developed.

[30] Mr. Smith was cross-examined with respect to the Nolfi Study. He explained that Dr. Manoj Venkiteshwar, from TearLab's Medical Affairs Department, collaborated with the authors to develop the study protocol. That protocol was under a TearLab letterhead and signed by Dr. Nolfi but not Dr. Caffery. He was not aware of any existing drafts or how the authors provided comments. Mr. Michael Berg, TearLab's head of regulatory affairs, was not involved in the study except with respect to TearLab's quality control procedures, which were not specific to the study and which every TearLab customer must adhere to. TearLab was not present during the measurements and does not know who performed them. Since Clinical Ophthalmology is an open-access journal, TearLab paid a fee for the study to be published.

[31] Mr. Smith was a credible witness.

B. *Dr. Ben Sullivan*

[32] Dr. Ben Sullivan ("Dr. Sullivan") is the Chief Scientific Officer of TearLab. He studied biomedical engineering at Boston University from 1993-97. After graduation, he worked from 1998-2001 as a research engineer at the Schepens Eye Research Institute, an affiliate of Harvard Medical School. In 2001, he left Schepens and enrolled in the Ph.D. program at the University of California, San Diego, researched DNA and its interactions with fluorescence at the nanoscale level, and obtained a Ph.D. in 2007.

[33] It was during his time at Schepens that Dr. Sullivan became interested in DED. He worked alongside his father, who was researching the hormonal and glandular aspects of DED. Dr. Sullivan recognized the need for a tool to quantitatively measure DED and in particular, a tear osmometer. He began working at home by himself on the development of a tear osmometer.

[34] Dr. Sullivan continued to work on the osmometer concept while working on his Ph.D. He studied under a professor who had access to "lab on a chip" devices used to study DNA. These microchips allowed Dr. Sullivan to more easily perform experiments using tear film and modified electrical signals. His lab set-up was complex and included a microchip, power source, multimeter, computer, LCR meter and other equipment. His goal was to make a portable and inexpensive tear osmometer, given that, in his opinion, while non-commercially viable tear osmometers already existed, they were not clinically available or cost-effective and efficient.

[35] This work lead to the filing of a provisional patent application in August, 2002, which Dr. Sullivan assigned to the University. A breakthrough came in late 2002, when he discovered that using a 100 kHz AC signal (instead of DC) allowed for stable measurements. He was approached by an investor, Mr. Eric Donsky, and OcuSense was incorporated in January, 2003. Later that year, a license was negotiated with the University and marketing materials and a protocol for clinical trials were created.

[36] Clinical trials were performed at the Shiley Eye Research Institute at the University during several months in 2004. In the years following the clinical trials, Dr. Sullivan developed his osmometer down to the size of a lunch tray and OcuSense sought investors. Eventually, the

company was purchased by OccuLogix and better equipment was used for product development. Regulatory approval was obtained in Canada, USA and the EU around 2009.

[37] On cross-examination, Dr. Sullivan admitted that in 2001-02, “small volume” could mean 100-200 nl, but that the term is relative. The current TearLab System collects approximately 50 nl. That sample volume is pulled into a channel by capillary action and thereby spread over 3 mm. Regarding the device Dr. Sullivan was working on during the 2001-02 timeframe, a 100-200 nl sample completed an electrical circuit by bridging at least two electrodes on a silicon chip. The electrodes were spaced 40-80 microns apart.

[38] Dr. Sullivan agreed that impedance is affected by the geometry of the fluid and that the electrodes, substrate and sample volume affect the geometry of the fluid. Generally, a sensor placed in tear fluid would produce a different reading from that produced by a drop of fluid on a substrate containing electrodes. He also stated that at a certain scale, impedance becomes relatively volume independent.

[39] Dr. Sullivan also agreed that in 2001-02, his idea was to develop a small-scale, cost effective impedance osmometer suitable for in-clinic use on a commercial scale. The patent refers to a need for a “clinically feasible nanolitre scale osmolarity measurement”. It took approximately ten years of research and development and millions of dollars of investment to eventually achieve a clinically feasible system.

[40] Dr. Sullivan explained that the ‘540 Patent’s statement regarding an existing *in vivo* method of measuring osmolarity directly on the ocular surface, refers to the Ogasawara Paper and its description of a pair of electrodes placed directly underneath the eyelid of a patient. He stated that placing electrodes on a flexible substrate, without compensating for the geometry of the tear fluid being measured, would cause osmolarity measurements to suffer from lack of precision. He explained that the current TearLab System extracts a sample of fluid from the eye using capillary action, once it is brought into contact with the eye, and deposits the sample on a microchip having a substrate and sample region such that that electrical energy imparted to the tear fluid produces an output signal that is used to provide an osmolarity reading.

[41] Dr. Sullivan was also asked about an OcuSense marketing document from 2003, which was co-authored by him and Mr. Eric Donsky. That document referred to OcuSense’s unique “lab on a chip” technology, including a chip, sample region, leads, a base unit, and the collection and placement of sample fluid. It mentioned that a nanolitre of tear will evaporate in just a few seconds. It also contained inaccurate statements, despite being directed at investors. For example, it described “electrodes that are hundreds of times smaller than the sharpest sewing needle”, as well as the “critical feature” of a neural network and ability to dynamically monitor sample behaviour, neither of which was ever implemented.

[42] Dr. Sullivan commented on the York Patent. He referred to it as a “foolish” patent, because there was no way of restricting circuit paths; however, he agreed that there would be current flow inside conjunctival tissue as well as tear film on the surface of the eyeball.

[43] Dr. Sullivan discussed the clinical trials that occurred in 2004. The trial log referred to the extraction of tears by a doctor using a capillary tube, the doctor delivering the sample to him in a different room, him depositing the sample fluid onto the substrate of a chip, the sample fluid bridging the electrodes on the chip and the production of an osmolarity reading. He admitted there was a problem with fluid sucking back into the capillary tube when it was being deposited on a chip. He also admitted the size of the electrode area was suboptimal. Furthermore, at that time he did not appreciate the depth to which temperature affected impedance. An improvement patent was filed was filed in 2006 as US Patent No. 7,111,502, which made narrow claims covering software addressing corruptive signals that were present during the clinical trials.

[44] Finally, Dr. Sullivan discussed a TearLab marketing document from 2010, which he designed when he was the company's Chief Scientific Officer. It was designed to look like a scientific journal article and handed out at conference attended by ophthalmologists and optometrists, who may have purchased the device after TearLab obtained regulatory approval. Dr. Sullivan referred to this as a "white paper" and said this practice was not uncommon.

[45] While there is no question that Dr. Sullivan was a credible witness concerning the development of the '540 Patent's invention, his credibility was weakened by his admissions of making inaccurate and exaggerated claims in his marketing publications.

V. Plaintiffs' Expert Witnesses

A. *Dr. James Wolffsohn*

[46] Dr. James Wolffsohn ("Dr. Wolffsohn") is the Associate Pro Vice Chancellor of the School of Life and Health Sciences and a Professor of Optometry at Aston University in Birmingham, UK, as well as adjunct professor at the University of Houston, College of Optometry. He obtained a Ph.D. in optometry and vision sciences in 1997 and received a clinical post-graduate diploma in advanced clinical optometry in 1999. He was also a committee member on the 2017 Tear Film and Ocular Surface Society ("TFOS") Dry Eye Workshop ("DEWS"), a global workshop concerning aspects of DED, and co-author of a seminal DEWS report. Dr. Wolffshon has extensive clinical practice with DED patients.

[47] Dr. Wolffshon is an expert in the physiology of the eye, clinical optometry and eye care and ophthalmic instrumentation. He is also an expert in the field of DED.

[48] Dr. Wolffsohn outlined the chronological development of the understanding of osmolarity as a biomarker for DED. Osmolarity was understood as a potential biomarker in 1995; however, it was not used in clinical practice. In his opinion, the situation remained the same in 2002. Freezing-point depression analyzers (the Clifton osmometer, the Fiske 110 osmometer and the Osmomat 030) were the primary technology for measuring tear osmolarity but were expensive, difficult to operate and only a few research facilities could access that technology. A trilogy of articles was published in the mid-1990s by Mitsubayashi and Ogasawra that discussed the use of electrodes to measure the conductance of tear film, which resulted in

osmolarity measurement, but that technology was not developed to the point of commercialization. Those articles were not cited until 2006, but were published in a reputable journal. Other known methods of diagnosing DED in 2002 included tear staining, Rose Bengal staining and Schirmer's test (to measure tear volume).

[49] On cross-examination, Dr. Wolffsohn was asked about his connections with TearLab. He is named in an international patent application that refers to a paper coauthored by him and Dr. Sullivan, among others, which mentioned that he received support from TearLab; TearLab provided their product for use in the research. As well, Dr. Wolffsohn is the principal investigator in an ongoing study in which TearLab set up clinical sites but did not provide funding. Furthermore, Dr. Sullivan was part of a committee that Dr. Wolffsohn was chairing, and he has worked on reports with both Dr. Sullivan and Dr. Sullivan's father, Dr. David Sullivan, who is the founder and chairman of the board of directors of TFOS; Dr. David Sullivan's wife and daughter are also involved with TFOS.

[50] Dr. Wolffsohn was shown an inconsistency between two of his reports. In his validity report, he referred to TearLab's osmolarity technology as the gold standard for DED diagnosis in 2007. However, he wrote in a 2017 journal publication, "[n]o single 'gold standard' sign or symptom that correlates perfectly with the DED state has been established." He explained that the statement in his validity report does not refer to the element of correlation between symptoms and DED, which he was discussing in the 2017 journal publication.

[51] While Dr. Wolffsohn was generally credible, his testimony did little to help deal with claim construction or the validity and infringement issues before the court.

B. *Dr. Brian Kirby*

[52] Dr. Brian Kirby ("Dr. Kirby") is a Professor at the Sibley School of Mechanical and Aerospace Engineering at Cornell University in Ithaca, New York, and Professor of Engineering and Medicine in the Department of Medicine, Division of Hematology/Oncology at Weill-Cornell Medicine College in New York, New York.

[53] He is an expert in electrical and medical engineering, bioengineering and analytical chemistry. He is also an expert in the field of microfluidics, which involves the development of micro-technology, including microchips, to manipulate and analyze small quantities of fluids, including DNA and other biological materials. Microfluidics is not well-defined. It could involve devices having fluids in micron-sized channels. It could also involve the placement of a fluid on the outer portion of a microchip.

[54] Dr. Kirby submitted two expert reports and provided testimony on issues directly related to infringement and validity of the '540 Patent. Portions of his submissions are provided throughout these reasons where they are relevant to the Court's analysis.

VI. Defendant's Fact Witnesses

A. *Mr. Daniel Hofmann*

[55] Mr. Daniel Hofmann ("Mr. Hofmann") is currently the President of I-MED. He has a Bachelor of Science in biochemistry and a certificate in human resources from McGill University, and a Master in Business Administration from the University of Montreal.

[56] Mr. Hofmann stated that I-MED was incorporated in Quebec in 1989. It has 20 full-time employees and one consultant. It was started by Mr. Hofmann's father, Dr. Ilan Hofmann. Generally speaking, I-MED sells medical equipment to eyecare professionals around the world, in both human and veterinary fields.

[57] Mr. Hofmann discussed I-MED's awareness of different methods of diagnosing DED prior to the i-Pen. Eyecare professionals relied on patient questionnaires, staining tests, volume tests (Schirmer's test) and osmolarity tests. Those tests had a low correlation to DED and were time consuming and expensive.

[58] Mr. Hofmann explained how the i-Pen was developed. Mr. Zvi Nachum ("Mr. Nachum") was introduced to I-MED in 2011. Mr. Nachum had a company called Life Care Ltd. and a prototype that consisted of a metal box, two leads, and an electrode attached to each lead, which he claimed could measure moisture in ocular tissue. Mr. Nachum used this device to measure moisture in the mouth, but was not an eye expert. In 2011 to 2012, I-MED guided Mr. Nachum and invested in his further research. Mr. Nachum eventually developed the prototype into a

device similar to the current i-Pen. I-MED did extensive testing on the device to confirm its functionality. The i-Pen's appearance was improved and a microchip was added to the SUS that contains a serial number, which the i-Pen stores to prevent a second use of that SUS. A patent application for the device was filed in 2012 by Mr. Nachum, but I-MED had no involvement with the patent filing or prosecution.

[59] Mr. Hofmann then demonstrated use of the i-Pen in accordance with the user manual, with counsel for I-MED acting as a patient. The patient closes their eyes for 30-60 seconds. Upon opening, the technician inverts the lower eyelid to expose the palpebral conjunctiva, approaches with the i-Pen at a 30-45 degree angle, allows the electrodes on the SUS to have good contact with the conjunctiva for up to four seconds, and then a resulting osmolarity reading is given.

[60] Mr. Hofmann explained that Life Care Ltd. manufactures the i-Pen and SUS in Israel. I-MED orders them from Life Care Ltd. and imports them into and sells them in Canada. Life Care Ltd. subcontracts the manufacturing of the i-Pen to a company named Medimor Ltd.

[61] On cross-examination, Mr. Hofmann stated there had been no change in the concept of the i-Pen since 2011, but some changes to the algorithm (the source code in the i-Pen software) were made between prototype 1 and 2, and then prototypes 2 and 3. The first commercially launched version was version 6 and the algorithm in the commercial device has never been changed.

[62] Mr. Hofmann believed that I-MED had never done experiments using the i-Pen on dry tissue. As well, his understanding is that all experiments using a solution only were done with an adaptor. His father did experiments involving solutions on dry wipes; he assumed this was done with a commercial i-Pen and adaptor but was not sure. He agreed that Mr. Nachum had done experiments that involved swabbing the lower eyelid and spraying it with a known solution, for the purpose of determining the accuracy of the i-Pen.

[63] Mr. Hofmann explained that the lower tear meniscus is located at the junction between the cornea and the conjunctive tissue, and a well of tear fluid sits in that junction. The i-Pen is not placed on the lower tear meniscus but it is placed on the palpebral conjunctiva.

[64] Mr. Hofmann stated that Dr. Richard Maharaj is a consultant of I-MED and sits on their medical advisory board. He has done post-market surveillance studies on the i-Pen. As well, Dr. Maharaj has worked for a publication sponsored by I-MED. I-MED provides a grant and topics they want discussed in the publication, but the publication decides which doctors to contact, which questions to ask, writes the draft and has final say on the editing. In one paper, Dr. Maharaj refers to the SUS as a “chip”.

[65] Mr. Hofmann admitted on cross-examination that a scale in the i-Pen user manual was similar to a scale in the TearLab Utility Guide. The scale helps eye care professionals compare osmolarity readings to severity of DED. The two scales are nearly identical, but the i-Pen scale has a slightly broader range.

[66] Mr. Hofmann agreed his father had sent him an email regarding experiments in 2015 that produced differing results between the i-Pen and the TearLab System. It was important to correlate readings of the devices because they would likely be compared in the market. The email stated, "[t]here is a difference and we can solve this difference by one of two means." The two options were to change the algorithm in the i-Pen or to shift the scales. In the end, I-MED created its own ranges. Mr. Hofmann thought it was theoretically possible to adjust the algorithm in the i-Pen to create a new calibration curve, but he did not know details of software programming and did not think this had been done.

[67] Mr. Hofmann explained that clarifications to the i-Pen user manual were brought to his attention due to this litigation but were not made for the purpose of the litigation. The January 2016 user manual states, "…a tear fluid collection and testing device for the quantitative measurement of osmolarity (concentration of dissolved, active particles in solution) of human tears." The March 2016 version states, "…a device for the quantitative measurement of osmolarity concentration of dissolved active particles in tissue immersed in solution of human tears…" As well, a change was made from "…provide a direct assessment of the osmolarity of the tissues surrounding the eye…" to "…provide an assessment of osmolarity of the conjunctival tissues surrounding the eye."

[68] Mr. Hofmann agreed none of the previous user manuals contained the phrase "conjunctival tissue", although each manual mentions the device touching the inner eyelid. As well, there was no significance difference between "tissues surrounding the eye" and "conjunctival tissues surrounding the eye". Furthermore, "active particles in solution" referred to

solutes that conduct electricity, specifically in the extracellular fluid of the conjunctival tissue, and it was not necessary to add “tissue immersed in solution” because it meant the same thing.

[69] Mr. Hofmann referred to an April 2007 email from his father to Mr. Nachum correcting a test report that erroneously said the i-Pen collected nanolitre quantities of tears. However, Mr. Hofmann admitted that a 2012 draft protocol for an i-Pen clinical study stated that the impedance that will be measured is the impedance of tears.

[70] Mr. Hofmann was a credible witness.

B. *Mr. Zvi Nachum*

[71] Mr. Nachum is from Israel. He spent five years in engineering school and then was enlisted in an elite group of the Israeli Defence Force (“IDF”). His role in the IDF was to oversee the ordering of products from high tech companies, and to train and educate people on them within the framework of the military. After leaving the military, he became involved in the private sector, specifically in the field of medical diagnostic and treatment tools. He has brought approximately 15 products to market. Mr. Nachum stated Life Care Ltd., which has been in existence for over 20 years and deals exclusively in the field of medicine.

[72] Prior to developing the i-Pen device, Mr. Nachum was contacted by a company who wanted an instrument to monitor the health of saliva glands. He developed a device that produced a steady voltage that was sent through two electrodes, which were placed inside the lip

of the mouth, and then into a device that measured impedance. Mr. Nachum patented his device but nothing more was done with it.

[73] A few years later, Mr. Nachum was introduced to Dr. Ilam Hofmann, who wanted him to create a device that could determine the degree of dryness in the tissue of the eyelid. Mr. Nachum developed a prototype; that device was tried on family and soldiers and a range of osmolarity readings was developed. Six prototypes were eventually built, with improvements made on size and accuracy. The fifth prototype involved a disposable SUS, with a serial number contained in a microchip; this was for the purpose of regulatory approval; such that the SUS could only be used once, to prevent the spread of disease from one patient to another. The sixth prototype made the SUS more visually appealing.

[74] Mr. Nachum explained that the Ogasawara Paper aided him in the development of the i-Pen. In particular, he learned that the quantity of salt is connected to impedance and dryness in the eye. As well, the Ogasawara researchers did not touch the tissues of the eye; an exact quantity of fluid collected into a material between the electrodes and the impedance of that fluid was measured. Mr. Nachum also relied on research done by Dr. Alan Tomlinson, which provided a range of osmolarity readings in subjects.

[75] Mr. Nachum explained that the i-Pen has a CPU microcontroller that produces a square wave, which is stabilized at a low voltage and converted into a sinusoidal wave with a constant source current. The current travels through the SUS into the tissues of the eyelid, and the information that comes out goes into a RMS converter that produces a steady voltage in

accordance with the impedance of the eye. It then goes into an analog-to-digital converter. As well, the microcontroller withdraws some of the information to produce more accurate results. The final result is displayed on an LCD screen as an osmolarity reading.

[76] Mr. Nachum was asked if he performed any experiments on measuring impedance of a solution without an adaptor. He agreed the experiments were conducted, but did not recall having any documentation or data. He explained that a solution of known osmolarity could be displayed in the i-Pen, despite being out of its range, through the use of a variable potentiometer (resistor). Such a resistor could be developed into an adapter for the i-Pen and calibrated in advance for a solution of known osmolarity.

[77] On cross examination, Mr. Nachum was asked about an experiment in which the i-Pen was compared to a freezing point osmometer. He was present for some of the experiment, but it was done by others. He stated that the results were incorrect, because the method was not appropriate for the i-Pen. In his opinion, it was impractical and virtually impossible to perform. He could not recall if the subject's eyelid was swabbed dry. Solutions were not placed on the eyelid. The i-Pen produced results, but he stated the results were unreliable. Improvements were made, but he stated that nothing was done with the report.

[78] Mr. Nachum was generally a credible witness, but his evasive answers to questions regarding experimentation on measuring impedance of a solution without an adaptor were not helpful to the Court, and undermined the weight to be given to his testimony.

VII. Defendant's Expert Witnesses

A. *Dr. Manfred Franke*

[79] Dr. Manfred Franke ("Dr. Franke") has a Diploma (the German equivalent of a Bachelors and Masters) in Electrical Engineering from the Dresden University of Technology and a Ph.D. in Biomedical Engineering from Case Western Reserve University. In 2014, he began working at a company called Oculeve Inc. that developed the ability to stimulate facial nerves to produce tears. His work at Oculeve Inc. involved researching DED as well as devices used to measure its signs and symptoms.

[80] He is an expert in electrical and biomedical engineering, including the use of electricity to measure or alter bodily functions such as tear production. He is also an expert in the detection and treatment of DED; however, his work in this field began in 2014.

[81] Dr. Franke submitted two expert reports and provided testimony on issues directly related to infringement and validity of the '540 Patent. Portions of his submissions are provided throughout these reasons where they are relevant to the Court's analysis.

[82] While his scientific expertise is not an issue, his admission that he had not been instructed on how to construe claims or read a Canadian patent through the eyes of a POSITA using a purposive construction weakens the weight to be given to his opinion on construction of terms used in the disclosure and claims of the '540 Patent.

VIII. Preliminary Issues

A. *TearLab's Standing*

[83] On the eve of trial the Plaintiffs sought an amendment to the statement of claim, to add a sublicense agreement between Tearlab Corp. and Tearlab Research Inc., which was opposed by the Defendant but which I allowed, with the stipulation that any added costs necessitated by this last minute amendment would be awarded to the Defendant in any event of the cause.

[84] I also agreed with the Plaintiffs that Tearlab Corp., as a sublicense under the '540 Patent, has standing to claim remedies under subsection 55(1) of the *Patent Act,* RSC 1985, c P-4 [*Patent Act*] as a person deriving rights to use the patented invention in Canada (*Signalisation de Montréal Inc v Services de Béton Universels Ltée et al,* [1993] 1 FC 341 (FCA); *Apotex Inc v Wellcome Foundation Ltd*, [2001] 1 FC 495 (FCA) at paras 98-99, aff'd 2002 SCC 77 [*Wellcome Foundation*]; and *Eli Lilly & Co v Novopharm Ltd*, [1998] 2 SCR 129 at para 49).

IX. Claim Construction

A. *Principles*

[85] Construction is a question of law for the Court and should be done before considering infringement or validity; the same issues of construction apply for both validity and infringement. The Supreme Court of Canada determined the canons of claim construction in a trilogy of cases: *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paras 49-55; *Free World Trust v*

Électro Santé Inc, 2000 SCC 66 [*Free World Trust*] at paras 44-54; and *Consolboard Inc v MacMillan Bloedel (Saskatchewan) Ltd*, [1981] 1 SCR 504 at paragraph 27.

[86] Those decisions state that:

a) claims are to be read in an informed and purposive way, with a mind willing to understand and viewed through the eyes of a POSITA, as of the date of publication, having regard to the common general knowledge;
b) adherence to the language of the claims allows them to be read in the manner in which the inventor is presumed to have intended, and in a way that is sympathetic to accomplishing the inventor's purpose, which promotes both fairness and predictability; and
c) the whole of the specification should be considered, in order to ascertain the nature of the invention, and the construction of the claims must be neither benevolent nor harsh, but instead should be reasonable and fair to both the patentee and the public.

[87] While experts may aid the Court in construing terms or elements of the claims, that assistance is only necessary when the Court deems it helpful or useful to do so – if the meaning of terms is evident from the patent specification, the Court does not need the advice of experts.

B. *Relevant Dates*

[88] International patent application No. PCT/US2003/009553 (the "PCT Application") was filed March 25, 2003, and laid open to public inspection on February 26, 2004. It claimed priority to US Provisional Patent Application No. 60/401,432, which was filed on August 6, 2002. The PCT Application entered the national phase in Canada on February 1, 2005, as Canadian Patent Application No. 2,494,540.

[89] The relevant date for construing the claims of the '540 Patent is the date of publication: February 26, 2004.

[90] The relevant date for assessing sufficiency of disclosure and utility is the filing date: March 25, 2003.

[91] The relevant date for assessing anticipation and obviousness is the claim date, which is the priority date of August 6, 2002.

C. *The Person of Ordinary Skill in the Art*

[92] Dr. Kirby opined that a Person of Ordinary Skill in the Art ("POSITA") to which the '540 Patent is directed is a researcher from one of the following disciplines: analytical chemistry, mechanical engineering, chemical engineering, electrical engineering or any other closely related discipline. As well, that individual would likely have to conduct further research into relatively unrelated disciplines. A POSITA could be an engineer who spoke with an optometrist to learn about DED and tools for its diagnosis, but an optometrist would lack the requisite expertise to design or build a micro-device. His view was that a POSITA would likely come from the microfluidics community, which involves the development of micro-technology, including microchips, to manipulate and analyze small quantities of fluids.

[93] While I disagree that the POSITA would likely come from the microfluidics community, the need for understanding measurement of microfluidics is a factor for the POSITA to understand in this field of technology.

[94] Dr. Franke opined that a POSITA is a medical scientist or medical engineer who has the intent to measure osmolarity for clinical research purposes. Such a person may be a clinician in

need of a clinical means to determine DED quickly and reliably, or a researcher looking to diagnose and treat DED. His view was that a POSITA would typically have a degree in engineering, medicine, or a related field, coupled with two or more years of relevant experience. A POSITA would understand enough about osmolarity and tear film to be able to assess if the measurement they collect is correct and to be able to apply the device clinically. Biomedical engineering generally requires a person to understand the technical as well as the clinical aspects, in order for an invention to be useful in a clinical setting.

[95] I agree with Dr. Franke's criteria used for the POSITA's understanding of the pertinent technology at the relevant dates; however, I also agree with Dr. Kirby's view that a POSITA would likely have to conduct further research into relatively unrelated disciplines, including use of microchip technology for measuring micro- and nano-volumes of fluids.

D. *Common General Knowledge*

(1) Principles

[96] Common general knowledge ("CGK") is the knowledge generally known by the POSITA at the claim date when considering anticipation or obviousness, or the publication date of the patent when construing the patent's claims.

[97] What comprises CGK has been articulated by this court in *Eli Lilly & Co v Apotex Inc*, 2009 FC 991 [*Eli Lilly*] at paragraph 97, aff'd in 2010 FCA 240 (adopted from *General Tire &*

Rubber Co v Firestone Tyre & Rubber Co, [1972] RPC 457, [1971] FSR 417 (UKCA) at 482-483):

> 1) Common general knowledge is distinct from what in patent law is regarded as public knowledge. Public knowledge is theoretical and includes each and every patent specification published, however unlikely to be looked at and in whatever language it is written. Common general knowledge, in contrast, is derived from a common sense approach to the question of what would be known, in fact, to an appropriately skilled person that could be found in real life, who is good at his or her job.
>
> 2) Common general knowledge will include patent specifications that are well known amongst those versed in the art. In particular industries, the evidence may show that all patent specifications form part of the relevant knowledge.
>
> 3) Common general knowledge does not necessarily include scientific papers, no matter how wide the circulation of the relevant journal or how widely read the paper. A disclosure in a scientific paper only becomes common general knowledge when it is generally known and accepted without question by the bulk of those engaged in the particular art.
>
> 4) Common general knowledge does not include what has only been written about and never, in fact, been used in a particular art.

[98] With regard to how to prove what comprises CGK, this Court in *Eli Lilly* at paragraph 100, quoted Simon Thorley et al, *Terrell on the Law of Patents*, 16th ed (London: Sweet & Maxwell, 2006):

> Proof of common knowledge is given by witnesses competent to speak upon the matter, who, to supplement their own recollections, may refer to standard works upon the subject which were published at the time and which were known to them. In order to establish whether something is common general knowledge, the first and most important step is to look at the sources from where the skilled addressee could acquire his information.
>
> The publication at or before the relevant date of other documents such as patent specifications may be to some extent prima facie evidence tending to show that the statements contained in them

> were part of the common knowledge, but is far from complete proof, as the statements may well have been discredited or forgotten or merely ignored. Evidence may, however, be given to prove that such statements did become part of the common knowledge.

[99] As per the scientific primer discussed above, by 2002 several analyses were being used to estimate osmolarity and therefore form part of the CGK: freezing point depression; boiling point elevation; vapour pressure depression; osmotic pressure and electrical impedance. Dr. Franke and Dr. Kirby both agreed that the construction and use of a calibration curve to correlate properties such as impedance and osmolarity, was CGK. As well, they agreed that the use of alternating current, rather than direct current, to avoid electrode polarization issues when measuring impedance, was known.

[100] The link between tear osmolarity and DED was also known by 2002 and forms part of the CGK. However, measurement of tear osmolarity at that time primarily relied on freezing point and vapour pressure analyses, which were complicated, expensive or required large sample volumes. Those challenges restricted the use of osmolarity as a diagnostic tool for DED in a clinical setting. Nevertheless, the Ogasawara Paper and preceding Mistubayashi Papers disclosed a means for measuring tear osmolarity *in vivo*, by measuring electrolyte conductivity in tear fluid in patients with DED, and are relevant prior art.

[101] Dr. Franke opined that scientists or engineers working in the field of tear fluid osmolarity in 2002-2004 would have consulted publications in the fields of ophthalmology, optometry and engineering, including scientific papers, abstracts, patents, newsletters, publications by companies and websites. They would have also attended and consulted materials from

conferences in these fields and would have access to online tools such as PubMed, Google and patent databases.

[102] Dr. Kirby stated that microfluidics was a nascent field in 2002-2004 and there were limited sources of written material such as textbooks. A POSITA would likely gain knowledge by attending conferences where he or she would have read papers, attended presentations, viewed photographs and had discussions with colleagues.

[103] Dr. Kirby also opined that patents would not form part of the CGK because they were not peer-reviewed by academics, were from the world of industry rather than academia, and their usefulness was speculative. A review of textbooks or academic articles from that time shows that patents were rarely if ever cited as a reference. I disagree with Dr. Kirby's limited approach to relevant prior art.

[104] I agree with both experts that academic papers form part of the CGK, and I agree with Dr. Franke that patents in the field of measuring conductance of bodily fluids, also form part of the CGK, to the extent these references are not obscure paper references with little or no availability to the POSITA at the relevant dates. Despite Dr. Kirby's opinion that patents do not form part of the CGK, he admitted he had consulted patent databases to locate prior art for the '540 Patent. He also admitted that he had reviewed them in the course of his own research and cited a patent in a book chapter that he co-authored.

[105] Several patents and academic papers, some of which I find form part of the CGK and all of which are relevant prior art, are discussed below. They include the use of electrical conductance measurements for both *ex vivo* analysis of bodily fluids, as well as *in vivo* analysis of tear film osmolarity.

(2) Prior Art

(a) *The Josefsen Patent*

[106] US Patent No. 4,123,701 (the "Josefsen Patent"), dated October 31, 1978, discloses several embodiments of a disposable sample card for testing bodily fluids and, in particular, various parameters of blood such as hematocrit. Also disclosed is an instrument for receiving the sample cards. The invention relates to the study of bodily fluid samples by evaluation of their electrical properties.

[107] The disposable, generally planar, sample card contains a chamber, or well, and supports two insulated electrodes that terminate in the region of the well. Various electrode configurations are disclosed. The sample card is made of non-conductive material, such as plastic. The well is sized to accommodate approximately one drop of blood; a well volume on the order of 50 μl is contemplated.

[108] The sample card is placed in the associated instrument such that its electrode leads come into contact with a circuit connector device. An electric current is sent through the test sample

and impedance is measured using conventional electronics. The measured impedance is related to conductance or other characteristics under study.

(b) *The Hill Patent*

[109] US Patent No. 4,301,412 (the "Hill Patent"), dated November 17, 1981, discloses a system for measuring conductivity of bodily fluids, in general, and for automatically measuring hematocrit and giving an approximation of hemoglobin, in particular. The invention is directed to filling the need for a simplified, safe and accurate electrical evaluation of liquid samples. It comprises a hand-held instrument and disposable sample card.

[110] The sample card is used for the one-time conveyance and application of a liquid sample, such as whole blood, to the instrument. It is a micro-volume conductivity cell (typically 200 µl), precision molded from plastic, with built-in stainless-steel electrodes. It comprises a planar base portion on which is defined a capillary tube. Electrodes are disposed within the capillary tube in a spaced relationship and define a volume within the tube. This volume constitutes the conductivity cell. Each of the electrodes is electrically connected to a conductive pad that provides a means for associating the blood sample with the electronics contained in the instrument to make a conductivity measurement of the sample.

[111] The instrument is a hand-held, battery-operated device. It comprises an electronic portion for processing data obtained from the liquid sample, a front-end mechanism for positioning the sample card within the instrument, and a digital display for displaying the results of a parameter measurement made in the instrument. The sample card is held in intimate contact with the front-

end mechanism such that the blood sample assumes its temperature, and data relating to the temperature of the base portion is presented to the electronic portion for processing. As well, the electronic portion is connected to the sample card such that the application of a current across the blood sample produces a measurement of its conductivity. The electronics in the instrument then compute a hematocrit measurement and display it on the digital display.

(c) *The Fouke Paper*

[112] JM Fouke et al, "Sensor for Measuring Surface Fluid Conductivity In Vivo" (1988) 35:10 IEEE Trans Biomed Eng 877 (the "Fouke Paper"), describes a micro-fabricated, miniature and flexible sensor that can be placed directly onto the surface of the trachea to measure the electrical conductance of the fluids present, which indicates the osmolarity of those fluids.

[113] The sensor consists of two elements: one for measuring fluid electrical conductivity and one for measuring temperature. The temperature sensor, a temperature-sensitive resistor, is used to account for the effect of temperature on fluid conductivity. The conductivity sensor consists of two gold electrodes that have been deposited on a polyimide substrate. The electrodes are separated by a 5 μm gap, which fills with fluid when the sensor is in contact with the trachea. As well, the electrodes are interdigitated to increase the effective gap length to 25.7 mm without increasing the size of the sensor.

[114] A 0.1 mA, 60 kHz AC signal is passed between the electrodes and the resulting voltage across the electrodes is related to the conductivity of the solution in which they are immersed. That voltage is measured and the fluid impedance value is displayed, which can then be

compared to a calibration curve obtained by measuring the impedance of solutions with known osmolarity values.

[115] The device was used *in vivo* by placing the sensor in the airway of mongrel dogs. Simultaneously, surface fluid from the airway was collected for comparison using atomic absorption spectroscopy and freezing point depression analysis.

(d) *The Davis Patent*

[116] US Patent No. 4,951,683 (the "Davis Patent"), dated August 28, 1990, discloses several embodiments of an *in vivo* tear osmometer, each of which involve a probe with a body that has an end portion. The body may be made of any rigid or semi-rigid material, and is shown in one depiction as a non-conducting material such as plastic.

[117] In one embodiment, a plurality of electrodes is mounted on the end portion of the body. The electrical contacts are meant to simultaneously contact the tear fluid of the ocular conjunctiva. An electrical potential is applied to at least one of the contacts and electrical activity between the contacts, such as conductance, is measured. In another embodiment, the end portion includes a solid, liquid or polymeric membrane that forms a chamber within the probe body. That membrane may be porous or reactive to ions found in the tear fluid.

[118] The Davis Patent also discloses means for measuring electrical activity between the electrical contacts. A 0.1-10 V DC power supply is suggested for providing electrical potential to the electrodes. That potential may be pulsed, e.g., 50-1000 Hz, or the electrical potential may be

switched among the electrical contacts, to avoid electrode polarization problems. The electrical activity measured (e.g., resistance, conductance, capacitance or potential) may be translated into a measurement of tear film osmolarity. Where the end portion of the probe includes a membrane that is reactive to a specific ion, the ion activity of interest may be measured against an internal reference by an outside meter.

(e) *The York Patent*

[119] US Patent No. 4,996,993 (the "York Patent"), dated March 5, 1991, discloses a device for the *in vivo* measurement of the osmolarity of a bodily fluid, such as tears or sweat. The device comprises a probe with two electrodes, as well as the means for measuring conductivity between those electrodes.

[120] The tips of the electrodes are either separated by an air gap or linked by a fine strip of absorbent material that is non-conducting until wet with bodily fluid. In either case, the tips of the electrodes make contact with the bodily fluid *in vivo* to complete a conductivity measurement circuit. The electrodes are attached via connection lines to a means for converting the measured conductivity into a corresponding value of osmolarity and for displaying a visible representation of that value.

[121] The York Patent also discloses an unrelated means of sensing physical qualities related to the vapour pressure of a bodily fluid.

(f) *Mitsubayashi Paper #1*

[122] Kohji Mitsubayashi et al, "Flexible Conductimetric Sensor" (1993) 65:24 Anal Chem 3586 ("Mitsubayashi Paper #1"), describes a flexible, non-toxic conductimetric sensor designed for direct contact with body surfaces and continuous measurement of conductivity in biological fluid.

[123] The sensor consisted of gold electrodes, formed directly by vapour deposition, on both sides of a hydrophilic poly(tetrafluoroethylene) membrane. The gold electrodes were 0.2 μm thick. The membrane was 3 mm wide, 80 μm thick and had 0.2 μm pores. A cyanoacrylate adhesive was used to insulate portions of the electrodes, allowing the membrane to be separated into a sensitive area (5 mm in length), lead area and electrical terminal area.

[124] A computer-controlled LCR meter was used to measure output signals from the sensor, using AC at a frequency of 100 Hz to 100 kHz and signal amplitude of 0.5 V. Impedance and phase angle were measured and conductivity was calculated. Behaviour of the sensor was calibrated using different solutions of NaCl in a 50 ml measuring cell, and calibration curves showing the relationship between NaCl concentration and conductivity were developed. Conductivity was linearly related to NaCl within the physiological range of interest, if a 100 kHz AC signal was used. Sensor performance was reproducible over multiple measurements and variance between sensors was low.

[125] The sensor was affixed to a contact lens and tested *in vivo* in rabbit eyes. Drops of solution with known NaCl concentrations were deposited in the eye and conductivity was continuously measured. The results showed the sensor was well-suited for use in conductivity sensing applications involving bodily fluids. No injury to the eye was observed; however, there was some decline in measured conductivity due to protein deposition on the sensor.

(g) *Mitsubayashi Paper #2*

[126] Kohji Mitsubayashi et al, "Measurement of tear electrolyte concentration and turnover rate using a flexible conductimetric sensor" (1995) 3:2 Technol Health Care 117 ("Mitsubayashi Paper #2), involves the application in human eyes of the same device discussed in Mitsubayashi Paper #1.

[127] The electrical conductivity of tear fluids was measured in healthy male and female subjects, ranging from 30 to 85 years of age, who had no history of ocular disease or trauma. A computer-controlled LCR meter was used with AC at 100 kHz and 0.5 V, which was applied to the sensor using a grip-type connector. The sensor tip was inserted into the temporal lower cul-de-sac, in a manner similar to the insertion of a Schirmer test strip. Conductivity values were allowed to stabilize and then measured continuously for more than 30 seconds. Solutions of known concentrations were syringed into the cul-de-sac and tear fluid conductivity was monitored for another 5 minutes.

[128] The authors concluded their method for evaluating tear osmolarity was very convenient for clinical analysis. The sensor permitted tear electrolyte concentration to be quickly evaluated

using a real-time display and did not cause any injury to the eye. The authors noted that a 3 mm x 4 mm sensor tip was selected for use after several trials. As well, some discrepancies in osmolarity values were likely due to protein and lipid deposition onto the electrodes.

(h) *The Ogasawara Paper*

[129] Katsunori Ogasawara et al, "Electrical conductivity of tear fluid in healthy persons and keratoconjunctivitis sicca patients measured by a flexible conductimetric sensor" (1996) 234:9 Graefes Arch Clin Exp Ophthalmol 542 (the "Ogasawara Paper), involves the use of the sensor discussed in Mitsubayashi Papers #1 and #2, to measure tear fluid conductivity in both healthy human eyes and human eyes with symptoms of DED.

[130] The same methods were used as in Mitsubayashi Paper #2. A LCR meter was used to measure electrical conductivity with 100 kHz AC signal. The sensitive area of the sensor was placed in the lower temporal cul-de-sac and conductivity was measured continuously for more than 30 seconds and monitored graphically on a computer display.

[131] The difference in measured electrolyte concentrations between DED eyes and healthy eyes was statistically significant. The authors predicted this method would be a new diagnostic tool for detecting tear abnormalities such as DED. Their sensor could monitor tear fluid conductivity in both healthy and DED eyes without ocular damage. As well, it eliminated problems with other DED diagnostic tools: tear fluid did not need to be removed from the eye; conductivity is quickly evaluated using real-time display; and only a small amount of tear fluid is required (the capacity of the sensitive area of the sensor is 0.96 μl).

[132] As stated above, this reference is described in part in the ‘540 Patent on page 3 at lines 21 to 26, and on page 4 at lines 1 to 4.

E. *Claim Construction*

[133] While the experts disagree on the meaning of a number of elements used in the claims in issue, I find that only the following terms need to be construed:

(1) “Sample receiving chip”

[134] Claim 1 of the ‘540 Patent clearly states that the “sample receiving chip” comprises two elements: (1) a substrate that receives an aliquot volume of a sample fluid; and (2) a sample region of the substrate whereupon energy properties of the sample fluid can be detected. In my opinion, it is unnecessary to read into the term “sample receiving chip” anything more than that.

[135] Dr. Kirby opined that the inventive concept of the ‘540 Patent is the ability to conduct osmolarity measurements that are substantially independent of the volume of the sample fluid. In that regard, he explained that the “sample receiving chip” is required to have properties such as rigidity, planarity and integrated electrodes. While Dr. Sullivan’s disclosure of his invention may have intended to incorporate those properties in at least one embodiment, the claims of the ‘540 Patent are not so limited. Only claim 56 refers to volume independence, and there is no mention of rigidity, planarity or integrated electrodes in any of the claims in issue.

[136] Furthermore, the "sample receiving chip" is not limited to *ex vivo* applications. While it is exemplified in the '540 Patent by what can only be fairly construed as *ex vivo* applications, and is distinguished from the *in vivo* device disclosed in the Ogasawara Paper, on page 3 at lines 21-26 and on page 4 at lines 1-4 of the '540 Patent, the claims in issue are not so limited. As well, any embodiment described in the '540 Patent as exemplary "is not necessarily to be construed as advantageous over other embodiments" ('540 Patent, page 24 at lines 24-45).

[137] Accordingly, I do not accept that the "sample receiving chip" is restricted to the properties suggested by Dr. Kirby, nor is it limited to *ex vivo* applications. Rather, it comprises two elements: (1) a substrate that receives an aliquot volume of a sample fluid; and (2) a sample region of the substrate whereupon energy properties of the sample fluid can be detected. Those terms are construed in more detail below.

(2) "Substrate that receives an aliquot volume of a sample fluid"

[138] Again, it is not necessary to construe these terms in a way that broadens or restricts what the '540 Patent is claiming.

[139] The term "sample fluid" does not refer only to tear film. While the '540 Patent disclosure only discusses tear fluid, with any particularity and through the illustrative figures, other than a few generic statements about measuring other bodily fluids, the claims in issue are not so limited. Only claim 14 refers specifically to tear film.

[140] The term “aliquot volume” does not restrict the invention to *ex vivo* applications. Aliquot simply means a portion of a larger whole. It does not matter whether the sample fluid is placed on the substrate or whether the substrate is placed in the sample fluid.

[141] The term “substrate” must be read in the context of the second element of the sample receiving chip, that is, the sample region of the substrate whereupon energy properties of the sample fluid can be detected. The substrate is the material upon which that process occurs. With respect to the claims in issue, which refer to electrical properties of the sample fluid, the substrate is necessarily a non-conducting material.

> (3) “A sample region of the substrate whereupon energy properties of the sample fluid can be detected”

[142] This refers to the portion of the substrate that includes further elements, which are specified in other claims dependent upon claim 1, and is sized or configured such that when it comes into contact with the sample fluid, energy properties of the sample fluid can be detected. With respect to the claims in issue, the further elements are electrodes that are part of an electrical circuit. The sample fluid bridges the gap between electrodes to complete the circuit such that the conductivity of the sample fluid can be measured and correlated to osmolarity.

[143] The electrical circuit may be as simple as two electrodes or as complex as an array of electrodes. The electrodes are coupled to connection lines that provide a means for transferring electrical energy to and from the sample fluid. As well, the electrodes may be attached to a separate processing unit. That unit is able to automatically correlate the measured conductivity to

an osmolarity value by using an algorithm related to a calibration curve. Furthermore, the processing unit may be entirely located on the sample receiving chip.

[144] Both Dr. Kirby and Dr. Franke construed the claims of the ‘540 Patent either too broadly or too narrowly; therefore, their constructions were generally not helpful to the Court.

X. Infringement

A. *Principles*

[145] A patent owner has a remedy against an alleged infringer who does not take the letter of the invention but nevertheless appropriates its substance (*Free World Trust* at para 28). However, the Court must be careful not to construe the claims of a patent so broadly such that it confers onto the patentee the benefit of inventions not in fact made.

[146] In determining whether there is infringement, the following principles help to ensure a fair and predictable result (*Free World Trust* at para 31):

> a) The *Patent Act* promotes adherence to the language of the claims.
>
> b) Adherence to the language of the claims in turn promotes both fairness and predictability.
>
> c) The claim language must, however, be read in an informed and purposive way.
>
> d) The language of the claims thus construed defines the monopoly. There is no recourse to such vague notions as the “spirit of the invention” to expand it further.
>
> e) The claims language will, on a purposive construction, show that some elements of the claimed invention are essential while

> others are non-essential. The identification of elements as essential or non-essential is made:
>
> > i) on the basis of the common knowledge of the worker skilled in the art to which the patent relates;
> >
> > as of the date the patent is published;
> >
> > ii) having regard to whether or not it was obvious to the skilled reader at the time the patent was published that a variant of a particular element would not make a difference to the way in which the invention works; or
> >
> > iii) according to the intent of the inventor, expressed or inferred from the claims, that a particular element is essential irrespective of its practical effect; and
> >
> > iv) without, however, resort to extrinsic evidence of the inventor's intention.
>
> f) There is no infringement if an essential element is different or omitted. There may still be infringement, however, if non-essential elements are substituted or omitted.

[147] The task of the Court, therefore, is to purposively construe the claims of a patent to define the scope of the patent holder's monopoly, and then determine whether the allegedly infringing product falls within the scope of those claims (*Free World Trust* at paras 48 to 49).

B. *Analysis*

[148] The Plaintiffs submit that the SUS infringes claims 1, 2, 5, 6, 8, 13 and 14, and the i-Pen infringes claims 16, 25 and 26, of the '540 Patent.

[149] Dr. Kirby opined that the SUS infringes claims 1, 2, 5, 6, 8, 13 and 14 of the '540 Patent. Regarding claim 1, the SUS is a chip comprising a substrate with electrodes on it where a

conductive fluid bridges the gap, allowing the electrodes to measure impedance, which can be related to osmolarity using a calibration curve. The fluid that is being sampled is representative of the whole and can be contacted both *in vivo* and *ex vivo*. The SUS has a plurality of electrodes (claim 2), a plurality of conductive connection lines (claim 5), is connected to a processing device (claim 6), has a sample region of less than 1 cm^2 (claim 8), and can measure osmolarity of tear film, which is a bodily fluid (claims 13 and 14).

[150] As well, Dr. Kirby opined that the i-Pen infringes claims 16, 25 and 26 of the ‘540 Patent. Regarding claim 16, the i-Pen is a system for measuring the osmolarity of a sample fluid. It contains the SUS, including its components outlined in the above paragraph, which is coupled to a processing device that receives the electrical signal from the SUS and calculates and displays an osmolarity value. As well, the SUS has an electrical circuit that enables a conductivity measurement to be taken (claim 25) and also has a plurality of electrodes (claim 26).

[151] Dr. Franke opined that the SUS does not infringe claims 1, 2, 5, 6, 8, 13 and 14 of the ‘540 Patent. Regarding claim 1, the SUS is a probe, not a chip, because it cannot do calculations onboard. It does not receive a sample because it is brought to the eye. The sample is not an aliquot volume because it is not removed or separated from a larger volume. It does not function by having a sample region covered by a sample fluid; rather, the two electrodes must be brought into contact with the eyelid conjunctiva. It neither detects energy properties of the sample nor produces an electrical signal; it is merely a conduit. It cannot indicate osmolarity because it has no processing means.

[152] As well, he opined that the electrodes are not disposed to contact a sample, and the connective lines are not a means for transferring electrical energy to a sample, because the SUS contacts the tear-soaked conjunctiva rather than a sample that has been removed from a greater volume (claims 2 and 5). It does not contain a processing unit (claim 6). It does not have a sample region less than 1 cm^2 because it does not receive a sample (claim 8). It cannot indicate the osmolarity of tear film or bodily fluid because it has no processing means (claims 13 and 14).

[153] Finally, Dr. Franke opined that the i-Pen does not infringe claims 16, 25 and 26 of the ‘540 Patent. The i-Pen does not measure a sample fluid; rather, it measures the osmolarity of the tear-soaked conjunctiva. As well, the SUS is not a chip that receives a sample fluid on a sample region, as outlined in the above paragraph. Furthermore, the electrical conductivity measurement is performed in the microcontroller, in the body of the handheld unit, which is not designed to contact the sample.

[154] In my opinion, the SUS infringes claims 1, 2, 5, 8, 13 and 14, and the i-Pen infringes claims 16, 25 and 26, of the ‘540 Patent. As discussed above with respect to claim construction, the claims of the ‘540 Patent do not limit the application or use of the invention to *ex vivo* measurements of tear fluid osmolarity. For that reason, I disagree with Dr. Franke’s view that terms such as “aliquot volume” and “sample region covered by a sample fluid” do not apply to the SUS and i-Pen.

[155] As well, I have construed the claims such that a “chip” could be as simple as two electrodes on a non-conducting substrate. It is not necessary for the chip to be able to perform

calculations onboard, with the exception of claim 6, which requires an onboard processing unit. The SUS has a plurality of electrodes and connection lines on a substrate, but does not contain a processing unit. The asserted claims of the ‘540 Patent and the SUS both require an electrical signal to be applied to the connection lines and electrodes, which travels through the sample and produces an output signal that is related to the conductivity of the sample. Claims 1, 2, 5, 8, 13 and 14 are infringed by the SUS.

[156] Furthermore, the SUS is coupled to a processing device, the microcontroller in the handheld unit of the i-Pen, which receives the electrical signal from the SUS and calculates and displays the osmolarity test result. Claims 16, 15 and 26 are infringed by the i-Pen.

[157] Dr. Franke admitted he was not aware that claims are to be read in an informed and purposive way, with a mind willing to understand. He has construed the claims of the ‘540 Patent too narrowly and Dr. Kirby’s opinion on infringement is more accurate, with the exception of claim 6.

[158] If the ‘540 Patent was construed to be limited to only *ex vivo* applications, as argued by the Defendant, then I agree that none of the claims asserted would be infringed. However, by broadly claiming both *in vivo* and *ex vivo* applications, for any bodily fluids, without limitations that have been expressed in the disclosure, the Plaintiffs have invited the validity problems set out below that cannot be avoided.

XI. Validity

[159] During the course of the trial, the Defendant abandoned its defences of overbroad and ambiguous claims; therefore, the only remaining validity issues are anticipation, the Gillette Defence, obviousness, utility and sufficiency for various asserted claims.

A. *Anticipation*

(1) Principles

[160] Section 2 of the *Patent Act* requires an invention to be novel. Anticipation is found where performance of the prior art necessarily infringes the patent under review (*Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 [*Sanofi*] at para 25). Both disclosure and enablement are required for a prior art reference or prior use to anticipate a claim in a patent (*Sanofi* at paras 25-27).

[161] The prior art must disclose subject matter that, if performed, would necessarily result in infringement of the patent under review. A POSITA reading the prior art must be able to understand, without trial and error, whether it discloses the special advantages of the patent under review (*Sanofi* at paras 25 and 32).

[162] The prior art must also enable a POSITA to work the invention disclosed by the prior art with a reasonable amount of trial and error allowed (*Sanofi* at paras 26-27). The meaning of “a

reasonable amount of trial and error" is described as follows (*Sanofi* at para 37):

> When considering whether there is undue burden, the nature of the invention must be taken into account. For example, if the invention takes place in a field of technology in which trials and experiments are generally carried out, the threshold for undue burden will tend to be higher than in circumstances in which less effort is normal. If inventive steps are required, the prior art will not be considered as enabling. However, routine trials are acceptable and would not be considered undue burden. But experiments or trials and errors are not to be prolonged even in fields of technology in which trials and experiments are generally carried out. No time limits on exercises of energy can be laid down; however, prolonged or arduous trial and error would not be considered routine.

(2) Analysis

[163] The Defendant asserts that claims 1, 2, 5, 8, 13 and 14 of the '540 Patent are anticipated by several references in the prior art.

[164] Dr. Franke opined that if the Court accepted his claim construction, claims 1, 2, 5, 8, 13 and 14 of the '540 Patent are anticipated by the Josefsen and Hill Patents.

[165] He opined that the Josefsen Patent discloses the following elements of claim 1 of the '540 Patent:

- The sample receiving card that receives a sample fluid is equivalent to the sample receiving chip in the '540 Patent;
- The sample card contains electrodes, as is the case of the sample receiving chip in the '540 Patent;
- The recessed well on the sample card, which contains electrodes and where the sample is deposited, is equivalent to the sample region of the substrate of the '540 Patent; and
- The electrodes allow for the detection of electrical properties of a sample fluid by passing an electrical current through the sample to determine its conductance, as is the case with the '540 Patent.

[166] He also opined that that the Hill Patent discloses the following elements of claim 1 of the ‘540 Patent:

- A sample card that receives a sample fluid is equivalent to the sample receiving chip in the ‘540 Patent;
- The capillary tube is equivalent to the sample region of the ‘540 Patent;
- The substrate of the capillary tube is electrically non-conductive, as is the substrate of the chip in the ‘540 Patent.
- Electrodes are placed within the capillary tube; and
- The electrodes allow for the detection of electrical properties by passing an electrical current through the sample to determine its conductance, as is the case with the ‘540 Patent.

[167] With respect to both the Josefsen and Hill Patents, Dr. Franke applied his analysis of claim 1 equally to claims 2 and 5. As well, the limited sample region size in claim 8 did not alter his opinion that all the elements of this claim were disclosed in either the Josefsen or the Hill Patent. Furthermore, those patents were directed at evaluating the electrical properties of bodily fluids, as is the case with claims 13 and 14.

[168] Dr. Franke also considered anticipation under the assumption that the claims of the ‘540 Patent are not limited to an *ex vivo* device but also include an *in vivo* device. He concluded that if the claims of the ‘540 Patent include an *in vivo* device, those claims are anticipated by the Fouke Paper, Davis Patent, York Patent and Ogasawara Paper.

[169] He explained that the only difference between the Ogasawara Paper and the asserted claims of the ‘540 Patent is that the Ogasawara device is *in vivo*. That device has a sensor consisting of electrodes and a non-conducting substrate, a sample region that is less than 1 cm^2, is connected to a processing unit and measures properties of tear film.

[170] Dr. Franke came to the same conclusions regarding the devices disclosed in the Fouke Paper, York Patent and Davis Patent; however, he acknowledged that the Fouke paper referred to tracheal fluid and not tear fluid. He noted that the York Patent primarily discusses a probe consisting only of two electrodes, but that the electrodes are held in place by a non-conductive "separation means" similar to the electrodes localized on the non-conductive substrate in the '540 Patent. I add that the York Patent also refers to a non-conducting absorbent material that is used to bridge the gap between the electrodes.

[171] Dr. Kirby disagreed with Dr. Franke on the issue of anticipation. Regarding the Josefsen and Hill Patents, he explained that a conductance measurement of blood does not indicate osmolarity but indicates hematocrit – the percentage by volume of red blood cells. Blood serum is a conductor, red blood cells are insulators and electrical current will primarily travel through serum.

[172] Dr. Kirby also opined that the inventive concept of the '540 Patent is that osmolarity measurements are substantially independent of the volume of the sample fluid. The placement of electrodes on a planar, rigid chip creates a well-defined electrical path that is relatively insensitive to other details. This differentiates the '540 Patent from the Hill and Josefsen Patents, in which the placement of electrodes does not create a well-defined path and conductance is dependent on the sample volume.

[173] Dr. Kirby further explained that:

- The Ogasawara device is flexible and the sampled fluid is "wicked" into pores such that the substrate could affect conductance measurements;

- The Davis device includes a concave sensor, not a planar chip, with a distance between electrodes that is large relative to the thickness of tear film, and uses a DC signal;
- The York device does not have a planar substrate but has parallel pairs of electrodes that are flexible and not at a fixed distance, and the absorbent material would compromise conductance measurements; and
- The Fouke device uses a flexible substrate and interdigitated electrodes.

Therefore, in his view, those devices lacked the well-defined electrical path and volume independent nature of the ‘540 Patent.

[174] As I have explained above, the asserted claims of the ‘540 Patent are not restricted to an *ex vivo* device comprising a rigid, planar chip with integrated electrodes. The claims of the ‘540 Patent suggest that the device will work so long as the sample fluid operatively covers the sample region, such that the gap between electrodes is bridged, thereby enabling an electrical signal to generate a measurement of the conductance of the sample fluid, which can be used to to indicate osmolarity.

[175] Based on my claim construction, I agree with Dr. Franke’s analysis of anticipation with respect to the *in vivo* devices disclosed in the prior art. Each of the York Patent, Davis Patent, Fouke Paper and Ogasawara Paper disclose devices that comprise a non-conducting substrate with a sample region that receives an aliquot volume of a sample fluid, such that the volume of the sample fluid bridges the gap between electrodes and conductivity of the sample fluid is measured using an electrical signal and then correlated to osmolarity.

[176] As well, each device includes a plurality of electrodes and connection lines, and a sample region that is less than 1 cm^2. However, the Fouke Paper only refers to tracheal fluid, not tear fluid.

[177] Accordingly, claims 1, 2, 5, 8, 13 and 14 are anticipated by each of the York Patent, Davis Patent and Ogasawara Paper, and claims 1, 2, 5, 8 and 13 are anticipated by the Fouke Paper.

[178] Finally, I do not accept that either the Josefsen or Hill Patent anticipates the claims of the ‘540 Patent. Claim 1 of the ‘540 Patent specifically refers to an indication of osmolarity of the sample fluid. The Josefsen and Hill Patents primarily refer to a conductance measurement of blood, which indicates hematocrit and not osmolarity. Although both the Josefsen and Hill Patents make reference to measuring electrical properties of bodily fluids generally, in addition to blood, they do not refer specifically to osmolarity and a POSITA would not be lead directly and without difficulty to the claimed invention, in view of either Josefsen or Hill, at the relevant date.

B. *Gillette Defence*

(1) Principles

[179] The Defendant also relies on the Gillette Defence, based on an early 1900’s decision from the House of Lords that provides that a defendant may plead that their alleged infringing actions are part of the prior art, and therefore the patent is either invalid for claiming subject

matter included in the prior art or, if the patent is valid, the defendant cannot infringe. As with respect to issues of infringement and validity, the patent claims are construed prior to determining if this defence is applicable (*Gillette Safety Razor Company v Anglo-American Trading Company Ltd*, [1913] 30 RPC 465 (HL)).

[180] The defence is arguably only available if a prior art reference is found to anticipate a claim or claims in issue, and while a recent decision of this Court has held it may also apply having regard to obviousness-based validity attacks, I need not comment on that approach, as I have found that the asserted claims are anticipated by a number of prior art references, as discussed above (*Arctic Cat Inc v Bombardier Recreational Products Inc,* 2016 FC 1047).

(2) Analysis

[181] As I have explained above, the claims of the ‘540 Patent are not restricted to *ex vivo* applications, nor are they limited by properties identified by Dr. Kirby such as rigidity, planarity or integrated electrodes. Rather, the claims suggest that the device will work so long as the sample fluid operatively covers the sample region, such that the gap between electrodes is bridged.

[182] Furthermore, as set out in detail above, those elements are found not only in several claims of the ‘540 Patent, but also the prior art and the SUS and i-Pen. Accordingly, the Defendant’s alleged infringing actions are part of the prior art, so even if those claims of the ‘540 Patent could be found to be valid, the Defendant would not infringe the anticipated claims – claims 1, 2, 5, 8, 13 and 14.

[183] That result flows directly from the dilemma created by the Plaintiff's urged broad construction for the asserted claims to include both *in vivo* and *ex vivo* applications of the invention, which, while I have agreed to that construction, leads to invalidity due to anticipation.

C. *Obviousness*

(1) Principles

[184] Section 28.3 of the *Patent Act* requires the subject matter of a claim to not have been obvious on the claim date. The Supreme Court of Canada set out a four-part test for obviousness in *Sanofi* at paragraph 67:

> (1) (a) Identify the notional "person skilled in the art";
>
> (b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[185] The question to be asked is would a POSITA, in the light of the state of the art and the common general knowledge, at the claimed date of the invention, have come directly and without difficulty to the invention in the patent (*Beloit Canada Ltd v Valmet OY* (1986), 8 CPR (3d) 289 [*Beloit*] at 294).

[186] Obviousness is a difficult test to meet. The "person skilled in the art" shall possess no scintilla of inventiveness or imagination (*Beloit* at 294). As well, the Court is cautioned that expert witnesses may unknowingly be biased by hindsight (*Bridgeview Manufacturing Inc v 931409 Alberta Ltd (Central Alberta Hay Centre),* 2010 FCA 188 at para 50).

(2) Analysis

[187] The Defendant asserts that claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 of the '540 Patent are obvious.

[188] Dr. Franke opined that since the Hill and Josefsen Patents do not disclose a processing device that converts impedance measurements into osmolarity, claims 6, 16, 25 and 26 were not anticipated by those patents. However, it would have been obvious to a POSITA how to output osmolarity by the use of a calibration curve; therefore, each of those claims would have been obvious by combining either of these patents with the Ogasawara Paper.

[189] He also opined that there was very little difference between the asserted claims of the '540 Patent and the Fouke Paper, Davis Patent, York Patent and Ogasawara Paper. Essentially, the only difference was that those pieces of prior art disclosed *in vivo* devices. In his view, that difference would readily and easily be bridged by a POSITA without the exercise of any inventiveness, by combining any of those papers or patents with either the Josefsen Patent or the Hill Patent.

[190] Dr. Kirby opined that a POSITA would not be motivated to combine the various references. Essentially, the Hill and Josefsen Patents refer to an *ex vivo* means of measuring conductance of blood to determine hematocrit, whereas the Fouke Paper, Davis Patent, York Patent and Ogasawara Paper refer to an *in vivo* means of measuring conductance of tear fluid (or tracheal fluid) to determine osmolarity. Even if a POSITA would combine two of those disclosures, there are countless directions that might be investigated and a POSITA would have to do further research to determine whether any of those possibilities might even work.

[191] Furthermore, he opined that a combination of the Hill Patent or Josefsen Patent, with any one of the Fouke Paper, Davis Patent, York Patent or Ogasawara Paper, would lack the inventive concept of the ‘540 Patent – osmolarity measurements that are substantially independent of the volume of the sample fluid – because the resulting device would lack a well-defined electrical path that is relatively insensitive to other details.

[192] I do not accept Dr. Kirby’s position. As I explained above, the asserted claims of the ‘540 Patent are not restricted by concepts such as volume independence or rigidity, planarity, etc. The claims suggest that the device will work so long as the sample fluid operatively covers the sample region, such that the gap between electrodes is bridged. Furthermore, the Josefsen and Hill Patents discuss the measurement of conductance of bodily fluids generally, not just blood, and the construction and use of a calibration curve was CGK such that a POSITA would know how to convert a conductance measurement of a bodily fluid (other than blood) into an osmolarity value.

[193] Therefore, I agree with Dr. Franke's opinion that it would be obvious to a POSITA at the relevant date to combine the Josefsen or Hill Patent with any one of the Davis Patent, York Patent or Ogasawara Paper, to create a device that can be used both *in vivo* and *ex vivo*, and includes a separate or onboard processing unit, to measure osmolarity of tear fluid.

[194] Accordingly, I find that claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 of the '540 Patent are obvious.

D. *Utility*

(1) Principles

[195] Section 2 of the *Patent Act* requires an invention to be useful. Utility must be established by either demonstration or sound prediction as of the filing date (*Wellcome Foundation* at para 56).

[196] A mere scintilla of utility is sufficient; however, it must be related to the nature of the subject matter of the proposed invention (*AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36 [*AstraZeneca*] at paras 53 and 55).

[197] There is a two-step analysis to determine whether a patent discloses an invention with sufficient utility: first, identify the subject-matter of the invention as claimed in the patent; and second, ask whether that subject-matter is useful — is it capable of a practical purpose (i.e., an actual result)? (*AstraZeneca* at para 54).

(2) Analysis

[198] The subject matter of the ‘540 Patent is a sample receiving chip used to measure osmolarity of tear fluid, and a tear fluid osmolarity measurement system, meant to be used in a clinical setting.

[199] The evidence shows that by late 2002, Dr. Sullivan’s device exhibited at least a scintilla of utility with respect to that subject matter. That is approximately when Dr. Sullivan began using an AC signal instead of a DC signal and overcame polarization issues to obtain stable osmolarity readings. Dr. Sullivan explained that the device he had in late 2002 was essentially the same as the one he used during clinical trials in 2004, in which the device showed some ability to differentiate between normal and DED patients.

[200] I accept that the device may not have been perfected as of the filing date – some aspects needed improvement, such as the sample collection and delivery methods, as well as the chip design – but there is no question there was demonstrated utility for measuring tear fluid osmolarity at the relevant date. While it may be true that no such demonstrated utility was shown for measuring other bodily fluids, or that utility may not have been soundly predicted for such other bodily fluids, that is not the test to be applied following the decision of the Supreme Court of Canada in *AstraZeneca*. I need not analyze this issue further.

E. *Sufficiency*

(1) Principles

[201] Disclosure lies at the heart of the patent system, which is based on a bargain between the inventor and the public: the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge (*Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 at paras 31 and 32).

[202] Disclosure requirements are found in subsections 27(3) and (4) of the *Patent Act*:

> **27 (3)** The specification of an invention must
>
> (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
>
> (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
>
> (c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and
>
> (d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.
>
> **(4)** The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.

[203] The Supreme Court of Canada in *Pioneer Hi-Bred Ltd v Canada (Commissioner of Patents)*, [1989] 1 SCR 1623 at 1637-1638, explained that disclosure is insufficient where it fails to describe how an invention is put into operation, and that:

> [t]he description must be such as to enable a person skilled in the art of the field of the invention to produce it using only the instructions contained in the disclosure and once the monopoly period is over, to use the invention as successfully as the inventor could at the time of his application.
>
> [Citations omitted]

(2) Analysis

[204] Dr. Franke opined that the '540 Patent specification neither properly defines the nature of the invention nor adequately describes how a skilled person could put such an invention into practice. The number and spacing of electrodes, as well as the sample volume, are not sufficiently disclosed in the '540 Patent. As well, the '540 Patent does not explain how to overcome evaporation problems.

[205] Dr. Kirby opined that the '540 Patent specification clearly describes the size and configurations of electrodes. As well, not only does the '540 Patent describe several techniques to overcome evaporation, a POSITA would understand to make a measurement quickly or develop trace profile to account for evaporation.

[206] I agree with Dr. Kirby. The '540 Patent specification sufficiently describes multiple configurations of electrodes, explains that a sample fluid must bridge the gap between electrodes and describes the electrical signal to be applied. On cross-examination, Dr. Franke admitted that

doing a measurement quickly to avoid evaporation is common knowledge, and that he had used that method himself when measuring tear osmolarity of rabbits. The disclosure is sufficient for support of the claims in issue.

XII. Costs

[207] Costs are awarded to the Defendant. The parties shall have two weeks from the date of judgement to either agree on costs or make separate written submissions, not to exceed 10 pages.

JUDGMENT in T-300-16

THIS COURT'S JUDGMENT is that:

1. The following claims are infringed by the Defendant:

   a. 1, 2, 5, 8, 13, 14, 16, 25 and 26.

2. The following claims are invalid:

   a. Claims 1, 2, 5, 8, 13 and 14 are anticipated.

   b. Claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 are obvious.

3. Costs to the Defendant. The parties shall have two weeks from the date of judgment to either agree on costs or make separate written submissions, not to exceed 10 pages.

"Michael D. Manson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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