Federal Court of Appeal | Cour d'appel fédérale

Date: 20190613

Docket: A-86-18

Citation: 2019 FCA 179

CORAM: **NADON J.A.**
DE MONTIGNY J.A.
GLEASON J.A.

BETWEEN:

TEARLAB CORPORATION

Appellant

and

I-MED PHARMA INC.

Respondent

and

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

Respondent

Heard at Montréal, Quebec, on December 12, 2018.

Judgment delivered at Ottawa, Ontario, on June 13, 2019.

REASONS FOR JUDGMENT BY: DE MONTIGNY J.A.

CONCURRED IN BY: NADON J.A.
GLEASON J.A.

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REASONS FOR JUDGMENT

DE MONTIGNY J.A.

[1] The appellant TearLab Corporation (TearLab) appeals from a judgment of the Federal Court (Manson J.) dated February 12, 2018 (Reasons), which dismissed TearLab's action for

infringement against the respondent I-MED Pharma Inc. (I-MED) with respect to Canadian Patent No. 2,494,540 (the ‘540 Patent). The Federal Court held that I-MED infringed certain claims of the ‘540 Patent, but that these claims were invalid due to anticipation and obviousness.

[2] The appellant essentially argues that the judge erred in not construing the claims of the ‘540 Patent in a purposive manner, which error, it says, led him to conclude that the claims at issue were both anticipated and obvious. For the reasons that follow, I would dismiss the appeal.

I. Factual Context

A. *The Parties*

[3] The Regents of the University of California (Regents) are the owners of the ‘540 Patent. The invention of the ‘540 Patent was developed by Dr. Ben Sullivan while he was a graduate student at the University of California, San Diego. He assigned his rights to the invention to the Regents, who in turn granted an exclusive licence to make, use and sell in Canada products claimed by the ‘540 Patent to a company that later became TearLab Research Inc., a wholly-owned subsidiary of TearLab. TearLab Research Inc. granted an exclusive sub-licence to TearLab to the ‘540 Patent.

[4] TearLab manufactures, markets and sells in Canada diagnostic products for eye-care professionals, most notably the TearLab Osmolarity System, which it claims to be the first osmometer for use at the clinical point-of-care for the diagnosis and treatment of Dry Eye Disease (DED).

[5] I-MED is a Québec-based company focused on human and animal eye-care. It markets medical devices, including the i-Pen Osmolarity System (the i-Pen), through a distributor in Canada.

B. *The Patent*

[6] The ‘540 Patent, entitled “Tear Film Osmometry”, was filed on March 25, 2003, and issued on June 3, 2014. It expires on March 25, 2023. It grants the patentee the exclusive right to make, use and sell the claimed invention in Canada.

[7] At trial, the parties filed a joint scientific primer with respect to relevant technology and principles that they both agreed upon, and to which the judge broadly referred to in the background section of his reasons. In a nutshell, the primer explains that DED 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, both of which lead to a tear fluid with increased osmolarity.

[8] The link between tear osmolarity and DED was explored between the 1970s and the 1990s. However, the measurement of tear osmolarity at that time relied predominantly on using freezing point depression and vapour pressure techniques, both of which presented many challenges that restricted the use of osmolarity as a diagnostic tool in a clinical setting.

[9] Broadly speaking, the ‘540 Patent discloses an invention used to measure the osmolarity of bodily fluids such as tear film. 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 the concentration of solutes. In 2002, tools that were commonly used to estimate osmolarity included freezing point depression, boiling point elevation, vapour pressure depression, osmotic pressure and electrical impedance.

[10] The invention claimed by the ‘540 Patent works as follows. A sample of the fluid to be measured is deposited on a receiving chip, such that it operatively covers the sample region and bridges the electrodes installed on it. Energy is then transferred to the fluid so as to make its energy properties (such as conductivity) detectable. The processing device then receives the measured electrical properties and translates them in terms of osmolarity. The purpose of the claimed invention, as described in the patent, is to provide an accurate osmolarity measurement with few inconveniences, little skill required and a high degree of repeatability. Earlier measurement methods were known to be complicated and expensive.

[11] The ‘540 Patent contains four independent claims, only two of which are at issue here. The first covers the “sample receiving chip” of the invention, and reads as follows:

> 1. A sample receiving chip comprising:
>
> a substrate that receives an aliquot volume of a sample fluid;

> 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.
>
> (Appeal Book, vol. 1, at p. 127.)

[12] The second claim at issue discloses the osmolarity measuring system made up of a sample fluid reception device and a platform for data communication. The reception device can be quite simple (as a set of electrodes on a chip) or more complex (as a logic-enabled microprocessor capable of enacting measurement dynamics). The platform for data communication receives output from the reception device, interprets it and then displays osmolarity. This second claim at issue reads as follows:

> 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.
>
> (Appeal Book, vol. 1, at p. 128.)

[13] The TearLab System, which the appellant claims to be covered by the ‘540 Patent, has three components: a reader base-station, a handheld pen and a single-use test card. The test card is attached by the user to the top of the pen, and the pen brought in contact with the corner of the eye. The system then extracts a sample of tear fluid from the eye using capillary action, and

deposits said fluid on the sample region. When electrical energy is imparted to the tear fluid *ex vivo*, it produces an output signal, which is then stored and used to provide an osmolarity reading.

[14] As for the i-Pen, it is designed to measure the conductivity of the moisture in the eyelid conjunctiva and tear film, which measurement can then be correlated to osmolarity. That measurement is provided by a single use sensor (SUS), which consists of two electrodes mounted on a non-conducting substrate. This *in vivo* sensor is placed against the moist tissue on the inner surface of an eyelid. The pen then produces electrical current, which travels through the SUS into the tissues of the eyelid. The current completes a circuit between the electrodes and its conductivity is measured by the i-Pen. A different SUS is used for each measurement, and is then disposed of.

[15] On February 18, 2016, TearLab issued a statement of claim against I-MED, in which it alleged that the i-Pen infringed Claim 16 (and its dependent claims) of the ‘540 Patent. It also claimed that its associated SUSs infringed Claim 1 (and its dependent claims) of the patent.

[16] In defence, I-MED asserted non-infringement, and argued that the claims at issue were invalid due to anticipation, obviousness, inutility, insufficient disclosure, as well as overbreadth and ambiguousness. At trial, it abandoned its defences of overbreadth and ambiguousness.

II. The Decision Under Appeal

[17] The Federal Court issued its decision on February 12, 2018. After providing an overview of the case, and of the evidence before him, the judge dealt with TearLab's standing. It found that TearLab was entitled to claim remedies under subsection 55(1) of the *Patent Act*, R.S.C. 1985, c. P-4 [*Patent Act*], as a person deriving rights from the patentee to use the patented invention in Canada.

[18] After having identified the Person of Ordinary Skill in the Art (POSITA) to which the '540 Patent is directed, he considered the common general knowledge of that person at the relevant dates. He relied essentially for that purpose on the joint scientific primer submitted by the parties, to which I have already referred in paragraphs 7 and 8 of these reasons. He found that academic papers, as well as patents in the field of measuring conductance of bodily fluids, form part of the common general knowledge to the extent that these references "are not obscure paper references with little or no availability to the POSITA at the relevant dates" (Reasons at para. 104). He also reviewed the state of the prior art at the relevant dates, those being February 26, 2004 for construing the claims of the '540 Patent, March 25, 2003 for assessing the sufficiency of disclosure and utility, and August 6, 2002 for assessing anticipation and obviousness.

[19] With respect to Claim 1, the judge construed it as comprising "(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" (at para. 137). It is "unnecessary", he found, "to read into the term 'sample receiving chip' anything more than that" (at para. 134).

More particularly, he held that this expression should not be restricted to the properties suggested by TearLab's expert (that is rigidity, planarity, integrated electrodes and independence of volume), nor limited to *ex vivo* applications, as was submitted by I-MED's expert.

[20] In a like manner, he found that the term "sample fluid" in the phrase "a substrate that receives an aliquot volume of a sample fluid" does not refer only to tear film (at para. 139), despite the fact that the disclosure only discusses that kind of bodily fluid. Similarly, he held that the term "aliquot volume" does not restrict the invention to *ex vivo* applications, since the word "aliquot" simply means a portion of a larger whole (at para. 140). As for the term "substrate", the judge was of the view that, in light of the second element of the claim (*i.e.* the sample region whereupon energy properties of the fluid can be detected), it must necessarily be a non-conducting material (at para. 141).

[21] As for the term "a sample region of the substrate whereupon energy properties of the sample fluid can be detected", the judge found that it refers to the portion of the substrate that includes further elements, those further elements being electrodes that are part of an electrical circuit (at para. 142). Such an electrical circuit may be simple (two electrodes) or complex (an array of electrodes). These electrodes may be attached to a separate processing unit, possibly located on the sample receiving chip, able to automatically correlate the measured conductivity to an osmolarity value by using an algorithm (at para. 143).

[22] The judge then considered whether or not I-MED had infringed the '540 Patent. First, he set aside the distinction drawn by I-MED between the SUS card and the "chip" referred to in

Claim 1 of the patent. Having adopted a broad construction of this term, one that did not require the chip itself to perform calculations onboard (except in Claim 6), the judge found that the SUS infringed Claim 1 and its dependent claims (at para. 155). Second, he rejected I-MED's argument that the i-Pen was distinct from the invention claimed in that its application was *in vivo*, and not *ex vivo* (at para. 154). No such limit, he found, was specified in the '540 Patent (at para. 154).

[23] Moving on to the issue of validity, the judge first contemplated whether the claims at issue had been anticipated. In light of his prior determination that "the asserted claims of the '540 Patent are not restricted to an *ex vivo* device comprising a rigid, planar chip with integrated electrodes" (at para. 174), he concluded that Claim 1 and its dependent claims were anticipated by each of the York Patent, Davis Patent, Ogasawara Papers and Fouke Paper (at para. 177). Based on this finding, he accepted I-MED's Gillette defence (at para. 182). He nonetheless rejected I-MED's claim that the Josefsen or Hill Patent had anticipated the claims of the patent (at para. 178). These patents, he wrote, deal with hematocrit, and not osmolarity, and would thus not have led a POSITA "directly and without difficulty" to the claimed invention (at para. 178).

[24] The judge then dealt with I-MED's allegations of obviousness. Once again, in light of his broad construction of the claims at issue, the judge held that it would have been "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" (at para. 193).

[25] Lastly, the judge rejected I-MED's submissions with respect to inutility (at paras. 195-200) and insufficiency (at paras. 201-206). These conclusions have not been appealed.

III. Issues

[26] The present appeal raises the three following questions:

A. Did the judge err in construing the claims of the '540 Patent?

B. Did the judge err in finding that the claims were obvious?

C. Did the judge err in finding that the claims were anticipated?

IV. Analysis

A. *Did the judge err in construing the claims of the '540 Patent?*

(1) Standard of Review

[27] On appeal from a decision of the Federal Court on an action for infringement, the usual appellate standard of review applies: palpable and overriding error for questions of fact and questions of mixed fact and law, and correctness for extricable questions of law (*Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235; *Ciba Specialty Chemicals Water Treatments Limited's v. SNF Inc.*, 2017 FCA 225 at para. 26 [*Ciba*]).

[28] Construction of a patent is a question of law for the judge (*Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at para. 76 [*Whirlpool*]; *Mylan Pharmaceuticals ULC v. AstraZeneca Canada Inc.*, 2012 FCA 109 at para. 20). As this Court stated in *Cobalt*

Pharmaceuticals Company v. Bayer Inc., 2015 FCA 116 [*Cobalt*], this stems from the fact that issued letters patent are understood to be "regulations" as that term is defined by subsection 2(1) of the *Interpretation Act*, R.S.C. 1985, c. I-21, and, therefore, "are laws whose interpretation should be reviewed on the basis of correctness" (at para. 13; see also *Whirlpool* at paras. 49(e) and 61).

[29] That being said, the appreciation of expert evidence as to how a skilled person would construe the claims, and what common general knowledge was available to such a skilled person at the date of publication, is a question of fact reviewable on a palpable and overriding error standard (*Bombardier Recreational Products Inc. v. Arctic Cat Inc.,* 2018 FCA 172 at para. 16; *AFD Petroleum Ltd. v. Frac Shack Inc.*, 2018 FCA 140, at paras 38-41 [*Frac Shack*]; *Apotex Inc. v. Astrazeneca Canada Inc.*, 2017 FCA 9 at paras. 29-30). As noted in *Cobalt*:

> [14] …in the process of interpretation, patents are to be read through the eyes of the skilled reader: *Whirlpool*, above at paragraph 45. The skilled reader approaches the patent with an appreciation of the common general knowledge in the art to which the patent relates. This is not within the purview of a judge, so almost always the parties adduce expert evidence to explain how the skilled reader would read and understand the patent…
>
> [15] The Federal Court's assessment of the expert evidence - for example, evidence concerning the state of scientific knowledge at the relevant time or how a reasonable person skilled in the art would understand the patent - is reviewable for palpable and overriding error…

(2) Applicable Law

[30] The general principles of claim construction are now well established and were set out by the Supreme Court in three cases (*Whirlpool* at paras. 49-55; *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at paras. 31-67 [*Free World Trust*]; *Consolboard Inc.*

v. MacMillan Bloedel (Sask.) Ltd., [1981] 1 S.C.R. 504 at p. 520 [*Consolboard*]). These principles can be summarized as follows.

[31] The *Patent Act* promotes adherence to the language of the claims, which in turn promotes fairness and predictability (*Free World Trust* at paras. 31(a), (b) and 41). The words of the claims must, however, be read in an informed and purposive way (at para. 31(c)), with a mind willing to understand (at para. 44). On a purposive construction, it will be apparent that some elements of the claimed invention are essential while others are non-essential (at para. 31(e)). The interpretative task of the court, in claim construction, is to separate and distinguish between the essential and the non-essential elements, and to give the legal protection to which the holder of a valid patent is entitled only to the essential elements (at para. 15).

[32] To identify these elements, the claim language must be read through the eyes of a POSITA, in light of the latter's common general knowledge (*Free World Trust* at paras. 44-45; see also *Frac Shack* at para. 60; *Whirlpool* at para. 53). As noted in *Free World Trust*:

> [51] …The words chosen by the inventor will be read in the sense the inventor is presumed to have intended, and in a way that is sympathetic to accomplishment of the inventor's purpose expressed or implicit in the text of the claims. However, if the inventor has misspoken or otherwise created an unnecessary or troublesome limitation in the claims, it is a self-inflicted wound. The public is entitled to rely on the words used *provided* the words used are interpreted fairly and knowledgeably. [Emphasis in the original.]

[33] Claim construction requires that the disclosure and the claims be looked at as a whole "to ascertain the nature of the invention and methods of its performance, … being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public" (*Consolboard* at p. 520; see also *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60,

[2012] 3 S.C.R. 625 at para. 50). Consideration can thus be given to the patent specifications to understand what was meant by the words in the claims. One must be wary, however, not to use these so as "to enlarge or contract the scope of the claim as written and … understood" (*Whirlpool* at para. 52; see also *Free World Trust* at para. 32). The Supreme Court recently emphasized that the focus of the validity analysis will be on the claims; specifications will be relevant where there is ambiguity in the claims (*AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, [2017] 1 S.C.R. 943 at para. 31; see also *Ciba* at paras. 74-75).

[34] Finally, it is important to stress that claim construction must be the same for the purpose of validity and for the purpose of infringement (*Whirlpool* at para. 49(b)).

(3) Analysis

[35] The appellant argues that the judge erred in his construction of the essential element "sample receiving chip" that is explicitly claimed in Claims 1 and 16. Specifically, the judge is said to have erred in finding that these words would not necessarily be understood by a POSITA as referring to a "microchip", with what the appellant says are the inherent properties of microchips, notably planarity and rigidity. In holding that a "chip" is anything with a substrate and sample region, the appellant contends, the judge also failed to take into account the inventive concept of substantial volume independence, and came to consider the "sample receiving chip" as a non-essential element of the claims.

[36] According to the appellant, such a construction must be set aside as it was made in complete disregard of the expert evidence and the disclosure, and is moreover inconsistent with

the principles of purposive claim construction laid down by the Supreme Court in *Free World Trust*. The appellant asserts that the inventive concept of the ‘540 Patent is an osmolarity measuring system which allows for osmolarity measurements to be made in a “substantially volume independent manner”, and that it is only by using a microchip with the “inherent properties” referred to above that the inventive concept would be fulfilled.

[37] In my view, these submissions are without merit and must be dismissed. While the reasons of the judge on this question are terse, I have not been convinced that he erred in finding that a “sample receiving chip” only comprises “(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”.

[38] First of all, it is worth stressing that the appellant does not take issue with the general principles of claim construction set out by the judge at paragraphs 85 to 87 of his reasons. It is with the application of these principles to the construction of the claims at issue that the appellant finds fault.

[39] It is true that the specification of the ‘540 Patent does contain some references to microchips (Appeal Book, vol. 1, at pp. 103, 104 and 114). The claims, however, never refer to microchips but only to a “chip”.

[40] The appellant makes much of statements from I-MED's expert, Dr. Manfred Franke, about the meaning of the word "chip". It bears reproducing the relevant excerpts from his testimony:

> DR. FRANKE: …In 2002, a person skilled in the art would understand the term "chip" to be an abbreviated word - version of the word "microchip". A microchip is a device that has an integrated circuit. Integrated circuit - microchip is sometimes - or chip is sometimes also called out as IC, integrated circuit. It is called an integrated circuit because it has integrated all the electronic elements[,] such as transistors, resistors, capacitors, et cetera onto one silicon substrate.
>
> …This chip as explained in Claim 1 is - has a substrate, is formed on the substrate, which is generally understood to be non-conductive. And this sample receiving chip, as described in Claim 1, also includes a sample region on that substrate which then receives the sample fluid to be analyzed…
>
> (Appeal Book, vol. 11, at pp. 2424-2425.)

[41] These excerpts of Dr. Franke's testimony do establish that, in his view, the word "chip" in the claims of the patent would have been understood by a POSITA to refer to a "microchip". What they do not establish, however, are the specific properties that, according to Dr. Franke, a POSITA would attribute to this "microchip". While I-MED's expert noted that this chip would have an "integrated circuit" (Appeal Book, vol. 6, at p. 1151, and vol. 11, at p. 2508), he did not go so far as to say that it ought to have a "specific substrate-sample region hierarchy" or that it should be planar, pseudo-planar, rigid or semi-rigid. In fact, other elements of the record seem to indicate that, according to Dr. Franke, a POSITA would not inevitably have understood the chip to have these particular features.

[42] In fact, when considering prior art references in the section of his validity report dealing with the Gillette defence, Dr. Franke expressly notes that "Claim 1 in the '540 Patent does not say whether the chip is flexible" (Appeal Book, vol. 6, pp. 1232-1233, at paras. 353 and 365). He

further states that there is "no fundamental difference between the chip as described in the '540 Patent and the sensor described in [the] Fouke [Paper]", which he describes as a "flexible sensor containing miniature electrodes" (Appeal Book, vol. 6, pp. 1193-1194, at paras. 242 and 243(b)). He even went as far as saying, during his examination in chief, that the Fouke Paper "describes a sensor that has been manufactured by microsystem technology… approaches similar to how I interpret the techniques used to manufacture the chip... in the '540 Patent" (Appeal Book, vol. 12, at p. 2962).

[43] It is also interesting to note that neither the specification nor the claims of the '540 Patent say anything about rigidity, as was recognized by the appellant's expert himself (see Dr. Kirby's cross-examination, Appeal Book, vol. 12, at pp. 3084-3085, and vol. 13, at pp. 3132-3133). Likewise, planarity is only mentioned when discussing a means to determine the size of a droplet with reference to Figures 2 and 3, which are described as alternative embodiments and are not part of any asserted claim (see '540 Patent, Appeal Book, vol. 1, at pp. 110-111).

[44] Moreover, I agree with the respondent I-MED that there appears to be a certain discrepancy between parts of Dr. Kirby's Infringement and Validity reports, as to how broadly the term "substrate" is to be construed (compare Appeal Book, vol. 3, at p. 308 and vol. 4, at pp. 582-583 with Appeal Book, vol. 4, at p. 597). That ambiguity in his reports illustrates the dilemma that the appellant finds itself in. If the claim is constructed broadly and without any limitation on the properties of the microchip, it is easier to argue that the i-Pen infringes the claim, as the judge found. But at the same time, a broader construction makes it more difficult to avoid a finding of invalidity.

[45] The appellant suggests a further limitation on Claim 1, being that the chips must have a "specific substrate-sample region hierarchy" (see Appellant's Memorandum of Fact and Law at para. 31). Yet, once again, no such language is found anywhere in the '540 Patent. The judge was clearly right to reject such a limitation, which appears to have been designed here with a view to avoid the prior art.

[46] As for the appellant's argument that the judge erred in construing the claims without any regard to what it considers to be the inventive concept, *i.e.* the substantially volume independent manner in which osmolarity measurements can be made, it is also mistaken. As rightly pointed out by the judge, the only claim that refers to volume independence is a dependent method claim, Claim 56, and that claim is not in issue in this proceeding (Reasons at para. 135). The '540 Patent's only other reference to volume independence is limited to a single embodiment described in Figure 1 (Appeal Book, vol. 1, at p. 108). The judge was therefore justified in concluding that "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" (Reasons at para. 192).

[47] In short, I am of the view that the judge cannot be faulted for adhering to the words of the claims and refusing to add limitations that were not expressly included. Instead of following blindly the claim construction suggested by either one of the experts, he focused on the claims without redrafting them. In keeping with the teachings of the Supreme Court in *Whirlpool*, at para. 52, he made reference to the disclosure when needed, but made sure not to use the patent

specifications in a manner that would enlarge or contract the scope of the claim as written (see also *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 at para. 77 [*Sanofi*]).

[48] For similar reasons, I also cannot accept the appellant's argument to the effect that the judge erred in finding the "sample receiving chip" to be a "non-essential element of the claims" (Appellant's Memorandum of Fact and Law at pp. 11-13). In my view, he actually did consider the "chip" to be an essential element of the claims, but he simply did not accept, in light of the evidence before him, the appellant's definition of that term.

[49] As for the inventive concept urged upon us by the appellant, the judge was correct to reject it. As mentioned earlier, the notion of "volume independence" is nowhere to be found in the claims at issue. If Claim 1 was to be construed as including that notion, it would necessarily make the only claim referring to it (Claim 56) redundant. As the judge noted, the inventor may well have intended to incorporate the volume independence property in one embodiment, but this is not sufficient to make it part of the claim itself in the absence of clear language to that effect (Reasons at para. 135). This is consistent with this Court's caution that the emphasis must be on the claim and on the inventive concept that can be derived from the wording of the claim, as opposed to the amorphous and ill-defined concept that could be derived from the specification as a whole (see *Ciba* at paras. 74-75, quoting from *Pozzoli SPA v. BDMO SA*, [2007] F.S.R. 37, [2007] EWCA Civ. 588 and *Whirlpool* at para. 45).

[50] For all of the foregoing reasons, I am therefore of the view that the judge did not make any reviewable error in construing the claims of the ‘540 Patent.

B. *Did the judge err in finding that the claims were obvious?*

(1) Applicable Law

[51] Section 28.3 of the *Patent Act* requires that the subject matter of a claim not be obvious to a POSITA at the claim date, in light of the relevant common general knowledge of that person. The proper legal analysis to determine whether a claim is obvious is not in dispute, and the appellant acknowledges that the judge set out the correct legal test at paragraphs 184 to 186 of his reasons. Relying on *Sanofi*, at paragraph 67, the judge correctly identified the four-step approach first developed in English jurisprudence and adopted by the Supreme Court in the following terms:

> (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?

[52] The appellant argues that the judge erred in his application of this four-part test to the facts of this case, and claims that he allowed hindsight to skew his obviousness analysis. As

such, the issues raised are of mixed fact and law, and must be reviewed against the standard of palpable and overriding error (*Alcon Canada Inc. v. Altavis Pharma Company*, 2015 FCA 191 at para. 11; *Wenzel Downhole Tools Ltd. v. National-Oilwell Canada Ltd.*, 2012 FCA 333 at para. 44).

(2) Analysis

[53] As will be recalled, the judge agreed with I-MED's expert and held that it would be obvious to a POSITA to combine either one of the blood hematocrit prior art references (the Josefsen or Hill Patent) with one of the Davis Patent, York Patent or Ogasawara Papers to create a device that can measure osmolarity both *in vivo* and *ex vivo* (Reasons at para. 193). Such a finding, according to the appellant, is flawed for a number of reasons, which I will consider in turn.

(a) *Citable Prior Art*

[54] First, the appellant contends that the judge erred in not determining whether the prior art at issue was citable, *i.e.* whether it would have been located using a reasonably diligent search. In this respect, the appellant makes much of the fact that I-MED's own expert, Dr. Franke, said in cross-examination that he conducted an exhaustive search of the literature many years after the relevant date and was not able to locate any of the prior art references at issue. It is also submitted that I-MED counsel first found the prior art and then asked its expert whether he could locate it, thereby tainting the prior art search with hindsight bias. Indeed, it is suggested that Dr. Franke provided an opinion on obviousness solely directed at conductivity disclosures, because

this is what the ‘540 Patent discloses, instead of looking at other, more widely used techniques in use at the relevant date to measure tear osmolarity, such as freezing point or vapour pressure techniques.

[55] I am unable to accept either of these arguments. The excerpts from Dr. Franke’s testimony relied on by the appellant in support of its argument are taken out of context. They relate to prior studies he performed while working for the private sector, with a view of designing a clinical study for a device his employer was developing (Appeal Book, vol. 11, at pp. 2412-2413, 2450-2452). It has nothing to do with a diligent search for cited prior art references relating to the ‘540 Patent.

[56] Moreover, I find that Dr. Franke followed the proper methodology for a prior art search. Before being provided with a copy of the ‘540 Patent, Dr. Franke was asked what techniques and equipment were known to measure osmolarity. Beginning at paragraph 59 of his Validity Report, he explained the various techniques that would have been used, and concluded at paragraph 66 that measuring impedance to determine osmolarity was advantageous over the other known methods available (Appeal Book, vol. 6, at pp. 1138-1140). It is in that context that he identified, at paragraph 80 of his Validity Report, relevant prior art that a POSITA looking to measure tear osmolarity would have located (Appeal Book, vol. 6, at pp. 1146-1148). As is made clear in the mandate section of his Validity Report, Dr. Franke had not been provided with the ‘540 Patent at that stage (Appeal Book, vol. 6, at pp. 1119-1120).

[57] Dr. Franke confirmed that all of the prior art references listed in paragraph 80 of his Validity Report, upon which he relied for his opinion on obviousness and anticipation, were the result of his own search. He stated, quite explicitly, that "[w]hile conducting [his] own search of the literature, [he] discovered the following patents and scientific papers, which the skilled person would have been able to locate by using databases and search methods available prior to 2002" (Appeal Book, vol. 6, at p. 1146). There is, quite simply, no basis for the appellant's suggestion that these references were located with the assistance of counsel.

[58] In fact, when Dr. Franke did not find all of the prior art listed in the original Defence and Counterclaim in the course of his own independent search, the ones missing were removed from the proceeding through amendments. Likewise, when Dr. Franke found references that were not included in the original Defence and Counterclaim, amendments were made to add these references to the proceeding (see Further Amended Statement of Defence and Counterclaim, Appeal Book, vol. 1, tab 4, at p. 163). There is nothing improper in this course of action.

(b) *The Sanofi Framework*

[59] The appellant claims that, while the judge identified the correct legal test for obviousness, he did not follow the four-part framework from *Sanofi* in his analysis. Specifically, the appellant argues that he erred in not identifying the differences between the state of the art and the subject-matter of the claims, and in not determining whether these differences constitute steps that would have been obvious to the POSITA. The judge is also said to have provided no justification for why a POSITA would be motivated to combine the hematocrit and the osmolarity references.

[60] In my view, these arguments must fail.

[61] It is clear from the judge's reasons that he accepted Dr. Franke's evidence with respect to the third and fourth stages of the *Sanofi* framework (Reasons at paras. 188-194).

[62] Concerning the third step of the *Sanofi* test, Dr. Franke opined, in his Validity Report, that the Hill and Josefsen Patents differ from the invention of the '540 Patent in that they "do[] not refer to osmolarity but to conductance" (Appeal Book, vol. 6, pp. 1161 and 1166, at paras. 134(f) and 138). He also stated that every element of the disputed claims in the '540 Patent are present in the Davis Patent, the York Patent and the Ogasawara Papers apart only from the *ex vivo* aspect (Appeal Book, vol. 6, pp. 1175, 1181 and 1188, at paras. 175, 195 and 220).

[63] Moving on to the fourth step of the *Sanofi* test, Dr. Franke wrote, in the sections of his Validity Report devoted to the York, Davis and Ogasawara references, that a POSITA "who wished to develop an *ex vivo* method to measure conductance would have located [the Josefsen or Hill patents]" (Appeal Book, vol. 6, p. 1175 at para. 173; see also Appeal Book, p. 1183 at para. 198, and p. 1189 at para. 222). Once again, according to Dr. Franke, the POSITA "would have been motivated to combine" the Josefsen or Hill Patent with any one of the Davis Patent, York Patent or Ogasawara Papers (Appeal Book, vol. 6, pp. 1175, 1183 and 1189, at paras. 175, 200 and 224).

[64] The judge explicitly endorsed that opinion at paragraph 193 of his reasons. He was certainly entitled to prefer Dr. Franke's opinion over that of Dr. Kirby, and to rely on his

evidence without repeating his entire rationale in his reasons. Absent a palpable and overriding error in assessing whether there were any differences between prior art references and the inventive concept of the claims at issue, and whether these differences were inventive in light of the relevant common general knowledge, a judge's conclusions in this regard should not be disturbed (*Arctic Cat, Inc. v. Bombardier Recreational Products Inc.*, 2018 FCA 125 at para. 6, leave to appeal to S.C.C. refused, May 16, 2019 (38416)).

[65] The appellant also submits that the judge did not explain why he rejected Dr. Kirby's opinion that there was no motivation to combine the various prior art references, nor why a POSITA would have been led directly and without difficulty to the combination of hematocrit references with tear osmolarity references. The appellant further argues, in this regard, that I-MED's expert was silent on this point.

[66] A careful reading of Dr. Franke's Validity Report, however, belies this reading. As a matter of fact, he describes, in a very detailed way, why the claims of the '540 Patent would be obvious in light of each prior art reference, and indicates why any differences would be readily and easily bridged by the POSITA without the exercise of inventiveness (Appeal Book, vol. 6, at pp. 1125-1127, 1169-1207). In doing so, Dr. Franke properly followed the approach dictated by *Sanofi*, and the judge was entitled to rely on his opinion.

(c) *Secondary Indicia of Obviousness*

[67] The appellant also claims that the judge failed to take into account relevant secondary indicia of obviousness, such as the "long-felt want or need" for an osmometer adaptable to the

clinical setting and the celebration by the industry of the commercialization of the TearLab System (Appellant's Memorandum of Fact and Law at p. 29). For a number of reasons, this argument is without merit.

[68] First, the commercial success of a patented product is never conclusive, in and of itself, and is clearly not sufficient to save an obvious claim (see, *e.g.*, *Pollard Banknote Ltd. v. BABN Technologies Corp.*, 2016 FC 883 at paras. 221-230). This Court made clear, in *Rothmans, Benson & Hedges Inc. v. Imperial Tobacco Ltd.* (1993), 152 N.R. 292 (F.C.A.), that it is "only one of many factual considerations whose weight is to be assessed in determining inventiveness" (at p. 308). Moreover, as Hughes J. suggested in *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FC 1234, affirmed 2007 FCA 217 and 2007 FCA 269, leave to appeal to S.C.C. refused, December 6, 2007 (32200), commercial success may reflect the fact that many persons were motivated to fill the commercial market, which in turn may suggest inventive ingenuity (at para. 113). However, it may also be the result of marketing efforts and factors other than the invention (*Ibid.*).

[69] I also agree with the respondent I-MED that, to the extent the evidence of commercial success and industry praises put forward by the appellant related not to the invention disclosed in the patent itself, but rather to the TearLab System, and that no nexus was clearly shown between the two, it was irrelevant to the obviousness inquiry. Indeed, there is no evidence (nor was it ever alleged by TearLab) that its commercial product was covered by any claim of the '540 Patent, or that what was celebrated was the imminent commercialization of Dr. Sullivan's technology.

(d) *Contradictory Findings*

[70] The appellant further submits that the judge erred in making contradictory findings of fact in his anticipation and obviousness analysis. Specifically, it says that the judge erred in not considering, in the course of his obviousness analysis, his prior finding that the Hill and Josefsen patents did not anticipate the ‘540 Patent because “they do not refer specifically to osmolarity and a POSITA would not be [led] directly and without difficulty to the claimed invention” in view of these references (Reasons at para. 178). This contradiction, it asserts, would be sufficient to overturn the decision. Once again, I find that submission unconvincing.

[71] On a fair reading of paragraph 178 of the decision, it is clear that the judge was talking about anticipation, not obviousness. While it is true that he erroneously employed the wording of the obviousness test to do so, that is the words “directly and without difficulty” from *Beloit Canada Ltd. v. Valmet Oy (1986)*, 8 C.P.R. (3d) 289 [*Beloit*], the meaning of what he says is nonetheless made clear from reading the whole paragraph in context:

> [178] Finally, I do not accept that either the Josefsen or Hill Patent anticipates the claims of the ‘540 Patent. … 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 le[]d directly and without difficulty to the claimed invention, in view of either Josefsen or Hill, at the relevant date.

[72] The confusion in terminology might be explained by the fact that the words used in *Beloit* to describe both the anticipation and obviousness tests display some similarities. In fact, in setting out the standard for anticipation, Hugessen J.A. did write that the “prior publication must contain so clear a direction that a skilled person reading and following it would in every case and

without possibility of error be led to the claimed invention" (*Beloit* at p. 297). This is not very far from the "directly and without difficulty" wording of the test for obviousness.

[73] Once properly understood as referring to the test of anticipation, the judge's finding in paragraph 178 of his reasons is clearly not inconsistent with his obviousness analysis. There is nothing "contradictory" in finding that a prior art reference, when considered alone, does not anticipate, but that it can nonetheless render a claim obvious when combined with another reference. As noted by Donald MacOdrum in *Fox on the Canadian Law of Patents*, 5th ed., looseleaf (Toronto, Ont.: Thomson Reuters Canada, 2019), at pp. 4-6 and 4-7 [MacOdrum]:

> There is a crucial difference in assessing the effect of prior documents on the question of anticipation and obviousness. When approaching an enquiry as to the novelty of an alleged invention, anticipation must be found in a single document. In other words, it is not legitimate to read several documents together and thus, as the cases put it, to make a mosaic of extracts. In addition, that single document must disclose the precise invention claimed in the patent under attack. But, in considering invention versus obviousness, the prior art should be reviewed and its cumulative effect considered. [References omitted.]

[74] Finally, the appellant finds fault with the obviousness analysis conducted by the judge because it is allegedly divorced from the inventive concept ("volume independence") and the language of the claims (the particular substrate-sample region hierarchy of the "microchip"). For the following reasons, I find that neither of these arguments can succeed.

(e) *Inventive Concept*

[75] With respect to the notion of an "inventive concept", the starting point of the analysis must be the seminal case of *Sanofi*, where the Supreme Court stated:

> [76] The construction of the claims in the ‘777 patent is not an issue. It is agreed that they constitute the dextro-rotatory isomer of the racemate and its pharmaceutically acceptable salts and processes for obtaining them.
>
> [77] The inventive concept of the claims is not readily discernible from the claims themselves. A bare chemical formula in a patent claim may not be sufficient to determine its inventiveness. In such cases, I think it must be acceptable to read the specification in the patent to determine the inventive concept of the claims. Of course, it is not permissible to read the specification in order to construe the claims more narrowly or widely than the text will allow.
>
> [78] In the present case, it is apparent that the inventive concept of the claims in the ‘777 patent is a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity than the other compounds of the ‘875 patent and the methods for obtaining that compound.

[76] In the years following *Sanofi*, many questions arose as to the significance and meaning of the inventive concept (see Joshua Sealy-Harrington, “The Inventive Concept in Patent Law: Not So Obvious”, (2015) 27 I.P.J. 385). There are hints, in *Sanofi*, that claim construction and the inventive concept are not identical inquiries. Indeed, the Supreme Court seemed to be saying, in that case, that while the construction of the claims led to a compound, its salts and the processes for obtaining them, the inventive concept was broader, encompassing the compound, its specific uses, its preferable properties to other compounds, and the methods for obtaining it (*Sanofi* at paras. 76-77). Be that as it may, the Supreme Court offered no description or explanation as to what the inventive concept actually is, which has led many to wonder whether, in practice, the inventive concept is really different from the construction of the claim at issue (see, *e.g.*, the discussion by Hughes J. in *Allergan Inc. v. Canada (Health)*, 2012 FC 767 at para. 135, affirmed on other grounds 2012 FCA 308, leave to appeal to S.C.C. refused, May 9, 2013 (35184)).

[77] In an attempt to lessen the confusion, this Court wrote, in *Ciba*, that until such time as “a workable definition of the inventive concept” is found, it is preferable to “avoid … the inventive

concept altogether and [to] pursu[e] the alternate course of construing the claim" (at para. 77). In *Bristol-Myers Squibb Canada Co. v. Teva Canada Limited*, 2017 FCA 76, a different panel of this Court similarly stated that "the obviousness analysis asks whether the distance between two points in the development of the art can be bridged by the [POSITA] using only the common general knowledge available to such a person", and that references in the jurisprudence to "the inventive concept", "the solution taught by the patent", or simply "the invention", are merely attempts to define the second point, and are treated as synonymous with "what is claimed" in the patent (at para. 65).

[78] The judge's analysis is consistent with the recent decisions of this Court, which have downplayed the importance of the "inventive concept" as an analytical tool in the context of an obviousness analysis. Instead, he focused his analysis on the claims themselves, in line with the principle notably expressed by Lord Hoffman in *Connor Medsystems Inc. v. Angiotech Pharmaceuticals Inc.*, [2008] UKHL 49 at para. 19, cited by this Court notably in *Ciba* at para. 74, and *Apotex Inc. v. ADIR*, 2009 FCA 222 at paras. 68-69, that the question of obviousness should be determined "by reference to [the] claim and not to some vague paraphrase based upon the extent of his disclosure in the description". This is no doubt why the judge did not feel compelled to discuss at length the inventive concept of the claims in issue beyond rejecting Dr. Kirby's suggestion that it includes "volume independence" (Reasons at para. 192).

[79] It is worth recalling, in this regard, that the notion of "volume independence" is nowhere to be found in the claims at issue. The judge was right to point out, moreover, that while the inventor may have wanted to incorporate the volume independence property in one embodiment,

this is not sufficient to make it part of the claims in the absence of clear language to that effect (Reasons at para. 135). Furthermore, it is generally accepted, notably in English law, that the inventive concept of claims should not be restricted by the content of one specific embodiment (see MacOdrum at p. 4-103). This is not to mention that, as the judge pointed out at paragraph 136 of his reasons, the '540 Patent clearly states that the claimed invention "should … not be seen as limited to the particular embodiments described herein" (Appeal Book, vol. 1, at pp. 125-126).

(f) *Obviousness Analysis Divorced from Claim Construction*

[80] As for the appellant's alternative argument that the judge's obviousness analysis is flawed because it is divorced from the wording of the claims, it must also fail for two reasons.

[81] First, the appellant appears to conflate the tests for obviousness and anticipation when it claims that the judge should have addressed each piece of prior art separately and identified the differences between each piece of prior art and the claims as construed. Every element of an obvious claim need not be found in single prior art reference; that is the test for anticipation. The test is rather whether a POSITA can bridge the gap between the state of the art at the relevant time and the claim as construed, without inventive ingenuity. Prior art will be used in the application of both anticipation and obviousness, but in a different manner; anticipation will be established if a single document can be found which gives a POSITA all the information which is needed to produce the claimed invention without the exercise of any inventive skill, whereas for obviousness it is the cumulative effect of the prior art that must be considered to determine whether the skilled but unimaginative technician would have come to the solution taught by the

patent directly and without difficulty. As stated by Harold G. Fox in his seminal book titled *Canadian Patent Law and Practice*, 4th ed. (Toronto, Ontario: Carswell, 1969), at p. 137:

> …Prior specifications are generally used to show anticipation if they disclose exactly and fully what the patentee has claimed. If such disclosure is not made by the prior specification and it cannot be used as an anticipation, it may be used as indicating the state of the art at the time that the patentee made his alleged invention and as showing that what the patentee did was so slight a contribution to existing knowledge as to lack the essential element of invention and to be merely obvious…

[82] Second, the appellant's argument that the judge failed to assess obviousness by reference to the language of the claims is premised on its construction of these claims as requiring notably the use of microchips with the specific hierarchy of a substrate/sample region. Yet the judge rejected that construction of the claims, finding that they did not incorporate the four concepts put forward by the appellant, namely volume independence, rigidity, planarity and integrated electrodes (Reasons at paras. 134-137). As a result, the appellant's submissions cannot succeed as they are not supported by the construction of the claims in issue. The analysis of obviousness must by necessity be informed by the claim construction.

[83] At the end of the day, I agree with the respondent I-MED that the appellant finds itself in a conundrum. It cannot at once argue that the judge's findings on infringement are correct and dispute the claim construction upon which those findings were made. If the claims are to be construed broadly to include *in vivo* uses and capture the i-Pen for the purpose of infringement, they cannot simultaneously be restricted with the limitations proposed by the appellant's expert in order to save them from invalidity due to obviousness and anticipation. The judge clearly saw through this dilemma when he wrote, at paragraph 158 of his reasons, that:

> If the ’540 Patent was construed to be limited to only *ex vivo* applications, as argued by the [respondent I-MED], 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 [appellant has] invited the validity problems set out below that cannot be avoided.

[84] Having concluded that the judge committed no palpable and overriding error in coming to the conclusion that the claims in issue are obvious, there is no need to decide whether the judge erred in deciding that the claims were also anticipated.

V. Conclusion

[85] For all of the foregoing reasons, I find that the appeal should be dismissed, with costs in the amount of $25,000.00 all inclusive.

“Yves de Montigny”
J.A.

“I agree
M. Nadon J.A.”

“I agree
Mary J.L. Gleason J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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APPEARANCES:

Patrick Smith Scott Foster Emilie Feil-Fraser	FOR THE APPELLANT
Brian Daley Vanessa Rochester Nikita Stepin Jonathan Chong	FOR THE RESPONDENT I-MED PHARMA INC.

SOLICITORS OF RECORD:

Gowling WLG (Canada) LLP Vancouver, British Columbia	FOR THE APPELLANT
Norton Rose Fulbright Canada LLP Montréal, Quebec	FOR THE RESPONDENT I-MED PHARMA INC.