Citation: Stukanov, Igor (Re), 2022 CACP 12
Commissioner's Decision #1619
Décision du commissaire nº 1619
Date: 2022-04-11

TOPIC:	A11	New Matter
	B00	Ambiguity or Indefiniteness
	C00	Adequacy or Deficiency of Description
	O00	Obviousness
SUJET:	A11	Nouvelle matière
	B00	Caractère ambigu ou indéfini
	C00	Caractère Adéquat ou Inadéquat de la Description
	O00	Évidence

Application No.: 2,672,611

Demande nº 2 672 611

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,672,611, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96–423) as they read immediately before October 30, 2019, has been reviewed in accordance with paragraph 199(3)(c) of the *Patent Rules* (SOR/2019–251). The recommendation of the Patent Appeal Board and the decision of the Commissioner are to refuse the application.

Applicant:

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INTRODUCTION

[1] This recommendation concerns the review of rejected patent application number 2,672,611, entitled “Intravaginal Device with Wireless Sensors of Fertility Indicators” and owned by Igor Stukanov.

[2] The Patent Appeal Board (PAB) has reviewed the rejected application pursuant to paragraph 199(3)(c) of the *Patent Rules* (SOR/2019–251). As explained in more detail below, our recommendation is that the Commissioner of Patents refuse the application.

BACKGROUND

The application

[3] Canadian patent application 2,672,611 (the instant application) was filed in Canada on August 6, 2009 and was laid open to the public on February 6, 2011.

[4] The application relates to devices for monitoring fertility and sexual health of humans and animals. The device includes a contraceptive barrier such as a cervical cap or a diaphragm with wireless sensors of fertility indicators, a control unit with a wireless transmitter and a wireless receiver, and a terminal for receiving, processing and displaying information about fertility and sexual health.

Prosecution history

[5] On August 28, 2018, a Final Action (FA) was written pursuant to subsection 30(4) of the *Patent Rules* (SOR/96–423) as they read immediately before October 30, 2019 (the former *Rules*). The FA summarized the following defects in the application:

- The amendments to the description made on April 8, 2016 are not reasonably inferable and do not comply with section 38.2 of the *Patent Act*.
- The claims are directed to subject matter that would have been obvious and do not comply with section 28.3 of the *Patent Act*.
- The description does not correctly and fully describe the invention and does not

comply with paragraph 27(3)(d) of the *Patent Act*.

[6] In the October 25, 2018 response to the FA (RFA), the Applicant argued for allowance of the application.

[7] As the Examiner considered the application not to comply with the *Patent Act* and *Patent Rules*, the application was forwarded to the PAB for review on December 14, 2018, pursuant to subsection 30(6) of the former *Rules*, along with an explanation outlined in a Summary of Reasons (SOR) that maintained the rejection based on the defects identified in the FA. With a letter dated December 17, 2018, the PAB sent the Applicant a copy of the SOR.

[8] A Panel was formed to review the application under paragraph 199(3)(c) of the *Patent Rules* and to make a recommendation to the Commissioner as to its disposition.

[9] In a Preliminary Review letter (PR letter) dated January 21, 2022, the Panel set out its preliminary analysis and rationale as to why, based on the written record, the application does not contain new matter and the claims are inventive. However, the Panel also set out its preliminary analysis and rationale that:

- The specification is insufficient and does not comply with subsection 27(3) of the *Patent Act*;
- Claims 13 is indefinite and does not comply with subsection 27(4) of the *Patent Act*;

[10] The PR letter offered the Applicant the opportunities to attend an oral hearing and to make further written submissions.

[11] In a response to the PR letter (RPR) dated January 31, 2022, the Applicant argued for allowance of the application and included a set of proposed claims 1-18.

[12] An oral hearing was held March 4, 2022.

ISSUES

[13] In view of the above, there are several issues to be considered by this review:

- Whether the description encompasses new matter and is non-compliant with section 38.2 of the *Patent Act*;
- Whether the claims are obvious and are non-compliant with section 28.3 of the *Patent Act*;
- Whether the specification is insufficient and does not comply with subsection 27(3) of the *Patent Act*; and
- Whether claim 13 is indefinite and does not comply with subsection 27(4) of the *Patent Act*.

[14] The Panel will also consider the latest proposed claims, that is, the proposed claims submitted by the Applicant in the RPR, and whether they constitute amendments necessary for compliance with the *Patent Act* and *Patent Rules*.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICE

Purposive construction

[15] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World*] and *Whirlpool Corp v Camco Inc*, 2000 SCC 67, purposive construction is performed from the point of view of the person skilled in the art in light of the relevant common general knowledge (CGK), considering the whole of the disclosure including the specification and drawings. In addition to interpreting the meaning of the terms of a claim, purposive construction distinguishes the essential elements of the claim from the non-essential elements. Whether or not an element is essential depends on the intent expressed in or inferred from the claim, and on whether it would have been obvious to the skilled person that a variant has a material effect upon the way the invention works.

New matter

[16] Section 38.2 of the *Patent Act* sets forth the conditions under which amendments

may be made to the specification or drawings of a patent application:

> Amendments to specifications and drawings
> 38.2 (1) Subject to subsections (2) to (3.1) and the regulations, the specification and any drawings furnished as part of an application for a patent in Canada may be amended before the patent is issued.
>
> Restriction
> (2) The specification and drawings contained in an application, other than a divisional application, may not be amended to add matter that cannot reasonably be inferred from the specification or drawings contained in the application on its filing date.
> …

[17] The question as to whether matter added to the specification or drawings by amendment complies with section 38.2 of the *Patent Act* is considered from the point of view of the person skilled in the art. Assessing whether there is new matter therefore requires a comparison of the pending specification with the originally filed specification and drawings and a determination as to whether the subject matter of the amendments would have been reasonably inferable from the original specification or drawings by the person skilled in the art.

Obviousness

[18] The *Patent Act* requires that the subject matter of a claim not be obvious to a person skilled in the art. Section 28.3 of the *Patent Act* states:

> 28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to
>
> (a) information disclosed more than one year before the filing date by the Applicant, or by a person who obtained knowledge, directly or indirectly, from the Applicant in such a manner that the information became available to the public in Canada or elsewhere; and
>
> (b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

[19] In *Apotex Inc v Sanofi–Synthelabo Canada Inc*, 2008 SCC 61 [*Sanofi*] at para 67, the Supreme Court of Canada stated that it is useful in an obviousness inquiry to

follow the following four-step approach:

(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?

Insufficient specification

[20] Subsection 27(3) of the *Patent Act* requires, among other things, a specification of a patent to correctly and fully describe an invention, and to enable its practice:

> 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;
> …

[21] A determination of whether the specification complies with paragraphs 27(3)(a) and 27(3)(b) of the *Patent Act* requires that three questions be answered: What is the invention? How does it work? Having only the specification, can the person of skill in the art produce the invention using only the instructions contained in the disclosure? see: *Teva Canada Ltd v Novartis AG*, 2013 FC 141 citing *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 [*Teva*] and *Consolboard v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504 at 526, 1981 CanLII 15 (SCC)

[*Consolboard*].

[22] Although the CGK can be relied upon when it comes to the latter two questions, an affirmative answer to the third question requires that the person of skill in the art not be called upon to display inventive ingenuity or undertake undue experimentation: *MOPOP* 22.05.01 (CIPO, October 2010); *Aventis Pharma Inc. v Apotex Inc*, 2005 FC 1283; *Mobil Oil Corp v Hercules Canada Inc*, (1995) 63 CPR (3d) 473 (FCA); *Merck & Co v Apotex Inc*, [1995] 2 FC 723, 1995 CanLII 3586 (CA).

[23] In *Consolboard* at pages 154-155, the Supreme Court referred to the textbook *Canadian Law and Practice Relating to Letters Patent for Inventions* (1969, 4th ed.) from which it quoted H.G. Fox as saying “the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired”.

[24] The relevant date for assessing compliance with subsection 27(3) of the *Patent Act* is the filing date (*Teva* at para 90).

Indefiniteness

[25] Subsection 27(4) of the *Patent Act* requires claims to distinctly and explicitly define subject matter:

> 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.

[26] In *Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306, 12 CPR 99 at 146, the Court emphasized both the obligation of an Applicant to make clear in the claims the ambit of the monopoly sought and the requirement that the terms used in the claims be clear and precise:

> By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. The terms of a claim must be

> free from avoidable ambiguity or obscurity and must not be flexible; they must be clear and precise so that the public will be able to know not only where it must not trespass but also where it may safely go.

ANALYSIS

Purposive construction: The person skilled in the art and the relevant CGK

Overview of the instant application

[27] As stated above, the instant application relates to devices for monitoring fertility and sexual health of humans and animals. The device includes a contraceptive barrier such as a cervical cap or a diaphragm with wireless sensors of fertility indicators, a control unit with a wireless transmitter and a wireless receiver, and a terminal for receiving, processing and displaying information about fertility and sexual health.

[28] The application at the time of the FA includes 15 claims. Claim 1 is the only independent claim. Dependent claims 2-12 and 14-15 depend on claim 1 and claim 13 depends on claim 1 through claim 3. All claims are directed to a device for wireless monitoring of fertility and sexual health of humans and animals.

[29] A patent is addressed to a person skilled in the art to which it pertains in light of their CGK (see for example, *Free World* at para 44). Thus, the Panel will first identify the person skilled in the art and the relevant CGK.

The person skilled in the art and their relevant common general knowledge

[30] The PR letter at pages 3-5 reviewed the prior art documents D1-D8 cited in the FA. The PR letter also introduced prior art documents D9-D12 as evidence of the CGK and relevant to our analysis. We begin with a brief overview of each document D1-D12.

D1:	CA 2,505,749	Lye et al	June 10, 2004
D2:	WO 2008/029130	James et al	March 13, 2008
D3:	US 6,080,118	Blythe	June 27, 2000
D4:	US 2005/0096562	Delalic et al	May 5, 2005
D5:	US 7,101,342	Caillouette	September 5, 2006
D6:	US 2006/0084848	Mitchnick	April 20, 2006
D7:	CA 2,463,450	Sarkis et al	April 26, 2003
D8:	US 5,851,188	Bullard et al	December 22, 1998
D9:	US 5,928,195	Malamud et al	July 27, 1999
D10:	US 5,209,238	Sundhar	May 11, 1993
D11:	Kothiyal et al, “Energy and Performance Evaluation of Lossless File Data Compression on Server Systems”, SYSTOR’09, May 4-6, 2009		
D12:	Fenwick, “Symbol ranking text compressors: review and implementation.” Software: Practice and Experience 28.5 (1998): 547-559		

[31] D1 discloses a wireless healthcare monitoring system and method in which a biosensor transmitter assigned to at least one individual is remotely monitored (D1, abstract). The biosensors can be in contact with the body or placed on or adjacent to the skin or other member of the body. D1 discloses, for example, that the biosensors may be located in an orifice of the body, inside the body (e.g., a surgically implanted device or a device that is swallowed or introduced by a catheter), or in an article that is worn next to the body (D1, page 4, lines 23-27).

[32] D2 discloses a method and apparatus of detecting and predicting ovulation and periods of fertility. The method is based on taking multiple temperatures from a female mammal and analysing one or more patterns in the temperature values that indicate or predict ovulation (D2, abstract). The temperature measuring device is preferably an indwelling device which is introduced into the vagina of the female mammal, smoothly shaped for hygiene and comfort and similarly sized and shaped like a tampon (D2, page 26, lines 14-21).

[33] D3 discloses a probe used to determine different possible body conditions of a human or animal subject. The probe includes an elongated insertable portion which is adapted for use orally, anally or vaginally, and along the probe are

provided a number of biosensors and/or temperature sensors (D3, abstract; Figure 1).

[34] D4 discloses systems, apparatus, and methods for telemetrically monitoring parameters within a body, such as within a urinary bladder of a human. The system includes an implantable device configured for insertion within the body that senses and stores one or more bodily parameters and transmits the stored bodily parameters for receipt by an external device (D4, abstract). The implantable device is contained within a housing and in the exemplary embodiment, sized for insertion into a urinary bladder via the urethra, measures less than 10 millimeters in diameter along one axis (D4, paragraph [0032]; Figure 2).

[35] D5 discloses a method of treating a human female menopausal condition by determining a need for increasing estrogen level in the blood from a lower level associated with reduced ovarian estrogen production. The method includes measuring vaginal moisture or urethral fluid pH level, at repeated time intervals over a series of days (D5, abstract). Measuring the vaginal moisture or urethral fluid pH level is performed by the use of a probe (D5, column 2, lines 53-59; Figure 2).

[36] D6 discloses a device, and a method and a system for its use, for monitoring participants in clinical trials of topical pharmaceutical agents for limiting or preventing sexual transmitted disease transmission. The invention can also be used in trials of other types of pharmaceutical agents, especially pharmaceutical agents relating to sexual activity (D6, abstract, paragraph [0009]). Preferred devices reside in a body cavity and can provide access to body-core values for, for example, temperature, glucose, partial pressure of oxygen (pO2), and the like (D6, paragraph [0010]). In one preferred embodiment, sensors are packaged into a single unit, ring-shaped and sized to reliably reside in the back of the vagina adjacent to the cervix much like a diaphragm or cervical cap (D6, paragraph [0014]; Figures 1, 5A, 5B and 5C).

[37] D7 discloses a portable, non-implanted intravaginally probe that can sense vaginal conditions, can deliver signals or medication, and/or can stimulate perineal musculature and nerves (D7, abstract). In an embodiment directed to a stimulation system, the stimulator is less than a 1 inch in diameter and less than 4 inches in

length (D7, page 4, line 23 to page 5, line 8; Figure 1).

[38] D8 discloses a device to hold and retain medical instrumentation probes at the cervix of a human female for real-time ultrasonic monitoring of cervical dilatation and effacement. The device includes a flexible elastomeric annulus-shaped membrane having a shape-retentive memory and exerting a force so as to assume and to maintain a predetermined closed-loop geometric shape, normally a circle, that fits circumferentially about the cervix (D8, abstract; Figure 9).

[39] D9 discloses a remotely controlled drug delivery device that administers a dose of a drug, agent or microbicide using a gas pressure delivery system (D9, abstract). In a preferred embodiment, the invention discloses a vaginal ring which is capable, upon receiving a remote command, of periodic release of a drug, agent or microbicide into the body, thereby providing protection from or treating sexually transmitted diseases. In addition, the device may be used to deliver a contraceptive drug (D9, column 1, lines 33-45; Figure 1).

[40] D10 discloses an electronic ovulation monitor to determine whether a viable egg is present. The monitor has a housing containing a power source, an audible component, a light emitting diode, and a micro-processor, with the microprocessor connected to sensors located external the housing. The micro-processor measures the basal body temperature, mucous density, pH level and luteinizing hormone (LH) level. The monitor housing is substantially rod-shaped (D10, column 2, lines 19-38; Figures 1-3).

[41] D11 presents a comprehensive evaluation of energy consumption for various file compression techniques implemented in software.

[42] D12 provides an overview of various data compressors and describes a symbol-ranking compressor for fast software compression suitable for hardware implementation.

[43] The PR letter at page 6 preliminarily identified the person skilled in the art as follows:

> In light of our review of the rejected application, the prosecution record and the prior art, it is our preliminary view that the person skilled in the art is comprised of a team of people including at least experts in fertility and

> sexual health of both humans and animals and an engineering technologist capable of devising sensing devices and means for the remote monitoring of such sensing devices under the direction of such experts.

[44] The Applicant made no comment regarding this characterization of the person skilled in the art in either the RPR or in oral submissions at the hearing and thus we adopt it for the purposes of this review.

[45] The PR letter at pages 6-7 preliminarily identified the CGK:

> Our preliminary view of the CGK includes the following:
>
> - Remote monitoring of patients for a number of health conditions (D1, page 1, lines 7-13) using hardwired sensors (D1, page 1, lines 20-27);
> - Use of portable or disposable biosensors equipped with electronic devices that can store or transmit data relevant to the health of a subject (D1, page 2, lines 3-11);
> - Sensors to monitor fertility and sexual health (FA, page 4)
> - Sensors to measure electromagnetic radiation and intra-nuclear radiation (Admitted CGK by the Applicant in a response dated December 5, 2016);
> - Monitoring of temperature to detect ovulation (D2, page 3, line 19 to page 5, line 32; D10, column 1, lines 53-55);
> - Techniques to detect ovulation by monitoring pH or luteinizing hormone levels, monitoring temperature, or monitoring the density of cervical mucous (D10, column 1, lines 35-63);
> - Monitoring of bodily parameters within a body, such as fluid pressure in a urinary bladder of a human (D4, paragraphs [0002]-[0003]);
> - Methods to determine whether or not a human menopausal female should be administered higher or lower levels of estrogen or estradiol (D5, column 1, lines 12-21);
> - Body implantable devices that release drugs, either continuously or periodically (D9, column 1, lines 15-23);
> - Passive and active intra-vaginal rings used for drug delivery (D6, paragraphs [0086] and [0088]);
> - Devices for the objective and continuous measurement of cervical dilatation based on (electro) mechanical, electronic and ultrasonic principles (D8, column 3, line 22 to column 7, line 23);
> - Vaginal or anal probes which are used to sense or measure a subject's body characteristics to provide an indication of a particular body condition (D3, column 1, lines 15-27; D7, page 1, lines 12-24);

- Contraceptive devices, such as cervical caps and diaphragms (FA, page 4; D9, column 2, lines 48-52);
- Data memory, power management circuitry, and other components of a sensor device (D6, paragraph [0013]);
- Construction of flexible, flat-form sensor substrates (D1, page 38, lines 8-10) and flexible printed circuit boards (D6, paragraph [0048]);
- General wireless transmitters and receivers and appropriate programming techniques (FA, page 4; D6, paragraphs [0016] and [0050]; D9, column 8, lines 42-44);
- Techniques for providing secure transmission of wireless data (D1, page 51, lines 9-26), including medical data (D1, page 51, line 27 to page 52, line 14); and
- Data compression techniques including popular utilities on Linux, such as gzip, lzop, bzip2, and compress (D11, page 1, right-hand column, paragraph 2) and Bloom's LZP compressors, including LZP1, LZP2, LZP3, and LZP4 (D12, spanning pages 7 and 8).

[46] Again, the Applicant made no comment regarding this characterization of the person skilled in the art in either the RPR or in oral submissions at the hearing. Thus we adopt all the preceding elements as CGK for the purposes of this review.

New matter

[47] Claims and a description were originally filed August 6, 2009. Amendments were made to both the claims and the description on April 8, 2016 in response to an Office Action. Subsequently, the Examiner raised a new matter defect on the amendments related to the description in an Office Action dated November 17, 2016. Subsequent amendments were made to the claims and description on December 5, 2016. The Examiner continued to identify a new matter defect related to the description in each subsequent Office Action, including the FA. We assess the description on file at the time of FA dated December 5, 2016 for new matter.

[48] The FA at page 6 identified a new matter defect for the amended description:

> The subject matter of pages 3 and 4 of the description (beginning on page 3 with: "Some examples are given below to demonstrate possible uses of this invention ....), as amended by the applicant's correspondence received on 8 April 2016 (08-04-2016), still does not comply with section 38.2 of the *Patent Act* because it is not reasonably to be inferred from the specification or drawings as originally filed. The new matter should be removed from the application. [emphasis removed from the original].

[49] The Applicant had previously contended that since the claims are disclosed in general terms, any specifics added to the description were inferable to the skilled person. The Examiner disagreed in the FA:

> Applicant's description as originally filed lacks any mention of a control unit compressing data using an LZOP or LZP2 algorithm. Nor is there any mention in the originally filed application of all parts of the terminal being placed into the same unit under a one cover hood. Furthermore, there is no indication in the originally filed application that all parts of the terminal are placed into several units under separate cover hoods.
>
> This information was not disclosed in the description, claims or drawings as originally filed. Therefore, this information is not reasonably inferred from the specification or drawings as originally filed. This matter is considered to be new matter and must be removed from the application.

[50] The PR letter on page 9 detailed the differences between the description dated December 5, 2016 and the originally filed description, specifically, three example implementations of the invention are described. The FA identified two problematic amendments: 1) the data compression techniques and 2) the terminal configurations.

[51] According to section 38.2 of the *Patent Act*, the question before the Panel is whether the subject matter of the amendments would have been reasonably inferable from the original specification or drawings by the person skilled in the art. The PR letter at page 10 preliminarily assessed these amendments as follows:

> With respect to the data compression techniques, the originally filed specification made reference to the use of data compression between the control unit and the terminal (see the description as originally filed, page 3, lines 1-2). As described above in the section on the CGK, D11 and D12 discloses known compression techniques LZOP and LZP2 as of the filing date of the patent application. Thus, the originally filed description would have led the person skilled in the art with their CGK to reasonably infer the use of specific data compression techniques.
>
> With respect to the terminal configurations, we acknowledge that the originally filed specification makes no mention of specific terminal configurations, such as those stated in the amendments, that is, parts of the terminal placed into the same unit under one cover hood or parts of the terminal placed into several units under separate cover hoods.

> However, given that the person skilled in the art includes at least an engineering technologist capable of devising sensing devices and means for the remote monitoring of such sensing devices, such design configurations for the terminal using either a single unit or multiple units would be a basic design consideration based on intended use and efficiency of the terminal design. Thus, in our preliminary view, given the person skilled in the art and the CGK, such amendments would be inferable from the specification as originally filed.

[52] The Applicant did not dispute this analysis in either the RPR or in oral submissions at the hearing.

[53] Although specific compression techniques and terminal configurations are not described in the original specification, in this case, the specifics are included in examples. No rationales were attributed to choosing these particular CGK choices of compression techniques and terminal configurations. Given this particular amendment, such details are inferable. Thus, our view is that the description dated December 5, 2016 does not encompass new matter and complies with section 38.2 of the *Patent Act*.

Obviousness

[54] We will assess this defect using the four-step approach from *Sanofi*.

Step 1: Identify the notional "person skilled in the art" and their CGK

[55] The person skilled in the art and their CGK is set out above in the section labelled "Purposive construction: The person skilled in the art and the relevant CGK".

Step 2: Identify the inventive concept of the claim in question or if that cannot readily be done, construe it

[56] The claims dated December 5, 2016 on file at the time of the FA (the claims on file), are subject to our review:

> 1. A device for wireless monitoring of fertility and sexual health of humans and animals having the following parts:
>
> (1) a female contraceptive barrier;
> (2) one or several sensors to measure female fertility and sexual health, placed on an internal side of said barrier;

(3) a wireless transmitter, via which information from said sensors is sent to a terminal for processing and displaying results;
(4) a control unit, which turns on and off said device, compresses said information from said sensors and sends said information via said wireless transmitter to said terminal for processing and displaying results.

2. A device as in claim 1, further including a sensor to measure a male fertility and sexual health, which is placed on an external side of said barrier.

3. A device as in claim 1, where said device has a wireless receiver, via which instructions to said control unit are sent from said terminal.

4. A device as in claim 1, wherein one of said sensors takes ultrasonic images of follicle collapse with egg release.

5. A device as in claim 1, wherein one of said sensors takes infrared images of follicle collapse with egg release.

6. A device as in claim 1, wherein one of said sensors measures a vaginal temperature.

7. A device as in claim 1, wherein some of said sensors measure physical and chemical properties of vaginal fluids.

8. A device as in claim 1, wherein some of said sensors measure concentration of hormones.

9. A device as in claim 1, wherein some of said sensors measure concentration of enzymes.

10. A device as in claim 1, wherein some of said sensors measure folliculogenesis and other ovarian functions.

11. A device as in claim 1, wherein some of said sensors measure concentration of antibodies.

12. A device as in claim 1, wherein some of said sensors measure concentration of harmful microorganisms.

13. A device as in claim 3, wherein some of said sensors measure fertility parameters of the male’s sperm.

14. A device as in claim 1, wherein some of said sensors measure electromagnetic radiation.

> 15. A device as in claim 1, wherein some of said sensors measure intranuclear radiation.

[57] Consistent with the approach adopted in the PR letter at page 13, the Panel will analyse the claims on file in this review by taking into account all the elements of the claims as recited, as identified above. By taking into account all the elements of the claims on file, it is possible to reach a conclusion regarding the obviousness defect that would not be affected by any error in identifying the inventive concept or in claim construction.

Step 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

[58] The PR letter at pages 13-14 assessed the differences between claim 1 and D6:

> The FA at pages 3-5 identified D6 as the prior art document most relevant to the obviousness analysis and then set out the differences between claims 1-15 and D6. The FA identified the differences between D6 and claim 1 as a "wireless receiver to receive instructions from an internal device" (FA, page 3) and "a control unit, which turns on and off said device" (FA, page 5).
>
> We note that the FA assessed that D6 disclosed the recited element of claim 1, namely, a female contraceptive barrier to which one or more sensors are attached. In our preliminary view, a more thorough assessment of this claimed element is determinative of our obviousness analysis.
>
> Regarding the D6 disclosure of a female contraceptive barrier, the obviousness analysis in the FA at page 3 stated (in part):
>
> > Regarding independent claim 1, document D6 discloses: a device for wireless monitoring of fertility and sexual health of humans and animals comprising the following parts:
> >
> > - a female contraceptive barrier (see D6: para. [0014]: "A preferred configuration is ring-shaped and sized to reliably reside in the back of the vagina adjacent to the cervix much like a diaphragm or cervical cap");
> >
> > …
>
> The RFA did not specifically address the identification of differences between D6 and claim 1. The RFA did note that the invention had been granted as US8656916 after a detailed review of the prior art and argued

that this lent support for the claims being inventive. More pertinent to our analysis however is the Applicant's response dated June 5, 2017 to an Office Action that stated:

> D6 uses a **HOUSING** as a frame to which other elements are attached. The proposed invention uses a **female contraceptive barrier** as a frame to which other elements are attached. The housing is not a female contraceptive barrier, therefore the invention based on the prior art D1-D8 is different from the proposed invention. [emphasis in the original]

The device as claimed is described in the description on file at page 2:

> Fig. 1 shows simplified scheme of the device, which includes a contraceptive barrier such as a cervical cap or a diaphragm with wireless sensors of fertility indicators, a control unit with a wireless transmitter and a wireless receiver.
>
> Sensors on the internal side of the contraceptive barrier monitor female fertility and sexual health by measuring direct and indirect fertility indicators such as ultrasonic or infrared images of follicle collapse with egg release, vaginal temperature, …
>
> Sensors on the external side of the contraceptive barrier monitor fertility parameters of male's sperm (motility, count, morphology), …

In our preliminary view, based on the specification, the claimed invention takes the form of a contraceptive barrier, such as a cervical cap or a diaphragm, in which sensors are mounted on the internal and external sides of the contraceptive barrier.

D6 discloses an intra-vaginal device in which sensors are mounted in a ring-shaped housing (D6, paragraphs [0014], [0020], and [0048]). Although D6 makes mention of a diaphragm or cervical cap (D6, paragraph [0014]), such references are made in the context of the placement of the device adjacent to the cervix. This is not the same as the claimed invention that mounts sensors on a contraceptive barrier.

D6 also discloses a membrane with selected pore size, surface properties, and other characteristics to preferentially admit target components of interest to the sensors (D6, paragraphs [0018] and [0062]). Such a membrane is not used in D6 as a contraceptive barrier.

In light of the above, in our preliminary view, the identified differences between claim 1 and D6 includes, at least, a female contraceptive barrier and one or several sensors to measure female fertility and sexual health, placed on an internal side of said barrier.

[59] The Applicant did not dispute this analysis in either the RPR or in oral submissions at the hearing.

[60] As the Applicant did not contest any of these detailed assessments, and consistent with our summary in the PR letter at page 14, we view that with respect to the *Sanofi* step 3 analysis, D6 does not explicitly disclose, at least, a female contraceptive barrier and one or several sensors to measure female fertility and sexual health, placed on an internal side of said barrier.

Step 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?

[61] We assess whether the identified difference in step 3 above, namely, a female contraceptive barrier and one or several sensors to measure female fertility and sexual health, placed on an internal side of said barrier, constitute a step which would have been obvious to the person skilled in the art.

[62] The PR letter on pages 14-16 considered the other prior art documents on record and the CGK as identified above and arrived at a preliminary finding that the difference constitutes a step that would not have been obvious to the person skilled in the art:

> D1 discloses a wireless healthcare monitoring system including a biosensor transmitter used to detect a health condition of a user (D1, abstract). D1 discloses a wide range of biosensor devices, generally a sensor placed on or adjacent to the skin or other member of the body, within a body orifice, inside the body, in an article worn next to the body, etc. (D1, page 4, line 23 to page 5, line 32). However, D1 does not disclose the use of a female contraceptive barrier on which sensors are placed.
>
> Prior art documents D2 (page 26, lines 20-22), D3 (Figure 1), D5 (Figure 1, probe 10), D7 (page 4, line 23 to page 5, line 8; Figure 1), and D10 (column 2, lines 19-38; Figures 1-3) all disclose a device shaped (and described) as either a probe, a rod, or a tampon. Again, none of these documents disclose the use of a female contraceptive barrier on which sensors are placed.
>
> D4 discloses a very small implantable device (D4, paragraph [0032]) without disclosure of a female contraceptive barrier on which sensors are placed.

> Prior art document D8 discloses a device to hold and retain medical instrumentation probes at the cervix of a human female. The device is in the shape of a annular disc, with an external rim region (D8, Figure 9 reference 91) and an internal rim region (D8, Figure 9 reference 93). The internal rim region is connected to the external rim region by an elastic annulus region (D8, Figure 9 reference 92) similar to a thin latex elastic of a condom or female diaphragm (D8, column 26, lines 24-65). However, unlike the claimed invention, the one or more medical probes are held in the cavities formed by the device's placement about the cervix (D8, column 26, line 66 to column 27, line 33; Figure 11). None of the various embodiments of D8 (see for example Figures 12-22) disclose placement of the probes on the elastic annulus region.
>
> Similar to the device in D6, prior art document D9 discloses a device in a toroidal or ring shape (D9, column 4, lines 13-35; Figure 1). D9 also makes reference to a diaphragm or cervical cap but only in the context of how the device is inserted into the vagina (D9, column 4, lines 50-52). D9 does not disclose the use of a female contraceptive barrier on which sensors are placed.
>
> D11 and D12 disclose specific CGK elements related to data compression techniques, but are not directed to the same art as the claimed invention and will not be considered further in this obviousness analysis.
>
> Finally, we consider whether the placement of sensors on an internal side of female contraceptive barrier would have been obvious to the person skilled in the art given the CGK. Even though all the elements of claim 1 were known and part of the CGK, including sensors and female contraceptive barrier such as diaphragms or cervical caps, the prior art did not disclose, teach, or suggest the placement of sensors on the female contraceptive barrier.
>
> Furthermore, the prior art does not provide any motivation for the person skilled in the art to arrive at the claimed invention.
>
> In light of our review of the prior art on record and the CGK, it is our preliminary view that it would not have been obvious to the person skilled in the art, starting with a device such as the one disclosed in D6, to place on an internal side of a female contraceptive barrier one or several sensors to measure female fertility and sexual health.

[63] The Applicant did not dispute this analysis in either the RPR or in oral submissions at the hearing.

[64] As the Applicant did not contest any of these assessments, and consistent with our summary in the PR letter at page 16, we view that claim 1 would have been

inventive having regard to any combination of the prior art on record D1-D10 and the CGK, either considered alone or in any combination. Furthermore, dependent claims 2-15 are also inventive in light of their dependence on claim 1. Thus, the subject matter of the claims on file complies with section 28.3 of the *Patent Act*.

Insufficient specification

[65] The FA at pages 6-8 identified a defect of insufficient specification, summarized on page 8 as follows:

> Nowhere in the description does it describe how these sensors gather data, what kind of sensors are being used, how these sensors are attached to the contraceptive barrier or how they are powered. There is no indication in the description of how one or more sensors is capable of taking ultrasonic or infrared images of follicle collapse with egg release. There is no indication of how the device actually operates with the sensors to measure: vaginal temperature, physical and chemical properties of vaginal fluids, concentration of hormones and enzymes, folliculogenesis and other ovarian functions, concentration of antibodies and harmful microorganisms for evaluation of sexual health of the female, fertility parameters of male's sperm (motility, count, morphology) and concentration of antibodies and harmful microorganisms for evaluation of sexual health of the male. It is merely a list of sensors that might be placed on a device without any actual description of how this can be achieved.

[66] The RFA did not specifically address this defect but did note such a defect contradicts the examination position in granting US8656916 and contradicts the Examiner's position that the claims are obvious. Pertinent to our analysis is the Applicant's response dated June 5, 2017 to an Office Action that stated:

> The proposed invention does not claim a new type of sensors, therefore there is no need to describe how sensors function. This information is in prior art and well known to any person skilled in the art.

[67] The PR letter at pages 17-18 preliminarily assessed this defect as follows:

> Considering the first two questions above to determine whether the specification is sufficient, that is, what is the invention and how does it work, in our preliminary view, the answer to the questions is yes, the person skilled in the art would understand that:
>
> - the broadest embodiment of the claimed invention is directed to a device comprising sensors placed on the internal side of a female

contraceptive barrier, a wireless transmitter, a control unit and a terminal; and

- the claimed invention works by sensors measuring female fertility and sexual health, the data from the sensors being compressed by the control unit and transmitted via the wireless transmitter to the terminal for processing and displaying results.

Considering the third question, whether the person skilled in the art with their CGK would be enabled to produce the invention, it appears that the main argument supporting this defect in the FA is a lack of enablement with respect to how these sensors gather data, what kind of sensors are being used, how these sensors are attached to the contraceptive barrier or how they are powered.

The CGK identified above includes knowledge of various sensors used to monitor fertility and sexual health. The Applicant further admits that the invention does not claim any new sensors but rather all claimed sensors are part of the CGK.

While we agree that the sensors and devices housing them are known, the specification provides no details on how the device is [*sic*] claim 1 is constructed. There are no details given on the construction or operation of the control unit and transmitter. Their connections and interfaces with the sensors are not described. There are no details on how the control unit and transmitter are housed and connected to the contraceptive barrier. There are no details on how the sensors are powered and controlled from the control unit.

Even more problematic is the lack of description regarding the placement of the sensor on the contraceptive barrier. As discussed above in the “obviousness” analysis, in our preliminary view, the placement of sensors on the contraceptive barrier contributes to the inventiveness of the invention. The CGK describes sensors in various housings, but does not describe how to make the sensors and housing small enough to be placed on such barriers or how to place the sensors and housings there. Thus, without any guidance from the CGK, the person skilled in the art would turn to the disclosure to understand how to place sensors on the contractive barrier, but these details are missing from the instant application.

Although the CGK does includes some technical aspects of constructing and operating sensors in terms of data memory and power management circuitry, such aspects of the CGK are insufficient to enable the person skilled in the art to construct the device of claim 1 without inventive ingenuity and/or significant experimentation. And the jurisprudence indicates that even a minor research project is too much (*Bombardier*

> *Recreational Products Inc v Arctic Cat Inc*, 2017 FC 207 at paragraph 568 citing *Teva* at paragraph 75).
>
> In light of the above, our preliminary view is that the specification does not inform the person skilled in the art to produce the claimed invention. Thus, the specification is insufficient and does not comply with subsection 27(3) of the *Patent Act*.

[68] The Applicant disagreed with our preliminary assessment and made three submissions in the RPR at page 2 and at the oral hearing. We consider each submission.

[69] First, the Applicant submitted that "[t]he examiners of USPTO in 2009 had found that the description of this invention allows any person skilled in the art to manufacture and practice this invention."

[70] We understand that a similar application was filed and granted in another jurisdiction. Although the general requirements for patentability are similar between jurisdictions, they are not exactly the same. A patent granted in one jurisdiction does not automatically confer patentability of a patent application in another jurisdiction.

[71] One reason for this difference is that the jurisprudence in each jurisdiction has evolved differently and puts different requirements, tests and thresholds on various aspects related to patentability. In Canada, as cited in the PR letter, the jurisprudence regarding enablement tells us that even a minor research project is too much. *Teva* at para 75 cited by *Bombardier Recreational Products Inc v Arctic Cat Inc, 2017 FC 207* at paragraph 568, states:

> …what must be considered is whether a skilled reader having only the specification would have been able to put the invention into practice. The trial judge clearly found that the skilled reader would have had to undertake a minor research project to determine what the true invention was.

[72] As we described in the PR letter, the jurisprudence is applicable to this application: the specification is not detailed enough to enable the person skilled in the art to construct the device of claim 1 without inventive ingenuity and/or significant experimentation.

[73] Second, the Applicant submitted that “[s]ince 2009, persons skilled in the art in many countries had developed products based on the published description.”

[74] With respect, the Applicant has not provided any evidence to support such a submission. Even if there was evidence to support this submission, the fact that there are products available does not assist us in assessing what effort was required to construct such products from the specification alone. If there was any inventive ingenuity and/or significant experimentation involved in developing such products, then the description is not enabled.

[75] Third, the Applicant submitted that “[t]he CIPO current position on this issue contradicts to the previous position (obviousness). If an invention is obvious then any person skilled in the art can practice this invention.”

[76] At the hearing we confirmed with the Applicant our current position, that is, the claims are inventive. This contradicts the previous Office position that found the claims obvious. However, the second part of submission is, with respect, incorrect: obviousness and enablement are two separate and distinct dimensions of patentability. The former assesses whether the claims would not have been obvious to a person skilled in the art as required by the *Patent Act*, section 28.3; the latter assesses whether a person of skill in the art could produce the invention using only the instructions contained in the disclosure, as required by the *Patent Act*, section 27(3). A finding that the claims are obvious to the person skilled in the art does not automatically confer sufficiency of the disclosure. And a sufficient disclosure does not automatically mean the claims are obvious.

[77] In light of the above, our view is that the specification is insufficient and does not comply with subsection 27(3) of the *Patent Act*.

Indefiniteness

[78] During the Panel’s preliminary review, a question arose as to whether there was a further contravention of subsection 27(4) of the *Patent Act* related to indefiniteness. According to subsection 86(9) of the *Patent Rules*, whenever the Commissioner has reasonable grounds to believe an application does not comply with the *Patent Act* or *Patent Rules* due to a defect not identified in an FA, the Applicant shall also be informed of this defect and be invited to submit arguments.

[79] The PR letter at page 19 identified an indefiniteness defect:

> Although an indefiniteness defect was not identified in the FA, the Panel notes that claim 13 depends on claim 3 and further refines sensors to those sensors that measure fertility parameters of the male's sperm. However, claim 3 introduces a wireless receiver to the device of claim 1 that includes sensors to measure female fertility and sexual health. Instead, claim 2 refines the sensors of claim 1 to includes those sensors that measure male fertility and sexual health.

[80] The PR letter informed the Applicant of our preliminary view that claim 13 on file is indefinite and does not comply with subsection 27(4) of the *Patent Act* and also informed the Applicant that the defect could be overcome by amending claim 13 to depend on claim 2, rather than claim 3.

[81] The Applicant did not dispute this preliminary view; rather, in the RPR at page 2, the Applicant agreed to amend the claims as suggested in the PR letter and included this correction in the proposed claims.

[82] In light of the above, claim 13 on file is indefinite and does not comply with subsection 27(4) of the *Patent Act*. We note that this defect would be overcome by the proposed claims (a full assessment of the proposed claims is provided below in "Proposed claims" section).

Proposed claims

[83] As discussed above under the section "Indefiniteness", the Applicant proposed to amend claim 13 as suggested in the PR letter. The Applicant also proposed new claims 16-18, directed to a terminal for displaying results of fertility and sexual health assessment based on measurements obtained from the device of claim 1.

[84] We note that the Applicant did not make a proposed amendment to the description to address the insufficient specification defect; rather the Applicant elected to make submissions regarding this defect, as we considered above.

[85] While we agree that the proposed claim 13 overcomes the identified indefiniteness defect, the claims themselves do not address the insufficient specification defect.

[86] In light of the above, it is our view that proposed claims 1-18 are not considered a necessary amendment under subsection 86(11) of the *Patent Rules*.

CONCLUSIONS AND RECOMMENDATION OF THE PATENT APPEAL BOARD

[87] In light of our analysis above, we view that the instant application does not contain new matter and that the claims are inventive.

[88] However, we conclude and recommend that the Commissioner refuse the application on the basis that:

- The specification is insufficient and does not comply with subsection 27(3) of the *Patent Act*; and
- Claim 13 on file is indefinite and does not comply with subsection 27(4) of the *Patent Act*.

[89] We also conclude that the proposed claims 1-18 are not considered a necessary amendment under subsection 86(11) of the *Patent Rules*.

Lewis Robart	Kristina Bodnar	Leigh Matheson
Member	Member	Member

DECISION OF THE COMMISSIONER

[90] I concur with the findings of the Patent Appeal Board and its recommendation to refuse the application on the basis that:

- The specification is insufficient and does not comply with subsection 27(3) of the *Patent Act*; and
- Claim 13 on file is indefinite and does not comply with subsection 27(4) of the *Patent Act*.

[91] Accordingly, I refuse to grant a patent for this application. Under section 41 of the *Patent Act*, the Applicant has six months to appeal my decision to the Federal Court of Canada.

Virginie Ethier
Assistant Commissioner of Patents

Dated at Gatineau, Quebec

this 11th day of April, 2022